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

DRUG EXPERIENCE REPORT

BUDGET 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 ACCESSION NO. (For FDA use only)

SECTION I. BASIC REACTION 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. IMPORTANT MODIFYING 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☐ DECOMPOSITION OF DRUG ☐ INTERACTION OF TWO OR MORE DRUGS ☐ DRUG NOT USED ACCORDING TO LABELING ☐ DRUG OUTDATED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.

GPO : 1969 O - 298-415