Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

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

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

FORM FDA 3500 (2/19)
The FDA Safety Information and Adverse Event Reporting Program

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-2018.

A. PATIENT INFORMATION

1. **Patient Identifier**
In Confidence

2. **Age**
☐ Year(s) ☐ Month(s)
☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 08 Feb 1925)*

3. **Gender** *(check one)*
☐ Female
☐ Male
☐ Intersex
☐ Transgender
☐ Prefer not to disclose

4. **Weight**
☐ lb
☐ kg

5. **Ethnicity** *(check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **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. **Type of Report** *(check all that apply)*
☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use/ Medication Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☐ Death *Date of death (dd-mmm-yyyy):*
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage

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

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

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

(Continue on page 2)

6. **Relevant Tests/Laboratory Data** **Date** *(dd-mmm-yyyy)*

(Continue on page 2)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(Continue on page 2)

C. PRODUCT AVAILABILITY

1. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

2. **Do you have a picture of the product?** *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1. **Name, Strength, Manufacturer/Compounder** *(from product label).*
Does this report involve cosmetic, dietary supplement or food/medical food? **#1** ☐ Yes **#2** ☐ Yes

#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 #

2. **Dose or Amount** | **Frequency** | **Route**
#1
#2

3. **Treatment Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or duration.)*
#1 Start
#1 Stop
Is therapy still on-going? ☐ Yes ☐ No
#2 Start
#2 Stop
Is therapy still on-going? ☐ Yes ☐ No

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Product Type** *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6. **Expiration Date** *(dd-mmm-yyyy)*
#1
#2

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

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

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2a. **Common Device Name** | 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** | **Lot #** | 5. **Operator of Device**
☐ Health Professional
☐ Patient/Consumer
☐ Other

Catalog # | **Expiration Date** *(dd-mmm-yyyy)*

Serial # | **Unique Identifier** *(UDI) #*

6a. **If Implanted, Give Date** *(dd-mmm-yyyy)* | 6b. **If Explanted, Give Date** *(dd-mmm-yyyy)*

7a. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

7b. **If Yes to Item 7a, Enter Name and Address of Reprocessor**

8. **Was this device serviced by a third party servicer?**
☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. **Product names and therapy dates** *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Last Name: | First Name:
Address:
City: | State/Province/Region:
ZIP/Postal Code: | Country:
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:** ☐

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

Reset Form

FORM FDA 3500 (2/19) *(continued)*
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B.5. **Describe Event or Problem** *(continued)*

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

Date *(dd-mmm-yyyy)*	**Relevant Tests/Laboratory Data**	**Date** *(dd-mmm-yyyy)*

Additional comments

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B.7. **Other Relevant History** *(continued)*

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F.1. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

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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 diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- 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
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to 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)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

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 an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

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.

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
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 above.

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