



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**MEDWATCH**

The FDA Safety Information and  
Adverse Event Reporting Program

Form FDA 3500

Form Approved: OMB No. 0910-0291, Expires: 06-30-2025  
See PRA statement on page 6.

**FDA USE ONLY**

Triage unit sequence #   
FDA Rec. Date

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

**Note:** For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.

**A. PATIENT INFORMATION**

1. Patient Identifier (In confidence)

2. Age  or Date of Birth (e.g., 01-Jan-1900)  
 Year(s)  Week(s)  
 Month(s)  Day(s)

3a. Sex: Enter the patient's sex at birth (the sex that a person has or was assigned to at birth).  
 Male  Undifferentiated  
 Female  Decline to answer

3b. Gender: Enter the patient's current gender (how the patient thinks of themself).  
 Cisgender man/boy (gender corresponds with birth sex)  Transgender woman/trans woman/male-to-female (MTF)  
 Cisgender woman/girl (gender corresponds with birth sex)  Other gender category; please specify:   
 Transgender man/trans man/female-to-male (FTM)  Decline to answer

4. Weight   lb  kg

5. Ethnicity (Check one)  
 Hispanic/Latino  Not Hispanic/Latino

6. Race (check all that apply)  
 American Indian/Alaska Native  Native Hawaiian/Other Pacific Islander  
 Asian  White  
 Black or African American

**B. ADVERSE EVENT, PRODUCT PROBLEM**

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

2. Outcome Attributed to Adverse Event (check all that apply)  
 Death – Date of death (e.g., 01-Jan-1900):   
 Life-threatening  Required Intervention to Prevent Permanent Impairment/Damage  
 Hospitalization (initial or prolonged)  Disability or Permanent Damage  
 Other Serious or Important Medical Events  Congenital Anomaly/Birth Defects

3. Date of Event (e.g., 01-Jan-1900)

4. Date of this Report (e.g., 01-Jan-1900)

5. Describe Event, Problem or Product Use/Medication Error Characters Remaining (max. 4,000):

(field continues on next page)

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

\* Please see instructions

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6. Relevant Test/Laboratory Data	Date (e.g., 01-Jan-1900)	Relevant Test/Laboratory Data	Date (e.g., 01-Jan-1900)

<b>Additional comments</b>	Characters Remaining (max. 2,000):

<b>7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, tobacco product use, liver/kidney problems, etc.)</b>	Characters Remaining (max. 2,000):

**C. PRODUCT AVAILABILITY**

1. Product Available for Evaluation? (Do not send product to FDA)

Yes  No  Returned to Manufacturer on (e.g., 01-Jan-1900)

2. Do you have a picture of the product?

(Check if you are including a picture)  Yes

**D. SUSPECT PRODUCTS**

**SUSPECT PRODUCT #1**

This report involves:  Cosmetic  Dietary supplement  Food/medical food  Other

1. Name, Strength, Manufacturer/Compounder (from product label).

Product Name	Strength	Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>

NDC # or Unique ID	Manufacturer/ Compounder Name	Lot #
<input type="text"/>	<input type="text"/>	<input type="text"/>

2. Dose or Amount	Frequency	Route
<input type="text"/>	<input type="text"/>	<input type="text"/>
Unit	Other Frequency	Other Route
<input type="text"/>	<input type="text"/>	<input type="text"/>

3. Treatment Dates/Therapy Dates (give best estimate of length of treatment (start/stop) or date of dose reduction.)

Therapy started on (e.g., 01-Jan-1900)	Therapy stopped on (e.g., 01-Jan-1900)	Dose reduced on (e.g., 01-Jan-1900)	OR	Duration	Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

Is therapy still on-going?  Yes  No

4. Diagnosis for use (indication)	5. Product Type (check all that apply)	6. Expiration Date (e.g., 01-Jan-1900)
<input type="text"/>	<input type="checkbox"/> OTC <input type="checkbox"/> Generic <input type="checkbox"/> Compounded <input type="checkbox"/> Biosimilar	<input type="text"/>

7. Event Abated after use Stopped or Dose Reduced? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply	8. Event Reappeared after Reintroduction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
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**SUSPECT PRODUCT #2**

This report involves:  Cosmetic  Dietary supplement  Food/medical food  Other

1. Name, Strength, Manufacturer/Compounder (from product label).

Product Name	Strength	Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>

NDC # or Unique ID	Manufacturer/ Compounder Name	Lot #
<input type="text"/>	<input type="text"/>	<input type="text"/>

2. Dose or Amount	Frequency	Route
<input type="text"/>	<input type="text"/>	<input type="text"/>
Unit	Other Frequency	Other Route
<input type="text"/>	<input type="text"/>	<input type="text"/>

3. Treatment Dates/Therapy Dates (give best estimate of length of treatment (start/stop) or date of dose reduction.)

Therapy started on (e.g., 01-Jan-1900)	Therapy stopped on (e.g., 01-Jan-1900)	Dose reduced on (e.g., 01-Jan-1900)	OR	Duration	Unit
<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

Is therapy still on-going?  Yes  No

4. Diagnosis for use (indication)	5. Product Type (check all that apply)	6. Expiration Date (e.g., 01-Jan-1900)
<input type="text"/>	<input type="checkbox"/> OTC <input type="checkbox"/> Generic <input type="checkbox"/> Compounded <input type="checkbox"/> Biosimilar	<input type="text"/>

7. Event Abated after use Stopped or Dose Reduced? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply	8. Event Reappeared after Reintroduction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
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**E. SUSPECT MEDICAL DEVICE**

<b>1. Brand Name</b> <input style="width:95%;" type="text"/>	<b>2a. Common Device Name</b> <input style="width:95%;" type="text"/>	<b>2b. Procode</b> <input style="width:95%;" type="text"/>
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**3. Manufacturer Name, City and State**

<b>4. Model #</b> <input style="width:95%;" type="text"/>	<b>Lot #</b> <input style="width:95%;" type="text"/>	<b>Catalog #</b> <input style="width:95%;" type="text"/>
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<b>Expiration Date (e.g., 01-Jan-1900)</b> <input style="width:95%;" type="text"/>	<b>Serial #</b> <input style="width:95%;" type="text"/>
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**Unique Device Identifier (UDI) #**

**5. Operator of device**  
 Health Professional   
 Patient/Consumer   
 Other

<b>6a. If Implanted, Give Date (e.g., 01-Jan-1900)</b> <input style="width:95%;" type="text"/>	<b>6b. If Explanted, Give Date (e.g., 01-Jan-1900)</b> <input style="width:95%;" type="text"/>
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<b>7a. Is this a single-use device that was reprocessed and reused on a patient?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>7b. If Yes to Item 7a, Enter Name, Address of Reprocessor</b> <input style="width:95%; height: 40px;" type="text"/>	<b>8. Was this device ever serviced by a third-party servicer?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
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**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

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

	Product Name	Therapy Start Date (e.g., 01-Jan-1900)	Therapy End Date (e.g., 01-Jan-1900)
1.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
2.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
3.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
4.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
5.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
6.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
7.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
8.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
9.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>
10.	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>	<input style="width:95%;" type="text"/>

**G. REPORTER** (See confidentiality section on next page)

**1. Name and Address**

Last Name		First Name	
<input type="text"/>		<input type="text"/>	
Address			
<input type="text"/>			
City		State/Province/Region	ZIP/Postal Code
<input type="text"/>		<input type="text"/>	<input type="text"/>
Country			
<input type="text"/>			
Phone #		Email	
<input type="text"/>		<input type="text"/>	

**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:

**ADVICE ABOUT VOLUNTARY REPORTING**

Detailed instructions available at:

<https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500>

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](http://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.

Where to submit adverse events related to the following products:

- If your report involves an animal drug, device, pet food and livestock feed problems, go to <http://www.fda.gov/vetproductreporting>
- If your report involves a health problem or a product problem with a tobacco product, go to <https://www.safetyreporting.hhs.gov> or call 1-877-287-1373 to report.
- 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:

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Food and Drug Administration  
Office of Chief Information Officer  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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