



FDA - Adverse Event Reporting System (FAERS)

FDACDER2557v2

FOIA Case Report Information

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



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Preferred Term (MedDRA Version:

17.0

ReC

Self injurious behaviour

Suicide attempt

Event/Problem Narrative:

(b) (6)



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FDACDER2559v2

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(b) (6)

Relevant Medical History:

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



FDA - Adverse Event Reporting System (FAERS)

FDACDER2560v2

FOIA Case Report Information

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: