



# ADVICE ABOUT VOLUNTARY REPORTING

## Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

## 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

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

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

## 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)

## Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

**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.

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

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 your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building,  
Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201  
ATTN: PRA

and to:  
Office of Management and  
Budget  
Paperwork Reduction Project  
(0910-0230)  
Washington, DC 20503

Please do NOT  
return this form  
to either of these  
addresses.

FDA Form 3500-back

**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

## BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

# MEDWATCH

The FDA Medical Products Reporting Program  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20852-9787



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