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 Â Version: **17.0** **ReC**

Self injurious behaviour

Suicide attempt

Event/Problem Narrative:

(b) (6)

Case ID: 7979016

(b) (6)

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: