



Date of Report:

Report Completed by:

Attach Clinical notes and all pertinent documentation (i.e. labs) associated with current ADR or Therapeutic failure.

Has patient tried generic before? Yes No If Yes, give date:

Has patient been compliant on regimen? Yes No If No, why not:

Is Patient currently on other medications? Yes No If yes, attached complete list.

**NOTE: Prescriber must have witnessed or has documentation that the manifestation of adverse events is linked to generic drug. Completion of form does not automatically grant approval. Incomplete forms will be returned.

A. PATIENT INFORMATION

Patient's Name:
MA ID #:
Sex: M F DOB:
Weight: lbs Age:
Phone #:

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

(Check all that apply)

1. Adverse Event
Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
Life-threatening
Hospitalization - initial or prolonged
Required Intervention to Prevent Permanent Impairment/Damage (Devices)
Other

3. Date of Event (mm/dd/yy)

4. Describe Event, Problem or Product Use Error

5. Relevant Tests/Laboratory Data, Including Dates

6. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
Yes No

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name:
Strength: Exp. Date:
Manufacturer: Lot #:

#2 Name:
Strength: Exp. Date:
Manufacturer: Lot #:

Table with 2 columns: 2. Dose or Amount, Frequency, Route; 3. Dates of Use; 5. Event Abated After Use Stopped or Dose Reduced?; 4. Diagnosis or Reason for Use; 6. Event Reappeared After Rechallenge?

E. DEGREE OF CERTAINTY THAT THE ADVERSE DRUG REACTION IS DUE TO GENERIC

Definite. The reaction follows a reasonable temporal sequence after generic drug exposure... Probable. The reaction follows a reasonable temporal sequence after generic drug exposure... Possible. The reaction follows as temporal sequence after generic drug exposure... Doubtful. The reaction is likely to be related to factors other than the suspected generic drug. Negative. The finding clearly eliminates the possibility of a drug reaction caused by the generic version of the drug.

F. REPORTER

Prescriber's Name:
Degree:
Signature:
NPI #
Address:
Phone #
Fax #
Did the prescriber witness the ADR? Yes No
Has the ADR been previously reported to the FDA? Yes No

PLEASE PRINT OR TYPE CLEARLY USING BLACK INK.