

# MEDWATCH

## The FDA Safety Information and Adverse Event Reporting Program

### FDA USE ONLY

Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Days(s)	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight NNN.N format <input type="checkbox"/> lb <input type="checkbox"/> kg
In Confidence	or Date of Birth (e.g., 08 Feb 1925) 2 4 - M a r - 2 0 1 5		

5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander
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B. ADVERSE EVENT, PRODUCT PROBLEM	
1. Check all that apply <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Product Use Error <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine	
2. Outcome Attributed to Adverse Event (Check all that apply) <input type="checkbox"/> Death Include date (dd-mmm-yyyy): 2 5 - A p r - 2 0 1 5 <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Congenital Anomaly/Birth Defects <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	
3. Date of Event (dd-mmm-yyyy) 2 6 - J u n - 2 0 1 5	4. Date of this Report (dd-mmm-yyyy) 0 6 - N o v - 2 0 1 6
5. Describe Event, Problem or Product Use Error  <b>Designer note: This is a "layout design" proof of this form. Entry fields and 508-compliance features will be added after this design is approved.</b>  (Continue on page 3)	

6. Relevant Tests/Laboratory Data, Including Dates  Buttons are not functional on layout design proof.  (Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)  (Continue on page 3)

C. PRODUCT AVAILABILITY	
2. Product Available for Evaluation? (Do not send product to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on (dd-mmm-yyyy) _____	

D. SUSPECT PRODUCTS	
1. Name, Manufacturer/Compounder, Strength (from product label)	
#1 - Name and Strength	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder	#1 - Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

E. SUSPECT MEDICAL DEVICE	
1. Brand Name	
2. Common Device Name	2b. Procode
3. Manufacturer Name, City and State	
4. Model #	Lot#
Catalog #	Expiration Date (dd-mmm-yyyy) _____
Serial #	Unique Identifier (UDI) #
5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other <b>Removed "Specify"</b> <small>This entry line now has no visual prompt.</small>	
6. If Implanted, Give Date (dd-mmm-yyyy) _____	7. If Explanted, Give Date (dd-mmm-yyyy) _____
8. Is this a single-use device that was reprocessed and reused on a patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	
9. If Yes to Item 8, Enter Name and Address of Reprocessor	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS	
Product names and therapy dates (Exclude treatment of event)  (Continue on page 3)	

G. REPORTER (See confidentiality section on back)	
1. Name and Address	
Last Name:	First Name:
Address:	
City:	State/Province/Region:
Country:	ZIP/Postal Code:
Phone #:	Email:
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation
4. Also Reported to: <input type="checkbox"/> Manufacturer/Compounder <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: <input type="checkbox"/>	

3. Dose or Amount	Frequency	Route
#1		
#2		

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy) #1	9. Event Abated After Use Stopped or Dose Reduced? #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

5. Diagnosis or Reason for Use (indication) #1 <b>The entry field will allow for two lines of entry text at about this size.</b>	10. Event Reappeared After Reintroduction? #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. Is the Product Compounded? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No	7. Is the Product Over-the-Counter? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No #2 <input type="checkbox"/> Yes <input type="checkbox"/> No
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8. Expiration Date (dd-mmm-yyyy) #1 _____ #2 _____
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E. SUSPECT MEDICAL DEVICE	
1. Brand Name	
2. Common Device Name	2b. Procode
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 <b>Removed "Specify"</b> <small>This entry line now has no visual prompt.</small>
Catalog #	Expiration Date (dd-mmm-yyyy) _____	
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date (dd-mmm-yyyy) _____	7. If Explanted, Give Date (dd-mmm-yyyy) _____
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8. Is this a single-use device that was reprocessed and reused on a patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	
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9. If Yes to Item 8, Enter Name and Address of Reprocessor	
--	--

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS	
Product names and therapy dates (Exclude treatment of event)  (Continue on page 3)	

G. REPORTER (See confidentiality section on back)	
1. Name and Address	
Last Name:	First Name:
Address:	
City:	State/Province/Region:
Country:	ZIP/Postal Code:
Phone #:	Email:
2. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation
4. Also Reported to: <input type="checkbox"/> Manufacturer/Compounder <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer	
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: <input type="checkbox"/>	

PLEASE TYPE OR USE BLACK INK

# ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: <http://www.fda.gov/medwatch/report/consumer/instruct.htm>

## Report adverse events, product problems or product use errors with:

- Medications (*drugs or biologics*)
- Medical devices (*including in-vitro diagnostics*)
- Combination products (*medication & medical devices*)
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products (*dietary supplements, medical foods, infant formulas*)
- Cosmetics
- Food (*including beverages and ingredients added to foods*)

## 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 (product didn't work)

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

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical events)

## 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 D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (*or both*)

## Other methods of reporting:

- 1-800-FDA-0178 - To FAX report
- 1-800-FDA-1088 - To report by phone
- [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) - To report online

**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.

**If your report involves a serious adverse event with a vaccine**, call 1-800-822-7967 to report.

**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, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

**PROOF**

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

*The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review 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  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov*

*Please DO NOT  
RETURN this form  
to the PRA Staff e-mail  
to the left.*

*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 (5/15) (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



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

### 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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# MEDWATCH

The FDA Safety Information and  
Adverse Event Reporting Program

FORM FDA 3500 (5/15) *(continued)*

(CONTINUATION PAGE)

For VOLUNTARY reporting of  
adverse events and product problems

Page 3 of \_\_\_\_

B.5. Describe Event or Problem *(continued)*

**Designer note:** The action buttons on pages 2 and 3 temporarily dropped out of the form when the functionally simpler "Acro" PDF file was generated for proof purposes (to allow for combining pages 2 and 3 with the new page 1 PDF that was designed in different software). Those buttons will continue to exist and work in the final "Adobe LiveCycle" functional and 508-compliant PDF form that will be made after FDA approves this revised layout.

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

**PROOF**

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

F. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*