

DRUG EXPERIENCE REPORT

FDA CONTROL NO. _____
ACCESSION NO. _____

REACTION INFORMATION

1. PATIENT ID (INITIALS)	2. AGE	3. SEX	4. WGT.	5. HT.	6. REPORTING DATE			7. REACTION ONSET DATE		
					MO	DA	YR	MO	DA	YR
					8	3	83	7		83

8. DESCRIBE SUSPECTED REACTION(S)
 WAS DC ON DAY 11 DUE TO TREATMENT FAILURE AND NAUSEA(2), ANOREXIA(2), AND DYSURIA(2) WHICH LASTED FROM DAY -7 THROUGH DAY 10. AT VARIOUS TIMES ALSO COMPLAINED OF FATIGUE(2), RESTLESSNESS(2), DRY MOUTH(1), DROWSINESS(1), HEADACHE(3), BLURRED VISION(1), INSOMNIA(3), AND AGITATION(3). THERE WERE NO ADDITIONAL FINDINGS. RECOVERED FULLY

9. OUTCOME OF REACTION TO DATE

Alive with sequelae
 Recovered
 Still under treatment for reaction
 Dead (Date: _____)

10. TESTS/LABORATORY DATA CONFIRMING REACTION (Include history and/or current results)
 TEST (RANGE) : TIME 1 : TIME 2 : TIME 3 : TIME 4 : TIME 5
 NONE

11. WAS OUTPATIENT TREATMENT FOR REACTION REQUIRED?
 Yes No

12. WAS HOSPITAL TREATMENT FOR REACTION REQUIRED?
 Yes No

13. SUSPECT DRUG(S) TRADE/GENERIC NAME(S); MANUFACTURER, INDINDA NO.
 SERTRALINE (CP-51,974) PFIZER IND 18,004

14. TOTAL DAILY DOSE
 50

15. MODE OF ADMINISTRATION
 oral

16. INDICATION(S) FOR USE
 DEPRESSION

19a. WAS TREATMENT WITH SUSPECTED DRUG REDUCED IN DOSAGE?
 Yes No
 DR: Discontinued

17. THERAPY DATES (From/To)
 07/08-07/19

20a. DID REACTION ABATE?
 Yes No

18. THERAPY DURATION
 12

20b. WAS DRUG REINTRODUCED OR DOSE INCREASED?
 Yes No

20c. DID REACTION REAPPEAR?
 Yes No

21. OTHER DRUGS

OTHER DRUGS	TOTAL DAILY DOSE	ROUTE	DATES/DURATION OF ADMINISTRATION	INDICATIONS
CHLORAL HYDRATE	500		06/24-06/24	INSOMNIA

22. DESCRIBE OTHER RELEVANT MEDICAL HISTORY (i.e., allergies, environmental or occupational exposure, previous drug reactions, pregnancy with gender/parity, other drugs)

Your cooperation is needed to assure completeness, accuracy, and timely use and interpretation of these data.

23. MFR NAME/ADDRESS
 Pfizer, Inc.
 Eastern Point Road
 Groton, CT 06340

24. Check one
 Initial Report
 Follow-up Report

25. REPORTER'S NAME AND ADDRESS (In confidence)
 ic1
 Study #07-1

NOTE: This report is summarized by 21 C.F.R. 310.300-310.307, and 431.80. While not required to respond, your cooperation is needed to make the results of the survey comprehensive, accurate and timely.

26. MAY THE SOURCE OF THIS REPORT BE RELEASED TO THE ARMED FORCES INSTITUTE OF PATHOLOGY? Yes No

8 21703

060233

PATIENT IDENTIFICATION



CP-51,974

INVESTIGATOR JOS: H MENDELS, M.D.

DATE 7/19/83

PATIENT TERMINATION
(Check appropriate boxes)

1. Completed as per protocol

2. Withdrawn from study by investigator

Date Withdrawn: 7/19/83

Reason:

- a. Improvement
- b. Inadequate response
- c. Required other anti-depressant medication
- d. Side effects
- e. Lab toxicity

3. Removed from study for reasons unrelated to therapy.

Date Removed: _____

Reason: _____

Comments on Above:

Pt. began to verbalize feelings of
killing other people, and then himself
Pt. stated much more anxious and depressed
than a baseline; even though this was not
reflected in Hamilton.

Other Comments

INVESTIGATOR'S SIGNATURE

all connections are...

[Handwritten Signature]

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