In Response Refer to File: F99-15489

Peter Breggin, MD
4628 Chestnut Street
Bethesda, MD 20814

Dear Dr. Breggin:

This is in response to your request of 7/7/99, in which you requested adverse events associated with the use of Fluvoxamine. Your request was received in the Center for Drug Evaluation and Research on 7/14/99.

Charges of $4.50 (Search $1.75, Review $1.75, Reproduction $1.00, Computer time $0) will be included in a monthly invoice. DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

Enclosed are copies of the adverse event cases. In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted material is not required to be publicly disclosed. If, however, you do desire to review the deleted material, please make an additional request to the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, Maryland 20857

Should the Agency then deny this information, you would have the right to appeal such a denial. Any letter of denial will explain how to make this appeal.

This concludes the response for the Center for Drug Evaluation and Research.

Sincerely,

[Signature]

Hal Stepper
Freedom of Information Technician
Office of Training and Communications
Freedom of Information Staff, HFD-205
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Patient information
1. Patient identifier (check all that apply) 
   - X"LOVOL0002221"
   - X"LOVOL0000221"
   - X"LOVOL000121"
   - X"LOVOL000121"

2. Age at time of event: 18 yrs
3. Sex
   - X Female
   - X Male
4. Weight
   - X Under 50 lbs
   - X 50 lbs to 75 lbs
   - X 75 lbs to 100 lbs
5. Date of birth: NZ

B. Adverse event or product problem
1. Adverse event and/or product problem (e.g., defects/malfunctions)
   - X"LOVOL0002221"
   - X"LOVOL0000221"
   - X"LOVOL000121"
   - X"LOVOL000121"

2. Outcomes attributed to adverse event (check all that apply)
   - X"death"
   - X"required intervention to prevent permanent impairment/damage"
   - X"hospitalization - initial or prolonged"
   - Other: 

3. Date of event: 04/20/99
4. Date of this report: 09/14/99
5. Describe event or problem

THE INITIAL CASE WAS REPORTED IN THE MEDIA:
ON APRIL 20, 1999 TWO MALE STUDENTS ( ) ENTERED THEIR HIGH SCHOOL EQUIPPED
WITH MANY DIFFERENT TYPES OF GUNS AND
EXPLOSIVES. THEY BEGAN SHOOTING STUDENTS
AND TEACHERS. IN THE AFTERMATH, 13
INDIVIDUALS WERE KILLED AND MANY SERIOUSLY
INJURED. IN ADDITION, BOTH STUDENTS DIED AS
A RESULT OF ASSUMED SELF-INFLICTED GUNSHOT
WOUNDS TO THE HEAD AND MOUTH. ON MAY 3,
1999, THE ALLEGATION WAS REPORTED THAT
"FURTHER TESTS REVEALS THE PRESENCE OF THE
ANTIDEPRESSANT LUVOX IN SYSTEM."

ON MAY 4, 1999 A SOLVAY REPRESENTATIVE
CONTACTED THE CHIEF DEPUTY OFFICER OF THE
HOSPITAL CORONER'S OFFICE. THE
CHIEF DEPUTY CONFIRMED THE PRESENCE OF A *

6. Relevant tests/laboratory data, including dates

LUVOX BLOOD LEVEL AT AUTOPSY
MAY 18 1999

C. Suspect medication(s)
1. Name (give labeled strength & manufacturer, if known)
   - X"LOVOL0002221"
   - X"LOVOL0000221"
   - X"LOVOL000121"
   - X"LOVOL000121"

2. Dose, frequency & route used
   - X"unk UNK PO"
   - X"UNK to UNK"

3. Therapy data (if unknown, give duration)
   - X"unk UNK"
   - X"UNK to UNK"

4. Diagnosis (for use [indication])
   - X"UNK"
   - X"UNK"

5. Event altered after use stopped or dose reduced
   - X"yes 
   - X"no 
   - X"unknown"

6. Lot # (if known)
   - X"UNK"
   - X"UNK"

7. Exp. date (if known)
   - X"UNK"
   - X"UNK"

8. Event reappeared after reintroduction
   - X"yes 
   - X"no 
   - X"unknown"

9. MDC # - for product problems only (if known)
   - X"UNK"
   - X"UNK"

10. Concomitant medical products and Therapy data (exclude treatment of event)
    - X"UNK"

G. All manufacturers
1. Contact office - name/address (if mailing site for devices)
   - X"Solvay Pharmaceuticals"
   - X"910 Sawyer Road"
   - X"Marietta, Georgia 31062"

2. Phone number
   - (770) 579-9000

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

4. Data received by manufacturer
   - 05/04/99

5. (A)NDA # 00-343
   - IND #
   - PLA #
   - pre-1938
   - OTC
   - product

6. R ING, process #
   - X"UNK"

7. Type of report (check all that apply)
   - X"5-day"
   - X"15-day"
   - X"10-day"
   - X"periodic"
   - X"initial"
   - X"follow-up "

8. Mfr. report number
   - X"LOVOL0002221"
   - X"LOVOL000121"

9. Initial reporter
   - Name, address & phone #
   - X"UNK"

10. Health professional?
    - X"yes 
    - X"no 

11. Occupation
    - X"UNK"

12. Initial reporter also sent report to FDA
    - X"yes 
    - X"no 

FDA
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.
**B.1. Description of event or problem**

[continuation:] "THERAPEUTIC BLOOD LEVEL" OF LOVOX FOR STUDENT [Redacted] THE REQUEST FOR THE SPECIFIC BLOOD LEVEL WAS DENIED AND NO ADDITIONAL INFORMATION WAS GIVEN SINCE THIS CASE IS UNDER CRIMINAL INVESTIGATION. THIS CASE HAS BEEN REFERRED TO THE LEGAL DEPARTMENT FOR ADDITIONAL INFORMATION SUCH AS THERAPY DATES, DOSAGE, AND INDICATION.

**B.2. Occupation**

CHIEF DEPUTY OFFICER

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**OSL**  
MAY 18 1999

**RECEIVED**  
MAY 17 1999