U.S. Department of Health and Human Services

MedWatch
Individual Safety Report

4869800-8-00-01

use by user-facilities,
istributors and manufacturers
ANDATORY reporting
Lilly and Company

Page 1 of 2

Retsys International, Inc., FDA Facsimile Approval: 12-AUG-2004

MW report # US_0502111748
UF/Importer Report #
FDA Use Only

A. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	10 Years	☐ Female	UNK lbs
In confidence	or Date of Birth: UNK	☒ Male	or UNK 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 UNK (mo/day/yr)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☒ Other: Medically Signif

3. Date of Event (mo/day/year): --/--/2000

4. Date of This Report (mo/day/year): 12/13/2005

5. Describe Event or Problem
Event Verbatim (PREFERRED TERM) (Related symptoms/diagnoses separated by commas)
(b) (6)

alleged sexual abuse[Victim of sexual abuse]
alleged domestic abuse[Victim of child abuse]
family stress[Family stress]
hostility[Hostility]
mania[Mania]

Case Description:
(b) (6)

continued in additional info section...

6. Relevant Tests/Laboratory Data, Including Dates
NI

RECEIVED
DEC 23 2005
CDR/CDER

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
#1 UNK to Ongoing, Medical Condition, Depression ("NO HISTORY OF VIOLENCE")
#2 UNK, Medical Condition, Anger (ANGRY AT HIS FATHER)

C. SUSPECT MEDICATION(S)

1. Name (Give labeled strength & mfr/labeler, if known)
#1. PROZAC(FLUOXETINE HYDROCHLORIDE UNKNOWN (continued)
#2.

2. Dose, Frequency & Route Used
#1. UNK, unknown, UNK
#2.

3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
#1. UNK
#2.

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

5. Event Abated After Use Stopped or Dose Reduced?
#1. ☐ Yes ☐ No ☐ Doesn't Apply UNK
#2. ☐ Yes ☐ No ☐ Doesn't Apply

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

7. Exp. Date (if known)
#1. UNK
#2.

8. Event Reappeared After Reintroduction?
#1. ☐ Yes ☐ No ☐ Doesn't Apply UNK
#2. ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# (For product problems only)

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
NI

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
Eli Lilly and Company

Lilly Corporate Center
Indianapolis, IN 46285 UNITED STATES

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 (mo/day/yr)
12/12/2005

5. (A)NDA # 18-936
IND #
PLA #
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. If IND, Give 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, Victim of sexual abuse, Victim of child abuse, Family stress, Hostility, Mania

9. Manufacturer Report Number
US_0502111748

E. INITIAL REPORTER

1. Name and Address
UNITED STATES
Name and address withheld.

Phone # Withheld

2. Health Professional?
☐ Yes ☒ No

3. Occupation
UNK

4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No ☒ Unk

FDA 2500A Facsimile

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

DSS
DEC 28 2005

DEC 23 2005

Eli Lilly and Company

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

MFR report # US 0502111748

UF/Importer Report #

FDA Use Only

Individual Safety Report

4869800-8-00-02

Submission of a report does not constitute
that medical personnel, user
ter, distributor, manufacturer or
ed or contributed to the event.

ADDITIONAL INFORMATION

B5. EVENT DESCRIPTION (cont.)

(b) (6)

C1. Name (cont.)
Suspect Medication #1: PROZAC(FLUOXETINE HYDROCHLORIDE UNKNOWN FORMULATION) Unknown

DSS
DEC 2 8 2005

DEC 2 3 2005

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7677022

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: FRA Outcomes: OT (A)NDA/BLA: 018936 /

FDA Rcvd Date: 19-Nov-2010 Mfr Rcvd Date: 05-Nov-2010 Mfr Control #: FR-ELI_LILLY_AND_COMPANY-FR201011001836

Patient Information:

Age: 55 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC	20 MG/	Oral	20 mg, daily (1/D)	BIPOLAR DISORDER	May-2010	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC		U					ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Dissociative amnesia	U
Dissociative disorder	U
Homicide	U
Off label use	U

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7677022

Preferred Term (MedDRA Version: 18.0 ReC

Event/Problem Narrative:

This legal case, reported by a legal psychiatrist expert, concerns a 55-year old male patient of unknown origin. Medical history included bipolar disorder diagnosed late in 2000, dissociative fugue during youth, several suicide attempts, chronic alcohol consumption, conflict with his partner and recent loss of employment. Concomitant medications included valpromide indicated for bipolar disorder and croton phytotheraphy (no indication for use was provided). The patient received fluoxetine hydrochloride (Prozac) capsules 20 mg daily orally, for the treatment of bipolar disorder (off label use), for about six months (approximately [redacted]. Sometime, whilst on fluoxetine hydrochloride treatment, he [redacted] and murdered his partner with [redacted]. The events were considered serious due to other medical significant reasons. Corrective treatment, outcome of the events and fluoxetine hydrochloride status were not reported. The reporting legal psychiatrist expert opinion was unknown concerning these events and fluoxetine causality. Update 16-Nov-2010 Additional information received on 12-Nov-2010 by the initial reporter and processed at the same time of initial case entry.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
[redacted]	2000		UNKNOWN
ALCOHOLISM			UNKNOWN
DISSOCIATIVE FUGUE			UNKNOWN
LOSS OF EMPLOYMENT			UNKNOWN
PARTNER STRESS			UNKNOWN
SUICIDE ATTEMPT			UNKNOWN

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7677022

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

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	VALPROMIDE		Oral	UNK, 3/D	BIPOLAR DISORDER	May-2010		

Reporter Source:

Study Report?: No Sender Organization: ELI LILLY AND CO

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7762506

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: USA Outcomes: OT (A)NDA/BLA: 021427 /

FDA Rcvd Date: 17-Jan-2011 Mfr Rcvd Date: 04-Jan-2011 Mfr Control #: US-ELI_LILLY_AND_COMPANY-US201101001146

Patient Information:

Age: 42 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	CYMBALTA			UNK, unknown	DEPRESSION		
2	PROZAC			UNK, unknown	DEPRESSION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	CYMBALTA							ELI LILLY AND CO
2	PROZAC							

Event Information:

Preferred Term (MedDRA® Version: 17.0) ReC

Abnormal behaviour

Bipolar disorder

Depressed mood

Homicide

Mania

Maternal exposure before pregnancy

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7762506

Event/Problem Narrative:

This spontaneous case, reported by a nurse who contacted the company reporting an adverse event, concerns a 42 years old male patient of unknown origin. The patient's medical history included depression, [redacted], [redacted] and behavior modifications. Concomitant medications were not provided. The patient received duloxetine hydrochloride (Cymbalta) for depression. At a different unspecified time, the patient received fluoxetine hydrochloride (Prozac) for depression. The dose, frequency and start dates were unknown for both medications. After taking fluoxetine, the patient would become more manic, a happy manic and was outgoing. After taking duloxetine, the patient would get depressed and could not see that his behavior was different. The patient [redacted] and was kept away from his [redacted] by a [redacted] When away from behavior modification provided by his parents, he got mixed up. On an unspecified date, the patient murdered [redacted]. The event of murder was considered serious for other reasons by the company. The patient was sent to prison where he was diagnosed with bipolar disorder. It was also reported that on an unspecified date the pateint's wife gave birth to an eight pound full term baby and the infant died of unknown cause six days after birth. No additional information was provided. The status of the fluoxetine therapy and the duloxetine therapy were not reported. The outcome of the events was unknown. The reporting nurse related murdering [redacted], would get depressed, could not see behavior was different and diagnosed with bipolar to duloxetine. The reporting nurse related more manic, happy manic, outgoing to fluoxetine.

Parent-Child Link: US201101001161. This case is also related to US201101001151 - same reporter.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
DEPRESSION			UNKNOWN
LOSS OF EMPLOYMENT			UNKNOWN

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 7762506

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization: ELI LILLY AND CO

Literature Text:

Case ID: 7979016

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: CAN Outcomes: OT, (A)NDA/BLA: 018936 /

FDA Rcvd Date: 22-Jan-2013 Mfr Rcvd Date: 14-Jan-2013 Mfr Control #: CA-ELI_LILLY_AND_COMPANY-CA201105008333

Patient Information:

Age: 16 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC			UNK UNK, unknown	Depression	24-Jun-2009	
2	PROZAC			UNK, unknown		2009	2009
3	PROZAC			UNK, unknown		Jun-2009	2009

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC			A				ELI LILLY AND CO
2	PROZAC			A				ELI LILLY AND CO
3	PROZAC			A				ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 18.0) ReC

Agitation
Anger
Condition aggravated
Feeling abnormal
Homicide
Mania
Mental impairment
Off label use

Case ID: 7979016

Preferred Term (MedDRA Version: 17.0 **ReC**

Self injurious behaviour

Suicide attempt

Event/Problem Narrative:

This spontaneous case, reported by a consumer, from the newspaper articles containing two psychiatrists published on [redacted], with additional information from another consumer from the newspaper articles by [redacted] with additional information from previous consumer reporters, and additional information from another consumer reporter from the [redacted], concerns a 16-year-old male patient of unknown origin.

Medical history included depression and drug and alcohol abuse. It was reported that he went from a [redacted] Concomitant medications were not provided.

The patient received fluoxetine hydrochloride (Prozac) tablets for treatment of depression starting on 24Jun2009; dosage regimen and route of administration were not provided. Starting on an unspecified date, he seemed to be getting worse (no details provided) while taking fluoxetine (time to onset not provided). On an unspecified date, after starting fluoxetine, he began to act out violently and even tried to harm himself on several occasions. On approximately [redacted], after starting the fluoxetine, he took an overdose of an unspecified medication that belonged to his [redacted] in an apparent suicide attempt. This prompted his doctor to increase the fluoxetine dosage (no details provided) despite indications his mental state was worsening/mental deterioration (conflicting start date of Jun2009 provided for increased dose). On a [redacted] in [redacted], [redacted] months after beginning fluoxetine, a friend of the patient went to the home of the patient and [redacted] He then stabbed the victim. The victim died after suffering a stab [redacted] The psychiatrist reporter in the article stated: [redacted] The psychiatrist reported [redacted] Health Canada rules stated fluoxetine was not for use by anyone younger than 18 (off label use). An attorney indicated the homicide was [redacted] he cold-bloodedly stabbed his friend who [redacted]. The patient pleaded guilty to second-degree murder and was sentenced as a youth to [redacted] years of custody and conditional supervision. The

Case ID: 7979016

homicide, tried to harm himself, suicide attempt, agitation with manic symptoms and mental state worsening/mental deterioration were considered serious by the company for their medical significance. He was weaned off of fluoxetine at his own request (dates not provided). Further information regarding the events, corrective treatment, and event outcomes was not provided.

The reporting psychiatrist assessed the homicide, self-injurious behavior, manic symptoms, and worsening of his condition as related to fluoxetine, it drove him over the edge and it contributed to his actions. He did not provide an opinion for the other events.

Update 21Sep2011: Additional information was received 17Sep2011 via a newspaper article containing HCP reporters; added 2 consumer reporters serious event of self harm. Upon review on 21Sep2011 it was determined that CA201106000890 is follow up to this case; therefore CA201106000890 will be deleted from the database. All information from CA201106000890 is contained in this case. Added fluoxetine indication for use and start date; entered serious events of suicide attempt, severe agitation and manic; non-serious events of feeling bad and off label use. Updated narrative and PSUR.

Update 13Oct2011: Additional information was received from previous consumer reporters from newspaper articles on 06Oct2011. Added medical history (depressed). Added address of patient. Added two fluoxetine dose tabs with start and stop dates. Added serious event of mental state worsening / mental deterioration. Added onset date for some events and stop date for off label use. Updated narrative. Regenerated PSUR comment.

Update 17Jan2013: Additional information was received on 14Jan2013 from a consumer via a company representative. Added consumer and company representative reporters. Updated health care professional reporter types. Updated patient demographics. Added suspect drug start date and event onset date for serious event of homicide. Narrative updated with additional information.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Alcohol abuse			
Depression			
Drug abuse			

Case ID: 7979016

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization: ELI LILLY AND CO

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8255398

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: FRA Outcomes: DE,OT (A)NDA/BLA: 018936 /

FDA Rcvd Date: 18-Nov-2011 Mfr Rcvd Date: 08-Nov-2011 Mfr Control #: FR-ELI_LILLY_AND_COMPANY-FR97106292A

Patient Information:

Age: 27 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC		Oral	UNK, unknown	DEPRESSION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC			U				ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 17.0)	ReC
Completed suicide	U
Delusion	U
Drug abuse	U
Homicide	U

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8255398

Event/Problem Narrative:

This case, reported by a healthcare professional and also described in a literature article, concerns a 27-year-old male patient of unknown origin. The medical history included depression without psychotic antecedent. Concomitant medications included methyltestosterone for an unspecified indication. The patient received an unspecified formulation of fluoxetine hydrochloride (Prozac) orally for the treatment of depression; the dosage regimen and start date were not provided. On [redacted], time to onset unspecified after beginning fluoxetine treatment, he had drug abuse, delusions, killed his wife and then committed suicide. Information regarding corrective treatment and outcome of the events drug abuse and delusions at the time of death was not provided. The status of fluoxetine at the time of death was unknown but the duration of regimen was 120 days. It was not reported if an autopsy was performed. The authors considered fluoxetine possibly related to the events of killed his wife and suicide. On opinion of relatedness was not provided for the other events. This case was described in the literature article: Rouve N,Bagheri H,Telmon N,Pathak A,Franchitto N,Schmitt L,Rouge D,Lapeyre-Mestre M,Montastruc J.L. Prescribed drugs and violence: A case/non case study in the French PharmacoVigilance Database. European Journal of Clinical Pharmacology. 2011, 67 (11): 1189-1198. Update 11-Nov-2011: Additional information received from a literature article on 10-Nov-2011. Updated source of the case. Added reporter information to the case. Added narrative and regenerated PSUR comment.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
DEPRESSION			UNKNOWN

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8255398

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	METHYLTESTOSTERONE		Oral	UNK, unknown				

Reporter Source:

Study Report?: No

Sender Organization: ELI LILLY AND CO

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8771880

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Outcomes: DE,OT, (A)NDA/BLA: 018936 /

FDA Rcvd Date: 06-Sep-2012 Mfr Rcvd Date: 28-Aug-2012 Mfr Control #: US-ELI_LILLY_AND_COMPANY-US201208009245

Patient Information:

Age: Sex: Female Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC		U					ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 17.0) ReC

Completed suicide

Homicide

Event/Problem Narrative:

This spontaneous case, reported by a company representative who is a physician, concerns a female patient of unreported age and ethnicity.

Medical history included: smoking marijuana laced with the hallucinogenic drug phencyclidine (PCP). Concomitant medications were not reported.

The patient began using fluoxetine hydrochloride (Prozac) beginning on an unreported date; dose, indication for use, and frequency not reported. On an unspecified date in [redacted], an indeterminable amount of time following the initiation of fluoxetine, she [redacted] her [redacted] year old child and [redacted] On an unspecified date in [redacted], she fatally stabbed herself [redacted] It was not reported if an autopsy was performed or when the last dose of fluoxetine had been ingested prior to her death. Follow up cannot be

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8771880

pursued due to no physician contact details provided.

The reporting physician did not provide an opinion whether the suicide was related to fluoxetine.

Relevant Medical History:

Disease/Surgical Procedure Substance use	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

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8771880

Reporter Source:

Study Report?: No

Sender Organization: ELI LILLY AND CO

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8989040

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Outcomes: OT, (A)NDA/BLA: 018936 /

FDA Rcvd Date: 28-Dec-2012 Mfr Rcvd Date: 21-Dec-2012 Mfr Control #: US-ELI_LILLY_AND_COMPANY-US201212007181

Patient Information:

Age: 55 YR Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	PROZAC						

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	PROZAC		U					ELI LILLY AND CO

Event Information:

Preferred Term (MedDRA® Version: 17.0) ReC

Drug ineffective
Facial nerve disorder
Homicide
Judgement impaired
Paranoia
Suicide attempt

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8989040

Event/Problem Narrative:

This spontaneous case, reported by a consumer via an internet newspaper, concerns a 55-year-old male; ethnicity was not reported.

Relevant medical history included substance abuse, victim of abuse, intelligence quotient (IQ) of [redacted] and depression. Concomitant medications included bupropion hydrochloride, sertraline hydrochloride, and zolpidem tartrate.

The patient began using fluoxetine hydrochloride (Prozac) on an unreported date; dosage, frequency, and indication for use were not provided. On [redacted], an undeterminable time after starting fluoxetine hydrochloride, he attempted suicide by shooting himself in the chest with a gun. On [redacted] he murdered his wife by [redacted]. On an unspecified date, he experienced cloudy judgment, paranoia, and uncontrollable [redacted]. Reportedly his medications changed three times and each time he just got worse. Corrective interventions were not reported. It was not reported if the events were resolved or if fluoxetine was continued. The reporter did not provide patient contact details therefore follow up cannot be pursued.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			
Intelligence test abnormal			
Substance abuse			
Victim of abuse			

Medical History Product(s)	Start Date	End Date	Indications	Events

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8989040

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	AMBIEN							
2	WELLBUTRIN							
3	ZOLOFT							

Reporter Source:

Study Report?: No Sender Organization: ELI LILLY AND CO

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10403643

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Outcomes: OT, (A)NDA/BLA: 018936 /

FDA Rcvd Date: 22-Aug-2014 Mfr Rcvd Date: 12-Aug-2014 Mfr Control #: US-ELI_LILLY_AND_COMPANY-US201408005078

Patient Information:

Age: Sex: Male Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Prozac		Unknown	UNK, unknown	Product used for unknown indication		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Prozac			U				UNKNOWN

Event Information:

Preferred Term (MedDRA Version: 17.0) ReC

Homicide

Event/Problem Narrative:

This spontaneous case, reported by a consumer, who contacted the company to report an adverse event, concerns a male patient of unknown age and ethnicity.

The medical history and concomitant medications were not provided.

The patient received fluoxetine hydrochloride (Prozac), dose, route, frequency, indication for use and start date not provided. On unknown date, unknown time after the beginning of the treatment with fluoxetine, it was stated that some guy killed people some years ago and that people thought that fluoxetine made him kill. This event was considered serious by the company due to its medical significance. Information regarding laboratory exams, corrective treatment and event outcome was not reported. The fluoxetine status was unknown.

The reporting consumer did not think that the event was related to fluoxetine therapy.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10403643

This case is cross-referenced to case US201408004818.

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

Concomitant Products:

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

Reporter Source:

Study Report?: No Sender Organization: ELI LILLY AND CO

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 10403643

Literature Text: