DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION (HFN-730)
ROCKVILLE, MD 20857

ADVERSE REACTION REPORT
(Drugs and Biologics)

Form Approved: OMB No. 0910-0230.

FDA CONTROL NO.

ACCESSION NO.

I. REACTION INFORMATION

1. PATIENT ID/INITIALS *(In Confidence)*

2. AGE YRS.

3. SEX

4.-6. REACTION ONSET — MO. | DA. | YR.

7. DESCRIBE REACTION(S)

13. RELEVANT TESTS/LABORATORY DATA

8.-12. CHECK ALL APPROPRIATE:

- ☐ PATIENT DIED
- ☐ REACTION TREATED WITH Rx DRUG
- ☐ RESULTED IN, OR PROLONGED, INPATIENT HOSPITALIZATION
- ☐ RESULTED IN PERMANENT DISABILITY
- ☐ NONE OF THE ABOVE

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) *(Give manufacturer and lot no. for vaccines/biologics)*

15. DAILY DOSE

16 ROUTE OF ADMINISTRATION

17. INDICATION(S) FOR USE

18. DATES OF ADMINISTRATION *(From/To)*

19 DURATION OF ADMINISTRATION

20. DID REACTION ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☐ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☐ NA

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION *(Exclude those used to treat reaction)*

23. OTHER RELEVANT HISTORY *(e.g. diagnoses, allergies, pregnancy with LMP, etc.)*

IV. ONLY FOR REPORTS SUBMITTED BY MANUFACTURER

24. NAME AND ADDRESS OF MANUFACTURER *(Include Zip Code)*

24a. IND/NDA. NO. FOR SUSPECT DRUG

24b MFR. CONTROL NO.

24c. DATE RECEIVED BY MANUFACTURER

24d. REPORT SOURCE *(Check all that apply)*

☐ FOREIGN ☐ STUDY ☐ LITERATURE
☐ HEALTH PROFESSIONAL ☐ CONSUMER

25 15 DAY REPORT?

☐ YES ☐ NO

25a. REPORT TYPE

☐ INITIAL ☐ FOLLOWUP

V. INITIAL REPORTER *(In confidence)*

26.-26a. NAME AND ADDRESS OF REPORTER *(Include Zip Code)*

26b. TELEPHONE NO. *(Include area code)*

26c. HAVE YOU ALSO REPORTED THIS REACTION TO THE MANUFACTURER?

☐ YES ☐ NO

26d. ARE YOU A HEALTH PROFESSIONAL?

☐ YES ☐ NO

Submission of a report does not necessarily constitute an admission that the drug caused the adverse reaction.

NOTE: Required of manufacturers by 21 CFR 314.80

INSTRUCTIONS FOR COMPLETING FORM FDA - 1639

GENERAL

- o Use a separate Form FDA - 1639 for each patient.
- o Additional pages may be attached if space provided on the Form FDA - 1639 is inadequate.
- o Non-manufacturers should send forms to the Food and Drug Administration, Division of Epidemiology and Surveillance, HFN-730, 5600 Fishers Lane, Rockville, MD 20857.
- o For questions call: 301 - 443-4580.
- o Patient and initial reporter identification is held in confidence by the FDA and is not subject to release under the Freedom of Information Act.
- o Reports of serious, suspect reactions are encouraged.

SPECIFIC INSTRUCTIONS

I. Reaction Information

Item 2. Age - For children under 5 years of age, also write date of birth (DOB) in Item 1. For congenital malformations, give the age and sex of the infant (even though the mother was exposed).

Item 7. Describe Reaction(s) - Give signs and/or symptoms, diagnoses, course, etc. Underline the single most important descriptive phrase.

II. Suspect Drug Information

Item 14. Suspect Drug - The trade name is preferred. If a generically produced product is involved, the manufacturer should be identified.

Item 15. Dose - For pediatric patients, also give body weights.

Item 20 and 21. NA - is defined as nonapplicable *(e.g. when only one dose given or outcome was irreversible).*

V. Initial Reporter

Item 26c. Have you also reported this reaction to the manufacturer? Your answer facilitates identification of duplicates in the central adverse reaction file. FDA encourages direct reporting even if a report has been submitted to the manufacturer.

NOTE TO MANUFACTURERS *(Refer to 21 CFR 314.80)* Detailed instructions are contained in the "Guideline for Postmarketing Reporting of Adverse Drug Reactions."