



# 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 counterfeit product
- 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:

<http://www.fda.gov/medwatch/report.htm>

-Fold Here-

-Fold Here-

*The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:*

*Department of Health and Human Services  
Food and Drug Administration  
MedWatch; HFD-410  
5600 Fishers Lane  
Rockville, MD 20857*

*Please DO NOT  
RETURN this form  
to this address.*

## OMB statement:

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."*

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

FORM FDA 3500 (12/03) (Back)

Please Use Address Provided Below -- Fold in Thirds, Tape and Mail

## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

### Official Business

Penalty for Private Use \$300

## BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

### MEDWATCH

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



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