

Reporting Adverse Events from Drugs and Medical Devices to the Food and Drug Administration

Consumers can play an important role in protecting the public health by reporting to the Food and Drug Administration (FDA) the serious health problems they experience while taking prescription drugs and dietary and herbal supplements, or while using medical devices.

Consumers should consider reporting serious reactions and problems to the FDA when the outcome is:

Death: Report if the patient's death is suspected as being a direct outcome of the use of the drug, supplement or medical device.

Life-Threatening: Report if the patient was at substantial risk of dying from the adverse reaction, or it is suspected that the use or continued use of the product would result in the patient's death. Life-threatening examples include pacemaker failure, gastrointestinal hemorrhage (stomach or intestines) and inability to produce new blood cells. Another life-threatening reaction could result from infusion pump failure, which permits uncontrolled free flow of the drug into the blood stream and can result in excessive dosing.

Hospitalization (initial or prolonged): Report if admission to the hospital or a prolonged hospital stay results from the use of the drug, supplement or device. Examples include a severe allergic reaction, acute inflammation of the colon (which is usually induced by antibiotics) and bleeding.

Disability: Report if the adverse event resulted in a significant, persistent or permanent change in the patient's body function/structure,

physical activities or quality of life. Examples include a stroke due to either a drug-induced increase in the tendency for the blood to clot and drug-induced bleeding and peripheral neuropathy (nerve problems).

Congenital Anomaly (Birth Defects): Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in birth defects in the child. Examples include vaginal cancer in female offspring from use of the synthetic non-steroidal estrogen diethylstilbestrol (DES) during pregnancy and malformation in the offspring caused by the anti-nausea medication thalidomide.

Danger of Permanent Impairment or Damage: Report if you suspect that the use of a medical product may result in a condition that requires medical or surgical intervention to preclude permanent impairment or damage to a patient. This could be acetaminophen (TYLENOL) overdose-induced liver damage requiring treatment with the drug acetylcysteine (ACC, MUCOMYST, ACETADOTE, FLUIMUCIL and PARVOLEX) to prevent permanent damage. Other examples include burns from radiation equipment requiring drug therapy and breakage of a screw used to aid in the healing of a fractured long bone requiring replacement of a medical device.

Product problems should also be reported to the FDA when there is a concern about the quality, authenticity, performance or safety of any drug or device.

Problems with product quality may occur during manufacturing,

shipping or storage. They include:

- Suspected counterfeit products
- Product contamination
- Defective components
- Poor packaging or product mix-up
- Questionable stability
- Device malfunctions
- Labeling concerns

What You Can Do

Individuals can report their serious drug or device reactions and problems to the FDA's MedWatch program. The FDA offers several ways for consumers or health professionals to submit MedWatch reports:

- Go to the MedWatch Web site at www.fda.gov/medwatch/ and follow the instructions for submitting a report electronically.
- Fill out and mail the MedWatch form on the next page to the FDA at the following address:

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

Submit a completed form to MedWatch's fax at 1-800-332-0178 or call the FDA's toll-free reporting number at 1-800-FDA-1088. ♦



For VOLUNTARY reporting of
adverse events, product problems and
product use errors

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FDA USE ONLY	
Triage unit sequence #	

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lb or _____ kg
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In confidence

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 - initial or prolonged 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, Problem or Product 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, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 _____
#2 _____

2. Dose or Amount	Frequency	Route
#1 _____	_____	_____
#2 _____	_____	_____

3. Dates of Use (If unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 _____	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 _____	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1 _____	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 _____	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 _____	#1 _____	
#2 _____	#2 _____	

E. SUSPECT MEDICAL DEVICE

1. Brand Name _____

2. Common Device Name _____

3. Manufacturer Name, City and State _____

4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other:
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
 Yes No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone # _____ E-mail _____

2. Health Professional?	3. Occupation	4. Also Reported to:
<input type="checkbox"/> Yes <input type="checkbox"/> No	_____	<input type="checkbox"/> Manufacturer <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK