MEDWATCH

DHMH-MARYLAND MEDICAID PHARMACY PROGRAM

Please fax form to 866-440-9345

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 #: _____

PLEASE PRINT OR TYPE CLEARLY USING BLACK INK.

2. Dose or Amount **Frequency** **Route**

#1 _____ _____ _____

#2 _____ _____ _____

3. Dates of Use *(If unknown, give duration from/to or best estimate)*

#1 _____

#2 _____

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes ___ No ___

#2 Yes ___ No ___

4. Diagnosis or Reason for Use *(Indication)*

#1 _____

#2 _____

6. Event Reappeared After Rechallenge?

#1 Yes ___ No ___

#2 Yes ___ No ___

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 or a toxic blood level of the generic drug has been established in body fluids or tissues. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by improvement on withdrawing the generic drug and reappears on re-exposure. "Other than drug causes" such as other or toxins or concomitant disease states that can cause similar clinical reactions are ruled out.

___ **Probable.** The reaction follows a reasonable temporal sequence after generic drug exposure. The reaction follows a recognized response to the suspected generic drug. The reaction is confirmed by withdrawal but not by re-exposure of the generic drug. The reaction cannot be reasonably explained by known characteristics of the recipient's clinical state.

___ **Possible.** The reaction follows as temporal sequence after generic drug exposure. The reaction follows a possible recognized pattern to the suspected generic drug. The reaction could be explained by the recipient's clinical state (i.e. other than the suspected generic drug).

___ **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

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