U.S. Department of Health and Human Services
Food and Drug Administration

Form Approved: OMB No.09010-0291

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier In confidence	2. Age at Time of Event or Date of Birth:	3. Sex ☐ Female ☐ Male	4. Weight ___ lbs or ___kgs.

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. ☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
(Check all that apply)
☐ Death (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)

5. Describe Event or Problem or Produce Use Error

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal problems, etc.)

C. PRODUCT AVAILABILITY
Product Available for Evaluation?
☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
2. Dose or Amount Frequency Route
3. Dates of Use (If unknown, give duration) from/to (or best estimate).
4. Diagnosis or Reason for Use (Indication)
5. Event Abated After Use Stopped or Dose Reduced?
☐ Yes ☐ No ☐ Doesn't Apply
6. Lot #
7. Expiration Date
8. Event Reappeared After Reintroduction?
☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# or Unique ID

E. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

F. REPORTER
(See confidentiality section on back)
1. Name and Address
Name
Address
City State Zip

Phone #	E-mail
2. Health Professional? ☐ Yes ☐ No	3. Occupation

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product contributed to the event.

Figure 24.6 MedWatch form. The MedWatch form is provided by the U.S. Food and Drug Administration for reporting adverse events