DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

DRUG EXPERIENCE REPORT

BUDORT BUREAU NO. 57-R0004
Approval Expires December 31, 1970

DATE SENT TO FDA (Mo, day, yr)

1. [ ] INITIAL REPORT
[ ] FOLLOW-UP REPORT

2. PATIENT INITIALS AND IDENTIFICATION NUMBER

3. ACKNOWLEDG. (FOR FDA USE ONLY)

SECTION I. PATIENT DATA

4. SEX: [ ] M [ ] F

5. HEIGHT: ins. WEIGHT: lbs

6. DATE OF BIRTH: mo / day / yr

7. ORIGIN: [ ] CAUC [ ] NEGRO [ ] ORIENTAL [ ] AMERICAN INDIAN [ ] OTHER

8. DATE OF REACTION ONSET: mo / day / yr

9. SOURCE OF REPORT (Mfg. Hospital, etc) (Name of reporting Physician is optional.)

10. ADDRESS OF SOURCE (Give Street, City, State, and Zip Code.)

11. DESCRIBE SUSPECTED ADVERSE REACTION(s) AND ANY POSSIBLE ASSOCIATION WITH THE DRUG(s) INVOLVED

12. OUTCOME OF REACTION TO DATE
[ ] ALIVE WITH SEQUELAE
[ ] RECOVERED
[ ] STILL UNDER TREATMENT
[ ] DIED (Give date and cause)

13. LIST ALL THERAPY IN ORDER OF SUSPICION (Manufacturer: List NDA or IND No.)

NAME OF DRUGS TRADE (Generic)	MANUFACTURERS CONTROL NO.	DOSAGE FORM (tab, cap, etc.)	TOTAL DAILY DOSE	ROUTE (po, im, iv, etc.)	DURATION OF THERAPY	DATES OF ADMINISTRATION	14. DISORDER OR REASON FOR USE OF DRUG

SECTION II. SUBSTANTIATING SUPPORTING DATA

15. SUBSTANTIATING LABORATORY STUDIES (Clinical Laboratory, Autopsy, X Ray, etc.)
CLINICAL LAB: [ ] DONE [ ] ATTACHED [ ] NOT DONE
BIOPSY/AUTOPSY: [ ] DONE [ ] ATTACHED [ ] NOT DONE

16. LIST POTENTIALLY NOXIOUS OR ENVIRONMENTAL FACTORS (Include household products, industrial and agricultural chemicals)

17. EXISTING OR PRIOR DISORDERS AND PAST DRUG REACTION OR ALLERGIC HISTORY

PREVIOUS EXPOSURE TO SUSPECTED DRUG OR RELATED COMPOUND
[ ] YES [ ] NO

18. (a) IF FEMALE
GRAVIDITY [ ][ ] PARITY [ ][ ]
(b) IF PREGNANT
WEEKS OF GESTATION [ ][ ]

19. MAY THE SOURCE OF THIS REPORT BE RELEASED TO THE ARMED FORCES INSTITUTE OF PATHOLOGY?
[ ] YES [ ] NO

FOR FDA USE ONLY

FOR MFG USE ONLY

20. REACTION FACTORS (Check all applicable boxes)
[ ] DECOMPOSITION OF DRUG [ ] INTERACTION OF TWO OR MORE DRUGS [ ] DRUG NOT USED ACCORDING TO LABELING [ ] DRUG OUTDATED
[ ] DRUG MISUSED BY PATIENT [ ] OVERDOSAGE [ ] DRUG MISLABELED [ ] CONTAMINATION OF DRUG [ ] OTHER DRUG MISUSE (Specify)

FORM FD-1639 (Rev 8/67)

Use additional sheet if necessary.