



FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

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

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Cover page Case ID(s) with an asterisk (**) indicate an invalid status and are not captured in the body of the report.

Esub Case ID(s) Submitted:

8500148 9252933 15368257

Run by: STEPPERH

Date - Time: 10-FEB-2020 10:47 AM

Total number of cases (Esub): 3

Total number of inactive cases: 0



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8500148

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 23-Mar-2012 **Outcomes:** DE **Application Type:**
FDA Rcvd Date: 09-Apr-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8268789 **Application #:**

Patient Information:

Age: 23 YR **Sex:** Male **Weight:** 79.38 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
1	ESCITALOPRAM 20 MG MYLAN		20 MG/			DEPRESSION	14-Mar-2012	20-Mar-2012	
#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ESCITALOPRAM 20 MG MYLAN		NA	NA				MYLAN	

Event Information:

Preferred Term (MedDRA @ Version: 22.1)	ReC
Abnormal behaviour	NA
Gun shot wound	NA
Intentional self-injury	NA
Partner stress	NA
Product substitution issue	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8500148

Event/Problem Narrative:

Had been taking Lexapro for about 10 months. He was doing well on it. He was doing very well at the Univeristy, had a great apartment, had a darling girlfriend, seemed on top of the world, happy as could be. When he went for his refill on 3/14/12 he was given the NEW generic substitute, Escitalopram. I did not know until 3/21/2012 he had a medicine change. He came to our home on 3/21/2012, running his hands thru his head, pacing around the drive way, and said, "I think this new medicine is making my head race." I asked what med, and he told me of the change. He also said he had broken up with his girlfriend, because he was not "good enough for her." I told him not to take anymore of the Escitalopram. The (b) (6) he called his doc and informed him of the change, and the doctor called the pharmacy to write as brand. (b) (6) went to get it and could not, because they said the insurance company would not cover for another week or two. I called the pharmacy and asked if I could come buy a weeks supply, they said yes, and I went and bought the pills. He was here on (b) (6) when I got home from the office, still acting dispondant saying his head was racing. I told him to spend the night here, and he did. The next morn, he did not want to go to his 9AM class, or his 10AM class. I told him I would drive him, he got in and out of the car several times, but said he could not do it. I had an appointment at my office at 10:30, so I left here about 10, told him I would be back when I was done. I then called his doctor and told them he needed to see him that day. I was told to tell him to be there at 1:40. About 10:15 am, I called (b) (6) on his cell and he did not answer, I called 3 times, left messages about the appointment, and then texted and emailed it to him. By 10:50 my husband called me screaming that (b) (6) had shot himself in the head. We firmly belief the escitalopram affected his brain so severely and quickly that he went totally out of his right mind. He was dead when he arrived at the hospital. (b) (6) : |*****| 2012-04-09-09.21.30 |*****|
 USFDAMWVOLUNTARY_204620_16894_20120406.xml Route To: AERS : Electronic Route To: DQRS : : Paper

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
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Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
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FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8500148

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9252933

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 29-Jun-2004 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 24-Apr-2013 **Mfr Rcvd Date:** 18-Apr-2013 **Mfr Control #:** US-FRI-S04-USA-08048-01 **Application #:** 021323

Patient Information:

Age: 42 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	LEXAPRO			Oral		Anxiety		
2	LEXAPRO					Depression		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	LEXAPRO		Yes	NA				FOREST	
2	LEXAPRO		Yes	NA				FOREST	

Event Information:

Preferred Term (MedDRA Version: 22.1)	ReC
Agitation	NA
Anxiety	NA
Feeling abnormal	NA
Hallucination, auditory	NA
Homicide	NA
Irritability	NA
Nervousness	NA
Withdrawal syndrome	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9252933

Event/Problem Narrative:

This U.S. spontaneous report from a forensic psychiatrist described the occurrence of auditory hallucinations, more anxious, accused of murder, nervous and agitated in a 42 year old male patient^{(b) (6)} after discontinuation of Lexapro (escitalopram) therapy indicated for anxiety and depression. There were no concomitant medications. Concurrent medical conditions were unknown by the reporter. The patient's father suffered from schizophrenia and dementia. The specific details regarding escitalopram therapy were unknown by the reporter. Escitalopram, dose unknown, was initiated, discontinued, restarted and then discontinued again by the patient on the dates unknown by the reporter. The patient stated that after escitalopram therapy was discontinued, he experienced auditory hallucinations and felt more anxious (date unknown). The patient verbalized to the reporter^{(b) (6)} (b) (6)

(b) (6)

The reporter stated that after the murder, the patient was jailed for approximately three months and on 21-DEC-2004, was admitted to the maximum security forensic unit in ^{(b) (6)}. The reporter stated that the patient's story is very "questionable" and that he believed the patient experienced "intrusive thoughts not auditory hallucinations". The reporter stated that while in custody at the maximum security forensic unit, the patient appeared nervous and agitated. The patient was prescribed Vistaril (hydroxyzine), as needed, for his anxiety. The reporter stated that approximately on 20-JAN-2005, the decision whether or not the patient is considered competent to stand trial will be made. No other information was provided. This case was determined serious due to its medical significance. Further information will be requested.

Follow-up information was received from the attending forensic psychiatrist in response to a written request from Forest Pharmaceuticals Inc. on 09-MAY-2005 via telephone. The reporter stated that he hasn't seen the patient since he went back to jail on 21-JAN-2005. No additional information was available.

Additional information received from the reporting psychiatrist on 13-May-2005 via telephone. The doctor stated that the first time he had seen the patient was following his crime and the patient had already been off escitalopram. The reporter stated that he is unaware of the time between stopping the escitalopram and the commission of the crime. In addition, he confirmed that the patient had no known previous history of psychological problems. No additional information was provided.

FPI 045710

Follow-up information was received on 18-Apr-2013 from a radio interview. Additional adverse events of SSRI withdrawal syndrome, irritable, brain didn't work right/felt "mentally retarded" were added. The event "accused of murder" was updated to "convicted of first degree murder." The patient's medical history included attention deficit disorder, sexual abuse from his father as a child, a motor vehicle accident after which he had memory loss for a duration of about 24 hours and couldn't remember who he was, who his wife was or that he was married (date



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9252933

unknown) and a divorce. Escitalopram was started on an unknown date at an unknown dose. On an unknown date (dates are conflicting between original information provided and the (b) (6)), approximately 2 days after discontinuing escitalopram, the patient (b) (6)

(b) (6) to prevent the body from being identified. The body was found on an unknown date. (Original information stated within a couple days, the (b) (6) stated the body was still warm when it was found). The patient went about his daily routine the next day. Following questioning from a detective after the murder, the patient ran. The patient was found (b) (6). Soon after, the patient confessed to strangling his father. The patient stated that a day or two before the murder, he had abruptly discontinued escitalopram and reacted "very badly." The patient became extraordinarily irritable, heard voices and he stated that his brain didn't work right, that he felt "mentally retarded." In a letter to a doctor the patient wrote from jail describing the voices he heard when he was off escitalopram the patient wrote "These are not voices that make a suggestion. This is a compulsion. The compulsion is trying to take over my consciousness. I fight the compulsion in the front part of my head. It is a hyper-anxious state. Pacing becomes mandatory, trying to walk off the pressure. The battle hurts badly." The patient stated that he had SSRI withdrawal syndrome, that his brain was "serotonin deprived." He describes this as extreme anxiety, jelly-fish like stings that come and go, and intermittent psychomotor agitation further described as uncontrolled movements of his face and arms that come and go especially when he is stressed. The patient also stated that when he resumed taking escitalopram again, in the days following the murder, his mind calmed down and he was able to go about his life normally. Escitalopram was discontinued on unknown date after the patient was imprisoned. After evaluation by a clinical psychologist, the patient was determined to be legally sane at the time of the offense. The psychologist stated that during the evaluation the patient was agitated further described as "spoke in a halting fashion, fidgeted while sitting, stood with a stooped posture, occasionally paced, and gesticulated broadly with his hands while talking" and that "it appeared the patient was exaggerating his symptoms for the benefit of the evaluator and treatment team." Another psychologist found the patient to be "evasive, dramatic, and manipulative." The prison doctors diagnosed the patient with atypical depression and malingering. It was stated that the patient would act fine when in the prison yard playing basketball with other inmates but when the patient saw an officer he would start shaking his head and arm. This was also observed during the patient's court trial in which he represented himself as his own lawyer. The patient would "act like he was nuts" when speaking to the court, but be "cool as anything" when speaking with his court appointed lawyer. The judge presiding the trial stated "It was clear that it was malingering and faking." The patient was convicted of 1st degree murder and sentenced to life in prison in a maximum security prison. The patient was eventually diagnosed with Huntington's disease (date unknown), allele number 1.743 repeat CAGs. His symptoms were treated with Celexa (citalopram) and the patient's began walking and talking better and is less anxious. The outcome of the remaining events was unknown. The patient remains in jail.

Relevant Medical History:

Patient's father suffered from schizophrenia and dementia.
The patient had no known history of psychological problems

Disease/Surgical Procedure	Start Date	End Date	Continuing?
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FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9252933

Amnesia

Attention deficit/hyperactivity disorder

Divorced

Road traffic accident

Sexual abuse

Medical History Product(s)	Start Date	End Date	Indications	Events
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Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
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Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
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Reporter Source:

Study Report?: No

Sender Organization: FOREST

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15368257

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** BRA **Event Date:** **Outcomes:** HO,OT, **Application Type:**

FDA Rcvd Date: 13-Sep-2018 **Mfr Rcvd Date:** 10-Sep-2018 **Mfr Control #:** PHHY2018BR094226 **Application #:**

Patient Information:

Age: **Sex:** Female **Weight:** KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	QUETIAPINE FUMARATE		1 DF/	Unknown	1 DF, QN	Depression		
2	ALPRAZOLAM		1 MG/	Unknown	1 mg, UNK	Depression		
3	CLOXAZOLAM		1 DF/	Oral	1 DF, QN	Sleep disorder		
4	ESCITALOPRAM		2 DF/QD	Oral	2 DF, QD (at lunch 11 AM)			
5	ESCITALOPRAM		1 DF/QD	Oral	1 DF, QD	Depressed mood		
6	LOSARTAN			Unknown	UNK	Blood pressure abnormal		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	QUETIAPINE FUMARATE		NA	NA	HP8549				
2	ALPRAZOLAM		Unk	Unk					
3	CLOXAZOLAM		No	NA					
4	ESCITALOPRAM		NA	NA					
5	ESCITALOPRAM		NA	NA					
6	LOSARTAN		Unk	Unk					



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15368257

Event Information:

Preferred Term (MedDRA ® Version: 22.1)	ReC
Aggression	NA
Agitation	NA
Anxiety	NA
Asthenia	NA
Choking	NA
Disorientation	NA
Disturbance in attention	NA
Dry mouth	NA
Emotional distress	NA
Hallucination	NA
Impatience	NA
Psychiatric symptom	NA
Screaming	NA
Speech disorder	NA
Tremor	NA
Weight decreased	NA

Event/Problem Narrative:

Case number# PHHY2018BR094226, is a spontaneous report initially received from a consumer (patient) via phone through call center on 04 Sep 2018. This is also a product technical complaint report (Product Tech Complaint 1469406). This report refers to a 60-year-old female patient. Family history included blood pressure problems/hypertensive (everyone in the family). The family also had the history of myotrophic lateral sclerosis. It was reported that, the patient used to fall but she knew to how to get up from the floor and go to bed, had will to fight and was independent even with difficulties. Past medications included Olcadil (cloxazolam) and Vitamin D (ergocalciferol) for short time. The patient entered into panic condition and consulted neurologist. Current conditions included amyotrophic lateral sclerosis, panic and bedridden. Concomitant medication was not reported. The patient received quetiapine fumarate (manufacturer unknown) film coated tablet 25 mg (batch/lot number: HP8549, expiration date: an unknown date in Oct 2019) for the treatment of depression from an unknown start date at a dose of 1 DF, QN (route: unknown). The patient received cloxazolam (manufacturer unknown) tablet 2 mg to sleep from an unknown start date at a dose of 1 DF, QN (oral). The patient received escitalopram (manufacturer unknown) tablet 10 mg for the treatment of to feel better from an unknown start date at a dose of 1 DF, QD (oral). The patient received alprazolam 1 mg for the treatment of depression from an unknown start date at a dose of 1 mg, unknown frequency (route: unknown). The patient received losartan for the treatment of blood pressure



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15368257

from an unknown start date at an unknown dose (route: unknown). On an unknown date, the patient developed dispirited/lost the will of taking care of herself/discouraged (psychiatric symptom), hallucinated (hallucination), disorientated (disorientation), without patience (impatience), speaking rolled up (speech disorder), screaming, very thin and losing a lot of weight (weight decreased), very weak (asthenia), chokes (choking), agitation, anxiety, trembling (tremor), aggressiveness (aggression), mental distress (emotional distress), lack of concentration (disturbance in attention) and dry mouth. On an unknown date, the patient received escitalopram at a dose of 2 DF, QD (oral). The patient informed that she was hospitalized. She informed that she did not know, she said that she did not know which drug caused this. She did not know if it was quetiapine, because she also used other drugs from other laboratories. She informed that she did not call all of the laboratories to ask about the other drugs. She gave up and went to the physician. She reported that she was hospitalized because she was disoriented, very disturbed. She informed that she was not using quetiapine anymore. She said that the physician suspended it and changed the drug, but that she informed that it might not have been quetiapine the cause of the symptoms. The patient did not wish the collection and refunding procedure. Action taken with alprazolam, losartan was unknown, while the treatment with escitalopram was ongoing. Treatment with cloxazolam and quetiapine fumarate was stopped on an unknown date. The outcome of the events psychiatric symptom, dry mouth, disorientation, impatience, speech disorder, screaming, weight decreased, asthenia, choking, agitation, anxiety, tremor, aggression, emotional distress, disturbance in attention and hallucination was reported as condition deteriorated. The seriousness of the events disturbance in attention, disorientation was reported as hospitalization, while the seriousness of other events was not reported. The causality of the events was not reported. Seriousness assessment of the event, choking (medically significant) was upgraded based on the European Medicines Agency-Important Medical Event List.

Follow up report was received from a consumer on 10 Sep 2018: Added verbatim for event disturbance in attention, seriousness (hospitalization) for events disturbance in attention, disorientation. Updated formulation (tablet to FCT) and action taken with quetiapine from ongoing to treatment discontinued.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Amyotrophic lateral sclerosis			YES
Bedridden			YES
Fall			
Hypertension			
Panic disorder			YES



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15368257

Medical History Product(s)	Start Date	End Date	Indications	Events
VITAMIN D OLCADIL				

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
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Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
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Reporter Source:

Study Report?: No

Sender Organization: SANDOZ

503B Compounding
Outsourcing Facility?:

Literature Text:

Printer: CDPEDQ5

User: STEPPERH

Date - Time: 10-Feb-2020 10:49 AM

Total Number of Cases (Non-Esub): 8

Total Number of Pages: 20

Print Job Number: 21449

Disclaimers:

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Processed Case Id's for Images:

5719092 5784479 5909892 5951554 6162314 6274354 6573327 6985357

Failed Case Id's for Images:

Total Failed Cases: 0

Individual Safety Report



4672852-1-00-01

The FDA Safety Information and Adverse Event Reporting Program

Forest Laboratories Inc.

Form Approved: OMB No. 0910-0230 Expires: 09/30/05
 Please Forward Facsimile FDA Facsimile Approval on 03/05/2005
 MF report # **S04-USA-08048-01**
 JF/DR report # _____
 FDA Use Only

Page 1 of 2

A. Patient information

1. Patient identifier (b) (6) in confidence	2. Age at time of event: 42 yrs or Date of birth: UNK	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> other: *

3. Date of event (m/d/yyyy) **UNK**

4. Date of this report (m/d/yyyy) **05/18/2005**

5. Describe event or problem

This U.S. spontaneous report from a forensic psychiatrist described the occurrence of auditory hallucinations, more anxious, accused of murder, nervous and agitated in a 42 year old male patient (b) (6) after discontinuation of Lexapro (escitalopram) therapy indicated for anxiety and depression. There were no concomitant medications. Concurrent medical conditions were unknown by the reporter. The patient's father suffered from schizophrenia and dementia. The specific details regarding escitalopram therapy were unknown by the reporter. Escitalopram, dose unknown, was initiated, discontinued, restarted and then discontinued again by the patient on the dates unknown by the reporter. The patient *

6. Relevant tests/laboratory data, including dates

Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Patient's father suffered from schizophrenia and dementia
 The patient had no known history of psychological problems

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 **LEXAPRO (ESCITALOPRAM)**

#2 _____

2. Dose, frequency & route used

#1 **UNK**

#2 _____

3. Therapy dates (if unknown, give duration) (month or best estimate)

#1 **Unknown to Unknown**

#2 _____

4. Diagnosis for use (indication)

#1 **Anxiety, Depression**

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 **UNKNOWN**

#2 _____

7. Exp. date (if known)

#1 **Unknown**

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # - for product problems only (if known)

#1 _____ #2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

1. None

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)

**Forest Laboratories Inc.
 Harborside Financial Ctr
 Plaza 3 Suite 602
 Jersey City, NJ 07311 USA**

2. Phone number

1 201 386-2000

3. Report source (check all that apply)

foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (m/d/yyyy)

05/09/2005

5. (A)NDA # **21-323**

IND # _____
 PLA # _____

pre-1938 yes
 OTC product yes

6. If IND, protocol # _____

7. Type of report (check all that apply)

5-day 15-day
 10-day periodic
 Initial follow-up # **1**

8. Adverse event term(s)

Murder, Hallucination, auditory, Anxiety, Nervousness, Agitation

9. Mfr. report number

S04-USA-08048-01

E. Initial reporter

1. Name & address phone # (b) (6)

(b) (6)

(b) (6) USA

2. Health professional? yes no

3. Occupation *

4. Initial reporter also sent report to FDA yes no unk



3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

MAY 23 2005

DSS
 MAY 24 2005

Individual Safety Report



4672852-1-00-02

MEDWATCH

(b)
(6)

S04-USA-08048-01

Page 2 of 2

B.2. Other outcome

Medically significant

B.5. Describe event or problem

[continuation:] stated that after escitalopram therapy was discontinued, he experienced auditory hallucinations and felt more anxious (date unknown). The patient verbalized to the reporter that

(b) (6)

(b) (6)

The reporter stated that he believed the patient (b) (6) for identification purposes. (b) (6)

(b) (6)

(b) (6)

The reporter stated that after the murder, the patient was jailed for approximately three months and on 21-DEC-2004, was admitted to the maximum security forensic unit in (b) (6). The reporter stated that the patient's story is very "questionable" and that he believed the patient experienced "intrusive thoughts not auditory hallucinations". The reporter stated that while in custody at the maximum security forensic unit, the patient appeared nervous and agitated. The patient was prescribed Vistaril (hydroxyzine), as needed, for his anxiety. The reporter stated that approximately on 20-JAN-2005, the decision whether or not the patient is considered competent to stand trial will be made. No other information was provided. This case was determined serious due to its medical significance. Further information will be requested.

Follow-up information was received from the attending forensic psychiatrist in response to a written request from Forest Pharmaceuticals Inc. on 09-MAY-2005 via telephone. The reporter stated that he hasn't seen the patient since he went back to jail on 21-JAN-2005. No additional information was available.

Additional information received from the reporting psychiatrist on 13-May-2005 via telephone. The doctor stated that the first time he had seen the patient was following his crime and the patient had already been off escitalopram. The reporter stated that he is unaware of the time between stopping the escitalopram and the commission of the crime. In addition, he confirmed that the patient had no known previous history of psychological problems. No additional information was provided.

FPI 045710

E.3. Occupation

FORENSIC PSYCHIATRIST

DSS

MAY 23 2005

MAY 24 2005

U.S. Department of Health and Human Services



ies Inc.

Form Approved: OMB No. 0910-0230 Expires: 06/30/05
 Please Forward Facsimile FDA Facsimile Approval on 03/05/2005
 Mfr report # S05-USA-01868-01
 J/F/Dial report #
 FDA Use Only

Page 1 of 3

A. Patient

1. Patient identifier (b) (6) (s) in confidence	2. Age at time of event: 31 yrs Date of birth: (b) (6)	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input checked="" type="checkbox"/> other: *	

3. Date of event (m/d/yyyy) ??/??/2005

4. Date of this report (m/d/yyyy) 04/19/2005

5. Describe event or problem

This U.S. spontaneous report from a wife describes the occurrence of violence in her 31-year-old husband taking Lexapro (escitalopram) for anxiety and while drinking alcohol (co-suspect). Concomitant medications included Klonopin (clonazepam). There was no past medical history. The patient was always "laid back and quiet." Escitalopram, taken every other day (dose unknown), commenced on an unknown date. In February 2005 the patient saw his physician who told him the escitalopram needed to be taken everyday, so the patient increased the dose to daily use (dose unknown). Subsequent to the increase to daily dosing the patient began to act violent described as acting angry, yelling and threatening his wife. *

6. Relevant tests/laboratory data, including dates

Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Laid back and quiet
 Drank same amount of alcohol prior to taking Lexapro everyday

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	3. Therapy dates (if unknown, give duration from to (or best estimate))
#1 LEXAPRO (ESCITALOPRAM)	#1 Unknown to 02/22/05
#2 LEXAPRO (ESCITALOPRAM)	#2 02/23/05 to Continuing
2. Dose, frequency & route used	4. Diagnosis for use (indication)
#1 UNK	#1 Anxiety
#2 UNK	#2 Anxiety
5. Event abated after use stopped or dose reduced	6. Lot # (if known)
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	#1 UNKNOWN
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	#2 UNKNOWN
7. Exp. date (if known)	8. Event reappeared after reintroduction
#1 Unknown	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 Unknown	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # - for product problems only (if known)	10. Concomitant medical products and therapy dates (exclude treatment of event)
#1 #2	1. KLONOPIN (CLONAZEPAM) Dates: Unknown to Continuing

G. All manufacturers

1. Contact office - name/address (8 mfring site for devices)	2. Phone number
Forest Laboratories Inc. Harborside Financial Ctr Plaza 3 Suite 602 Jersey City, NJ 07311 USA	1 201 386-2000
4. Date received by manufacturer (m/d/yyyy)	5. (A)NDA #
04/06/2005	21-323
6. # IND, protocol #	IND #
	PLA #
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #	
9. Mfr. report number	8. Adverse event term(s)
S05-USA-01868-01	Aggression

E. Initial reporter

1. Name & address (b) (6)	phone # (b) (6)
(b) (6)	(b) (6)
(b) (6)	USA

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation *	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
---	-----------------	--



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

APR 20 2005

DSS
 APR 21 2005

U.S. Department of Health a



The FDA Safety Information and Adverse Event Reporting Program

Individual Safety Report



4641686-6-00-02

Form Approved: OMB No. 0910-0230 Expires: 08/30/05
 Base Forward Facsimile FDA Facsimile Approval on 03/05/2003
 R report # S05 - USA - 01868 - 01
 Dist report #
 FDA Use Only

A. Patient information

1. Patient identifier (b) (6) in confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
---	--	--	-------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (m/d/yyr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyr)

4. Date of this report (m/d/yyr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#3 ALCOHOL

#4

2. Dose, frequency & route used

#3 UNK

#4

3. Therapy dates (if unknown, give duration) (m/d/yyr to m/d/yyr)

#3 04/04/05 to 04/04/05

#4

4. Diagnosis for use (indication)

#3 Unknown

#4

5. Event abated after use stopped or dose reduced

#3 yes no doesn't apply

#4 yes no doesn't apply

6. Lot # (if known)

#3 UNKNOWN

#4

7. Exp. date (if known)

#3 Unknown

#4

8. Event reappeared after reintroduction

#3 yes no doesn't apply

#4 yes no doesn't apply

9. NDC # - for product problems only (if known)

#3 NI

#4

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)

2. Phone number

3. Report source (check all that apply)

- foreign
- study
- literature
- consumer
- health professional
- user facility
- company representative
- distributor
- other:

4. Date received by manufacturer (m/d/yyr)

5. (A)NDA # _____

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

- 5-day 15-day
- 10-day periodic
- Initial follow-up # _____

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name & address phone #

2. Health professional? yes no

3. Occupation

4. Initial reporter also sent report to FDA yes no unk



3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

DSS

APR 20 2005

APR 21 2005

Individual Safety Report



4641686-6-00-03

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. report number	
	(b) (6)	S05-USA-01868-01	Page 3 of 3

B.2. Other outcome

Medically significant

B.5. Describe event or problem

[continuation:] On 04-APR-2005 the patient drank (b) (6)
(b) (6) He was arrested and taken to jail for domestic violence. The wife moved out of the house with his children. She stated she and the patient had been together for 9 years and he drank the same amount of alcohol prior to taking escitalopram every day and had never acted that way. The physician's nurse reported, via phone, that the patient's last visit was 23-FEB-2005. At that visit the physician stressed the clonazepam was an as needed medication and the escitalopram needed to be taken daily. They were unaware of any of the events as they had not seen or heard from the patient since 23-FEB-2005. As of 07-APR-2005 no other information was available. Further information was requested. This case was deemed serious due to its medical significance.

FPI 051210

E.3. Occupation

PRIMARY CARE PHYSICIAN

APR 20 2005

DSS

APR 21 2005

Individual Safety Report



4805514-8-00-01

Adverse Event Reporting Program

Forest Laboratories Inc.

Form Approved: OMB No. 0910-0230 Expires: 09/30/05
Phase Forward Facsimile FDA Facsimile Approval on 03/05/2003
Mfr report # S05-USA-04561-01
USF/Dis report #
FDA Use Only

Page 1 of 3

A. Patient information			
1. Patient identifier (b) (6)	2. Age at time of event: 61 yrs or Date of birth: UNK	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight UNK lbs OR UNK kgs
in confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death (b) (6) (m/d/yy)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other:			
3. Date of event (m/d/yy)	10/05/2005	4. Date of this report (m/d/yy)	10/17/2005
5. Describe event or problem			
<p>This U.S. spontaneous report from a (b) (6) reporter describes the occurrence of violence (b) (6) and suicide by gunshot in a 61 year-old male patient prescribed Lexapro (escitalopram) for an unknown indication. Concomitant medications existed, but were not specifically identified. Concurrent medical conditions included depression and an unstable mental condition, details otherwise not reported. Past medical history was not reported. The only information provided regarding escitalopram therapy was: "Police seized several prescription drug bottles - including the anti-depressant Lexapro - in the dad's [patient] name" from the *</p>			
6. Relevant tests/laboratory data, including dates			
None			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>Depression Unstable mental condition (nos) Mild-mannered temperament No documented domestic disturbances in the home</p>			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 LEXAPRO (ESCITALOPRAM)			
#2			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/b to best estimate)	
#1 UNK		#1 Unknown to Unknown	
#2		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Unknown		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 UNKNOWN		#1 Unknown	
#2		#2	
9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction	
#1		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1. Unknown medications (nos) Dates: Unknown to Unknown			
G. All manufacturers			
1. Contact office - name/address (& mailing site for devices)		2. Phone number	
Forest Laboratories Inc. Harborside Financial Ctr Plaza 3 Suite 602 Jersey City, NJ 07311 USA		1 201 386-2000	
4. Date received by manufacturer (m/d/yy)		5. (A)NDA # 21-323	
10/06/2005		IND #	
6. If IND, protocol #		PLA #	
7. Type of report (check all that apply)		pre-1938 <input type="checkbox"/> yes	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day		OTC product <input type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic		8. Adverse event term(s)	
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #		Aggression, Completed suicide	
9. Mfr. report number			
S05-USA-04561-01			
E. Initial reporter			
1. Name & address		phone # None reported	
(b) (6)			
(b) (6)		USA	
2. Health professional?		3. Occupation	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		NEWSPAPER WRITER	
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			

FDA

3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

OCT 18 2005

DSS
OCT 19 2005

Individual Safety Report



4805514-8-00-02

t Laboratories Inc.

MEDWATCH

A.1. Patient Identifier

(b)
(6)

G.9. Mfr. report number

805-USA-04561-01

Page 2 of 3

B.5. Describe event or problem

[continuation:] patient's home. The (b) (6) is summarized as follows:
(b) (6)



On the same date, a different (b) (6) reporter described the events as follows: A clinically depressed man took his own life (b) (6)
(b) (6)



OCT 18 2005

DSS
OCT 19 2005

Individual Safety Report



4805514-8-00-03

t Laboratories Inc.

MEDWATCH

A.1. Patient Identifier
(b)
(6)

G.9. Mfr. report number

S05-USA-04561-01

Page 3 of 3

B.5. Describe event or problem

[continuation:] (b) (6)

(b) (6)

FPI 053205

OCT 18 2005

DSS
OCT 19 2005

Individual Safety Report



4859864-X-00-01

U.S. Department of Health and Human Services

Forest Laboratories Inc.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Page 1 of 2

Form Approved: OMB No. 0910-0230 Expires: 06/30/05	FDA Facsimile Approval on 03/05/2005
Phase Forward Facsimile	FDA Facsimile Approval on 03/05/2005
Mfr report #	805-USA-05129-01
UF/DIA report #	
	FDA Use Only

A. Patient information			
1. Patient Identifier (b) (6) in confidence	2. Age at time of event: 14 yrs or Date of birth: UNK	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (medically)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other:			
3. Date of event (month/year) UNK	4. Date of this report (month/year) 12/14/2005		
5. Describe event or problem			
<p>This U.S. spontaneous report from the mother of a 14 year old female patient describes her experience of being argumentative, abnormal behavior, self injury, overdose, panic attack, and suicidal thoughts while taking Lexapro (escitalopram) for depression. Concomitant medications included Allegra (fexofenadine), albuterol, and Singulair (montelukast). Concurrent medical conditions included allergies, asthma and self-injury. The patient had cut her self on her arms in the past. The patient had a family history of depression and suicide. Escitalopram 10mg daily was initiated on approximately 25-OCT-2005 and was increased to 20mg daily on 08-NOV-2005. The patient had an argument with a teacher at school *</p>			
6. Relevant tests/laboratory data, including dates			
None			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)			
<p>Allergies Asthma Self injury: cutting arms Family history of depression and suicide</p>			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 LEXAPRO (ESCITALOPRAM)			
#2 LEXAPRO (ESCITALOPRAM)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) (month to best estimate)	
#1 20 MG QD PO		#1 11/08/05 to Continuing	
#2 10 MG QD PO		#2 10/25/05 to 11/07/05	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Depression		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Depression		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot# (if known)		7. Exp. date (if known)	
#1 UNKNOWN		#1 Unknown	
#2 UNKNOWN		#2 Unknown	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
9. NDC #- for product problems only (if known)			
#1 #2			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1. ALLEGRA (FEXOFENADINE HYDROCHLORIDE) Dates: Unknown to Continuing			
2. ALBUTEROL Dates: Unknown to Continuing			
3. SINGULAIR (MONTELUKAST) Dates: Unknown to Continuing			
C. All manufacturers			
1. Contact office - name/address (8 mfring site for devices)		2. Phone number	
Forest Laboratories Inc. Harborside Financial Ctr Plaza 3 Suite 602 Jersey City, NJ 07311 USA		1 201 386-2000	
4. Date received by manufacturer (month/year) 12/06/2005		3. Report source (check all that apply)	
6. If IND, protocol #		<input type="checkbox"/> foreign	
7. Type of report (check all that apply)		<input type="checkbox"/> study	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day		<input type="checkbox"/> literature	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic		<input checked="" type="checkbox"/> consumer	
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		<input type="checkbox"/> health professional	
9. Mfr. report number 805-USA-05129-01		<input type="checkbox"/> user facility	
6. (A)NDA # 21-323		<input type="checkbox"/> company representative	
IND # _____		<input type="checkbox"/> distributor	
PLA # _____		<input type="checkbox"/> other:	
pre-1938 <input type="checkbox"/> yes			
OTC product <input type="checkbox"/> yes			
8. Adverse event term(s)			
Intentional self-injury, Suicidal ideation, Abnormal behaviour, Overdose, Aggression, Panic attack			
E. Initial reporter			
1. Name & address (b) (6)		phone # (b) (6)	
No address reported USA			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		3. Occupation CONSUMER	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			

3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

* Item completed on continuation pages.

DSS
DEC 16 2005

DEC 15 2005

Individual Safety Report



4859864-X-00-02

Forest Laboratories Inc.

MEDWATCH	A.1. Patient Identifier	G.S. Mfr. report number	Page 2 of 2
	(b) (6)	S05-USA-05129-01	

B.5. Describe event or problem

[continuation:] on an unknown date. During this argument the patient displayed abnormal behavior. The patient (b) (6) The event was reported to the patient's physician. He prescribed Adderall (amphetamines) 20mg daily on 15-NOV-2005. On (b) (6) the patient reported to her mother that she had taken 80mg of amphetamines and cut her arm. The cut to her arm was worse than the cutting she had done in the past. She was taken to an emergency room. While in the emergency room she had a panic attack. This event included an outburst of yelling, shaking and twitching. Her laceration was closed with skin adhesive. She did not report having suicidal thoughts. During her visit to the emergency room she was not given any medications and no testing or additional procedures were performed. The patient was monitored in the emergency room and sent home. That evening the symptoms of her panic attack resolved. On (b) (6) the patient told her mother she had suicidal thoughts. She was taken to an inpatient mental health center and admitted for treatment. Amphetamines therapy was discontinued. As of (b) (6) escitalopram therapy continued and the events of being argumentative and suicidal thoughts continued. The events overdose and panic attack were resolved. No other information was provided.

FPI 053814

DSS
DEC 16 2005

DEC 15 2005



5135598-1-00-01

U.S. Department of Health and Human Services

Forest Laboratories Inc.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Form Approved: OMB No. 0910-0230 Expires: 09/30/05
 Phase Forward Facsimile FDA Facsimile Approval on 03/05/2003
 Mfr report # S06-USA-04294-01
 JF/Dist report #
 FDA Use Only

Page 1 of 2

A. Patient information

1. Patient identifier (b) (6) in confidence	2. Age at time of event: 17 yrs or Date of birth: (b) (6)	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 230 lbs or kgs
--	---	---	-----------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (b) (6) (mortality)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event (m/d/yyyy): 07/26/2004
 4. Date of this report (m/d/yyyy): 10/18/2006

5. Describe event or problem

This U.S. spontaneous report was received from an attorney in the form of a summons and describes the occurrence of suicide and a possible attempted homicide in a 17-year-old male taking Lexapro (escitalopram oxalate) for depression. There were no concomitant medications or reported concurrent medical conditions. There was no personal medical history. Family history included father's death in a "suicide by (b) (6) incident in 1995. Escitalopram, one tablet per day (nos), commenced on 17-JUN-2004. On (b) (6) (via information from the County Sheriff's Department statements in which the patient was being charged with (b) (6)), the patient's (b) (6)

6. Relevant tests/laboratory data, including dates

Unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Family history - father died in "suicide by (b) (6) incident in 1995
 Race: CAUCASIAN

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 LEXAPRO (ESCITALOPRAM)
 #2

2. Dose, frequency & route used
 #1 UNK
 #2

3. Therapy dates (if unknown, give duration) (month/year)
 #1 06/17/04 to 07/26/04
 #2

4. Diagnosis for use (indication)
 #1 Depression
 #2

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known)
 #1 UNKNOWN
 #2

7. Exp. date (if known)
 #1 Unknown
 #2

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # - for product problems only (if known)
 #1 #2

10. Concomitant medical products and therapy dates (exclude treatment of event)
 1. None

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
 Forest Laboratories Inc.
 Harborside Financial Ctr
 Plaza 3 Suite 602
 Jersey City, NJ 07311 USA

2. Phone number
 1 201 386-2000

3. Report source (check all that apply)
 foreign
 study
 literature
 consumer
 health professional
 user facility
 company representative
 distributor
 other:

4. Date received by manufacturer (m/d/yyyy)
 08/09/2006

5. (A)NDA # 21-323
 IND #
 PLA #
 pre-1938 yes
 OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)
 5-day 15-day
 10-day periodic
 Initial follow-up #

8. Adverse event term(s)
 Completed suicide, Physical assault

9. Mfr. report number
 S06-USA-04294-01

E. Initial reporter

1. Name & address (b) (6)
 phone # (b) (6)

2. Health professional?
 yes no

3. Occupation
 ATTORNEY

4. Initial reporter also sent report to FDA
 yes no unk



3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
 * Item completed on continuation pages.



OCT 20 2006

DSS
 OCT 23 2006



Forest Laboratories Inc.

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 2 of 2
	(b) (6)	S06-USA-04294-01	

B.5. Describe event or problem

[continuation:] reported to police that while attempting to (b) (6) from the patient that same day, he was holding a small handgun, (b) (6)

(b) (6) She stated that, "As she was walking away from him, he told her to stop. She stated that she turned and looked at him and he was pointing the gun at the (b) (6)

(b) (6) She told him not to be stupid. (The patient) swung the gun into (b) (6)

(b) (6) (She) stated she does not know where the gun was shot because (b) (6)

(b) (6) The (b) (6) stated that the patient had made threats of suicide in the past, (b) (6)

(b) (6) The (b) (6) left the patient and reported the incident to the police. Within a short time, the police arrived at the patient's house and found him with a gunshot wound (b) (6) He was reportedly "still breathing but was unconscious," and (b) (6) was noted by officers. He was transported to a medical facility and pronounced dead a few hours later. Officers did not find a suicide note. They reported finding (b) (6)

(b) (6) No further information has been provided for this case.

S06-USA-04294-01

E.1. Name & address

[continuation:] (b) (6) USA

OCT 20 2006

DSS
OCT 23 2006



U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
FORM FDA 3500A (10/05)

Forest Laboratories Inc.

Form Approved: OMB No. 0910-0291 Expires: 10/31/08
Phase Forward Facsimile FDA Facsimile Approval on 07/13/2006

Mfr report #
S07-USA-01063-01

JF/Importer report #

Page 1 of 2

FDA Use Only

A. Patient information			
1. Patient identifier (b) (6) in confidence	2. Age at time of event: 16 years or Date of birth: (b) (6)	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply) (b) (6) <input checked="" type="checkbox"/> death (mortality) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> required intervention to prevent permanent impairment/damage (devices) <input type="checkbox"/> disability or permanent damage <input type="checkbox"/> congenital anomaly/birth defect <input type="checkbox"/> other serious (important medical events)			
3. Date of event (mm/dd/yyyy) 10/??/2004	4. Date of this report (mm/dd/yyyy) 03/14/2007		
5. Describe event or problem This U.S. spontaneous report from an attorney in the form of a summons describes the occurrence of not eating, continued anxiety and depression, and suicide in a 16 year old female patient while taking Lexapro (escitalopram) for anxiety and depression. Concomitant medications were unknown. Concurrent medical conditions included two recent suicide attempts, stress, insomnia and fatigue. Past medical history was unknown. The patient presented to a university wellness center, accompanied by her mother, on 20-OCT-2004 for the purpose of obtaining medical treatment for attempted suicide, stress, anxiety, depression, insomnia and fatigue. The patient was seen by an advanced registered nurse (cont.)			
6. Relevant tests/laboratory data, including dates Unknown			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Two recent suicide attempts Stress Insomnia Fatigue			
C. Suspect product(s)			
1. Name (give labeled strength & mfr/labeler)			
#1 LEXAPRO (ESCITALOPRAM)			
#2 LEXAPRO (ESCITALOPRAM)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from to (or best estimate))	
#1		#1 Unknown to 11/01/04	
#2		#2 10/20/04 to Unknown	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Anxiety, Depression		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Anxiety, Depression		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot#	7. Exp. date (if known)		8. Event reappeared after reintroduction
#1 UNKNOWN	#1 Unknown		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 UNKNOWN	#2 Unknown		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # or unique ID			
#1 #2			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1. Unknown			
G. All manufacturers			
1. Contact office - name/address (& mailing site for devices)		2. Phone number	
Forest Laboratories Inc. Harborside Financial Ctr Plaza 3 Suite 602 Jersey City, NJ 07311 USA		1. 201 386-2000	
4. Date received by manufacturer (mm/dd/yyyy) 03/07/2007		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:	
6. If IND, protocol #		5. (A)NDA # 21-323 IND # STN # PMA/510(k)# Combination product <input type="checkbox"/> yes pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> periodic <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> Initial <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> follow-up # _____		8. Adverse event term(s) Completed suicide, Anorexia, Drug ineffective	
9. Mfr. report number S07-USA-01063-01			
E. Initial reporter			
1. Name & address (b) (6)		phone # (b) (6)	
(b) (6)		USA	
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no		3. Occupation ATTORNEY	
		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

DSS

MAR 15 2007

MAR 16 2007

Individual Safety Report



5270459-9-00-02

Lundbeck Laboratories Inc.

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 2 of 2
	(b) (6)	S07-USA-01063-01	

B.5. Describe event or problem

[continuation:] practitioner (ARNP) at the facility. The ARNP was made aware of the patient's two recent suicide attempts. According to the summons this included (b) (6) (b) (6). On 20-OCT-2004 the ARNP placed the patient on escitalopram. The dosage of escitalopram initiated was not provided. On 28-OCT-2004 the patient returned to the clinic for an appointment with the same ARNP. At that appointment it was reported to the ARNP that she was not eating, and continued to suffer anxiety and depression. The patient's dose of escitalopram was doubled by the ARNP. The summons stated, the patient's "symptoms were those of Lexapro-induced psychosis and/or akathisia" On (b) (6) the patient "shot herself to death (b) (6) gunshot (b) (6)". The summons also included the following statement regarding the patient's experience "suffered great pain and suffering and emotional distress, including but not limited to the knowledge of her impending death". No additional information was provided. Additional information will be requested.

S07-USA-01063-01

DSS

MAR 15 2007

MAR 16 2007



5766138-1-00-01

MEDWATCH

FORM FDA 3500A (10/05)

Forest Laboratories Inc.

CaseID: 6573327
Form Approved OMB No 0910-0291 Expires 10/31/08
Phase Forward Facsimile FDA Facsimile Approval on 07/13/2006

Mfr report # S08-USA-00477-01
UF importer report #
FDA Use Only

Page 1 of 5

A. Patient information			
1. Patient identifier UNKNOWN in confidence	2. Age at time of event: 16 years or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mm/dd/yyyy) <input type="checkbox"/> disability or permanent damage <input type="checkbox"/> life-threatening <input type="checkbox"/> congenital anomaly/birth defect <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> other serious (important medical events) <input type="checkbox"/> required intervention to prevent permanent impairment/damage (devices)			
3. Date of event (mm/dd/yyyy) 07/28/2007	4. Date of this report (mm/dd/yyyy) 06/03/2008		
5. Describe event or problem			
<p>This U.S. spontaneous report from the mother of a 16-year-old female patient describes the occurrence of her prescribed overdose, irrational behavior, violent behavior, agitation and acting withdrawn while taking Lexapro (escitalopram) for depression. Concomitant medications included Adderall (amphetamine) and birth control (nos). There were no concurrent medical conditions or past medical history. Family history included bipolar disorder in the patient's grandfather, paternal aunt and 2 paternal uncles. Escitalopram, 5mg daily commenced on 28-APR-2006, was increased to 10mg daily on 10-JUN-2006, increased further to 20mg daily on 04-JUN-2007 and then up to 30mg on 28-JUL-2007. In September 2007, the (cont.)</p>			
6. Relevant tests/laboratory data, including dates			
None			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>History of mild irritability Bipolar disorder in patient's grandfather, paternal aunt and 2 paternal uncles</p>			

C. Suspect product(s)			
1. Name (give labeled strength & mfr/labeler)			
#1 LEXAPRO (ESCITALOPRAM)			
#2 LEXAPRO (ESCITALOPRAM)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/b to (or best estimate))	
#1 30 MG QD PO		#1 07/28/07 to 10/05/07	
#2 40 MG QD PO		#2 10/06/07 to 12/10/07	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Depression		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Depression		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot #		7. Exp. date (if known)	
#1 UNKNOWN		#1 Unknown	
#2 UNKNOWN		#2 Unknown	
8. Event reappeared after reintroduction		9. NDC # or unique ID	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		#1	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		#2	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1. ADDERALL XR (AMPHETAMINE EXTENDED RELEASE) Dates:09/20/07 to Continuing Daily Dose:30MG			
2. BIRTH CONTROL (NOS) Dates:Unknown to Continuing			
G. All manufacturers			
1. Contact office - name/address (& mfrng site for devices)		2. Phone number	
Forest Laboratories Inc. Harborside Financial Ctr Plaza 3 Suite 602 Jersey City, NJ 07311 USA		1 201 386-2000	
3. Report source (check all that apply)		4. Date received by manufacturer (mm/dd/yyyy)	
<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:		05/28/2008	
5. (A)NDA # 21-323		6. If IND, protocol #	
IND #			
STN #			
PMA/510(k)#		7. Type of report (check all that apply)	
Combination product <input type="checkbox"/> yes		<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day	
pre-1938 <input type="checkbox"/> yes		<input type="checkbox"/> 7-day <input type="checkbox"/> periodic	
OTC product <input type="checkbox"/> yes		<input type="checkbox"/> 10-day <input type="checkbox"/> Initial	
		<input checked="" type="checkbox"/> 15-day <input checked="" type="checkbox"/> follow-up # 2	
8. Adverse event term(s)		9. Mfr. report number	
Thinking abnormal, Overdose, Aggression, Agitation, Irritability, Social avoidant behaviour		S08-USA-00477-01	
E. Initial reporter			
1. Name & address		phone # (b) (6)	
(b) (6)			
USA			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation PSYCHIATRIST	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

DSS

JUN - 6 2008

JUN - 5 2008



5766138-1-00-02

Forest Laboratories Inc.

Form Approved OMB No 0910-0291 Expires: 10/31/08
Phase Forward Facsimile FDA Facsimile Approval on 07/13/2006

Mfr report #	S08-USA-00477-01
JF/Importer report #	
	FDA Use Only

MEDWATCH

FORM FDA 3500A (10/05)

Page 2 of 5

A. Patient information			
1. Patient identifier UNKNOWN	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
in confidence			
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mm/dd/yyyy)		<input type="checkbox"/> disability or permanent damage	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly/birth defect	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> other serious (important medical events)	
<input type="checkbox"/> required intervention to prevent permanent impairment/damage (devices)			
3. Date of event (mm/dd/yyyy)	4. Date of this report (mm/dd/yyyy)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect product(s)	
1. Name (give labeled strength & mfr/labeler)	
#3	LEXAPRO (ESCITALOPRAM)
#4	LEXAPRO (ESCITALOPRAM)
2. Dose, frequency & route used	
#3	20 MG QD PO
#4	5 MG QD PO
3. Therapy dates (if unknown, give duration) from to (or best estimate)	
#3	12/11/07 to Continuing
#4	04/28/06 to 06/09/06
4. Diagnosis for use (indication)	
#3	Depression
#4	Depression
5. Event abated after use stopped or dose reduced	
#3	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#4	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot #	
#3	UNKNOWN
#4	UNKNOWN
7. Exp. date (if known)	
#3	Unknown
#4	Unknown
8. Event reappeared after reintroduction	
#3	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#4	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # or unique ID	
#3	#4
10. Concomitant medical products and therapy dates (exclude treatment of event)	
G. All manufacturers	
1. Contact office - name/address (& mailing site for devices)	
2. Phone number	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input type="checkbox"/> health professional	
<input type="checkbox"/> user facility	
<input type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other:	
4. Date received by manufacturer (mm/dd/yyyy)	5. (A)NDA #
	IND #
	STN #
6. # IND, protocol #	PMA/510(k)#
	Combination product <input type="checkbox"/> yes
	pre-1938 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes
7. Type of report (check all that apply)	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day	
<input type="checkbox"/> 7-day <input type="checkbox"/> periodic	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial	
<input type="checkbox"/> 15-day <input type="checkbox"/> follow-up # _____	
8. Adverse event term(s)	
9. Mfr. report number	
E. Initial reporter	
1. Name & address	phone #
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	
3. Occupation	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

DSS

JUN - 6 2008

JUN - 5 2008



5766138-1-00-03

MEDWATCH

FORM FDA 3500A (10/05)

Forest Laboratories Inc.

CaseID: 65713327
Form Approved. OMB No 0910-0291 Expires 10/31/08
Phase Forward Facsimile FDA Facsimile Approval on 07/13/2006

Mfr report #	S08-USA-00477-01
JF/Importer report #	
FDA Use Only	

Page 3 of 5

A. Patient information			
1. Patient Identifier UNKNOWN in confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mm/dd/yyyy)		<input type="checkbox"/> disability or permanent damage	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly/birth defect	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> other serious (important medical events)	
<input type="checkbox"/> required intervention to prevent permanent impairment/damage (devices)			
3. Date of event (mm/dd/yyyy)	4. Date of this report (mm/dd/yyyy)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect product(s)			
1. Name (give labeled strength & mfr/labeler)			
#5 LEXAPRO (ESCITALOPRAM)			
#6 LEXAPRO (ESCITALOPRAM)			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#5 10 MG QD PO		#5 06/10/06 to 06/03/07	
#6 20 MG QD PO		#6 06/04/07 to 07/27/07	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#5 Depression		#5 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#6 Depression		#6 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot #	7. Exp. date (if known)		8. Event reappeared after reintroduction
#5 UNKNOWN	#5 Unknown		
#6 UNKNOWN	#6 Unknown		#5 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # or unique ID		#6 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#5		#6	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office - name/address (& mfging site for devices)		2. Phone number	
4. Date received by manufacturer (mm/dd/yyyy)		5. (A)NDA #	
6. If IND, protocol #		IND #	
7. Type of report (check all that apply)		STN #	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day		PMA/510(k)#	
<input type="checkbox"/> 7-day <input type="checkbox"/> periodic		Combination product <input type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial		pre-1938 <input type="checkbox"/> yes	
<input type="checkbox"/> 15-day <input type="checkbox"/> follow-up # _____		OTC product <input type="checkbox"/> yes	
9. Mfr. report number		8. Adverse event term(s)	
3. Report source (check all that apply)			
<input type="checkbox"/> foreign			
<input type="checkbox"/> study			
<input type="checkbox"/> literature			
<input type="checkbox"/> consumer			
<input type="checkbox"/> health professional			
<input type="checkbox"/> user facility			
<input type="checkbox"/> company representative			
<input type="checkbox"/> distributor			
<input type="checkbox"/> other:			
E. Initial reporter			
1. Name & address		phone #	
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

DSS

JUN - 6 2008

JUN - 5 2008



Laboratories Inc.

MEDWATCH	A.1. Patient Identifier	G.9. Mfr. report number	Page 4 of 5
	UNKNOWN	S08-USA-00477-01	

B.5. Describe event or problem

[continuation:] patient's family began to notice that the patient was becoming agitated and withdrawn. Around this time, the patient's parents discovered that the patient was dating a (b) (6) (b) (6). The parents believed that the patient was acting irrational, further described as making choices she would not normally make. The patient's parents forbid her from seeing him. Then, she became increasingly agitated and withdrawn from her family. She did not want to be near any member of her family and would yell at them if anyone came near her. She wanted to be alone all the time. Escitalopram was increased to 40mg daily on 06-OCT-2007. The increase in dosage caused the agitation to worsen and it quickly escalated to violent behavior. The patient would threaten her family and make statements such as (b) (6) (b) (6). The agitation and irrational behavior quickly led to physical violence. The patient began punching her family and trying to hurt them, although no one ever sustained any injury that required medical intervention. On (b) (6) the patient was admitted to the hospital because she was a danger to others. The reporter denied that the patient had ever sustained self inflicted injury or made suicidal comments. Upon admission to the hospital, escitalopram was decreased to 20mg daily. The patient remained withdrawn and refused to talk to staff or participate in group activities. There was one episode of violence during the hospitalization; the patient had tried to punch a hospital staff member during a family therapy session. However, the patient's behavior gradually showed improvement and no other violent events occurred. She was discharged from the hospital on (b) (6). The reporter stated that the hospital physicians had mentioned that her daughter may be bipolar or have a personality disorder; however, no new official diagnoses were ever made. While in the hospital and upon discharge, the patient refused to initiate any new medication. Then soon after coming home, the reporter stated that her daughter became "a different kid". She was no longer violent and was less agitated, withdrawn and irrational. The reporter attributed the change in her daughter's behavior to the decreased dose of escitalopram. The reporter stated that when her daughter's dose of escitalopram was increased to 30mg and 40mg, the patient's doctor had been required to sign paperwork from the insurance company to fill the prescription because the prescribed dosage was above the regular recommended dose. The patient's mother stated that the events had most likely been caused because the dose of escitalopram had been too high. Three weeks after the patient was discharged, Lamictal (lamotrigine) therapy was initiated. As of 07-FEB-2008, escitalopram continued at 20mg daily and the violent behavior and prescribed overdose remained resolved. The agitation, acting withdrawn and irrational behavior continued to abate. No further information was provided. Further information will be requested for this case.

Follow-up information was received from the physician via mail on 02-APR-2008. Additional events included extreme irritability/explosiveness. Additional past medical history included mild irritability. The physician reported that "agitation, explosiveness and extreme irritability resulted in the patient running out of the house and receiving an ER (emergency room) evaluation and brief hospitalization." The physician reported that it was possible that escitalopram had caused the events. As of 02-APR-2008, escitalopram continued and the events continued to abate. No further information was provided.

Follow-up information was received from the physician via mail on 28-MAY-2008. The physician further described the patient's history of "mild irritability" by stating that the patient had "no frank mania or racing thoughts but instead low levels of agitation and being easily (cont.)"

DSS

JUN - 6 2008

JUN - 5 2008



5766138-1-00-05

est Laboratories Inc.

<p>MEDWATCH</p>	<p>A.1. Patient Identifier UNKNOWN</p>	<p>G.9. Mfr. report number S08-USA-00477-01</p>	<p>Page 5 of 5</p>
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B.5. Describe event or problem

[continuation:] angered/frustrated". The extreme irritability/explosiveness, agitation, acting withdrawn and irrational behavior had resolved. The violent behavior had not recurred. The physician reported that the patient's diagnosis upon discharge from the hospital was depression. As of 28-MAY-2008, escitalopram continued at 20mg daily and all of the events were resolved. No further information was provided.

S08-USA-00477-01

DSS

JUN - 6 2008

JUN - 5 2008

Individual Safety Report



6168094-3-00-01

TARY reporting of product problems and use errors

ion - Page 1

FDA USE ONLY

Triage unit sequence #

374424

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event, or Date of Birth: 33 Years	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 210 lb or _____ kg
--	--	---	------------------------------------

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

Death: (b) (6) (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defect
 Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)

09/27/2008 04/21/2009

5. Describe Event, Problem or Product Use Error

MY HUSBAND WAS PRESCRIBED LEXAPRO AND AFTER TAKING IT ON A DAILY FOR A SHORT TIME HE BECAME EXTREAMLY VIOLENT ,HAD MAJOR MOOD SWINGS AND TWO ATTEMPTS FOR SUICIDE AND ON (b) (6) HE SHOT AND KILLED HIMSELF WHILE ALONE IN OUR LINING ROOM. THE SIDE AFFECTS WHERE SO BAD HE BECAME A DIFFERENT PERSON ALL TOGETHER. THIS DRUG IS DANGEROUS AND HAS CAUSED WAY TO MANY DEATHS!

More

6. Relevant Tests/Laboratory Data, including Dates

More

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
LEXAPRO 20 MG ?

#1

#2

2. Dose or Amount	Frequency	Route
#1 ONCE DAILEY		po
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 01/01/2006 -- 09/27/2008

#2 --

4. Diagnosis or Reason for Use (Indication)
ANXIETY

#1

#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't Apply

#2 Yes No Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply

#2 Yes No Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	<input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

RECEIVED
APR 24 2009 APR 23 2009
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

LEXAPRO ZANAX AND AMBIAN USED FOR TWO YEARS AND ENDED IN MY HUSBAND KILLING HIMSELF.

More

G. REPORTER (See confidentiality section on back)

1. Name and Address (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: