U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

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**

In Confidence

2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)

or Date of Birth *(e.g., 08 Feb 1925)* 24-Mar-2015

3. **Sex** ☐ Female ☐ Male

4. **Weight** NNN.N format ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. **Check all that apply**
☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):* 25-Apr-2015
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)* 26-Jun-2015

4. **Date of this Report** *(dd-mmm-yyyy)* 06-Nov-2016

5. **Describe Event, Problem or Product Use Error**

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.

(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)*
☐ Yes ☐ No ☐ 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 #

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
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1 The entry field will allow for two lines of entry text at about this size.
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 __-___-____ #2 __-___-____

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

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** ☐ Health Professional ☐ Lay User/Patient ☐ Other Removed "Specify" This entry line now has no visual prompt.
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)* __-___-____

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ 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?** ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:** ☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

PROOF

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

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)

-Fold Here-

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 - 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.

-Fold Here-

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

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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

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)*