U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 04/30/03
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

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 or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)
2. **Outcomes attributed to adverse event** (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____
3. **Date of event** (mo/day/yr)
4. **Date of this report** (mo/day/yr)
5. **Describe event or problem**
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 dysfunction, etc.)

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known) #1 #2
2. **Dose, frequency & route used** #1 #2
3. **Therapy dates** (if unknown, give duration) from/to (or best estimate) #1 #2
4. **Diagnosis for use** (indication) #1 #2
5. **Event abated after use stopped or dose reduced** #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
6. **Lot #** (if known) #1 #2
7. **Exp. date** (if known) #1 #2
8. **Event reappeared after reintroduction** #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply
9. **NDC #** (for product problems only) - -
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**
2. **Type of device**
3. **Manufacturer name & address**
4. **Operator of device** ☐ health professional ☐ lay user/patient ☐ other: ____
5. **Expiration date** (mo/day/yr)
6. model # ____ catalog # ____ serial # ____ lot # ____ other #
7. **If implanted, give date** (mo/day/yr)
8. **If explanted, give date** (mo/day/yr)
9. **Device available for evaluation?** (Do not send to FDA) ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)
10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. **Name & address** **phone #**
2. **Health professional?** ☐ yes ☐ no
3. **Occupation**
4. **Also reported to** ☐ manufacturer ☐ user facility ☐ distributor
5. **If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.** ☐

FDA

Mail to: **MEDWATCH** 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- cosmetics
- medication errors

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-1088 to report by phone or for more information
- 1-800-822-7967 for a VAERS form for vaccines

To Report via the Internet:
https://www.accessdata.fda.gov/scripts/medwatch/

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

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Food and Drug Administration
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