



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 5.

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) <input type="text"/>		2. Age <input type="text"/> <input type="checkbox"/> Year(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Day(s)	or Date of Birth (e.g., 01-Jan-1900) <input type="text"/>
3a. Sex: Enter the patient's sex at birth (the sex that a person has or was assigned to at birth). <input type="checkbox"/> Male <input type="checkbox"/> Undifferentiated <input type="checkbox"/> Female <input type="checkbox"/> Decline to answer		3b. Gender: Enter the patient's current gender (how the patient thinks of themself). <input type="checkbox"/> Cisgender man/boy (gender corresponds with birth sex) <input type="checkbox"/> Cisgender woman/girl (gender corresponds with birth sex) <input type="checkbox"/> Transgender man/trans man/ female-to-male (FTM) <input type="checkbox"/> Transgender woman/trans woman/ male-to-female (MTF) <input type="checkbox"/> Other gender category; please specify: <input type="text"/> <input type="checkbox"/> Decline to answer	
4. Weight <input type="text"/> <input type="checkbox"/> lb <input type="checkbox"/> kg	5. Ethnicity (Check one) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino	6. Race (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/ Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> White	

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Type of Report (check all that apply) <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Use/Medication Error <input type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine		2. Outcome Attributed to Adverse Event (check all that apply) <input type="checkbox"/> Death – Date of death (e.g., 01-Jan-1900): <input type="text"/> <input type="checkbox"/> Life-threatening <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage <input type="checkbox"/> Hospitalization (initial or prolonged) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Other Serious or Important Medical Events <input type="checkbox"/> Congenital Anomaly/Birth Defects	
3. Date of Event (e.g., 01-Jan-1900) <input type="text"/>	4. Date of this Report (e.g., 01-Jan-1900) <input type="text"/>		

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)

Additional comments	Characters Remaining (max. 2,000):

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, tobacco product use, liver/kidney problems, etc.)	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

Unit

Frequency

Other Frequency

Route

Other Route

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)

 OTC Generic
 Compounded Biosimilar

7. Event Abated after use Stopped or Dose Reduced?

 Yes No Doesn't apply

8. Event Reappeared after Reintroduction?

 Yes No Doesn't apply**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

Unit

Frequency

Other Frequency

Route

Other Route

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)

 OTC Generic
 Compounded Biosimilar

7. Event Abated after use Stopped or Dose Reduced?

 Yes No Doesn't apply

8. Event Reappeared after Reintroduction?

 Yes No Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name		2a. Common Device Name		2b. Procode
<input type="text"/>		<input type="text"/>		<input type="text"/>
3. Manufacturer Name, City and State				
<input type="text"/>				
4. Model #	Lot #	Catalog #	Expiration Date (e.g., 01-Jan-1900)	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Serial #	Unique Identifier (UDI) #	5. Operator of device		
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> Other		
6a. If Implanted, Give Date (e.g., 01-Jan-1900)		6b. If Explanted, Give Date (e.g., 01-Jan-1900)		
<input type="text"/>		<input type="text"/>		
7a. Is this a single-use device that was reprocessed and reused on a patient?	7b. If Yes to Item 7a, Enter Name, Address of Reprocessor		8. Was this device ever serviced by a third-party servicer?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	

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 type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>	<input type="text"/>
8.	<input type="text"/>	<input type="text"/>	<input type="text"/>
9.	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.	<input type="text"/>	<input type="text"/>	<input 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?	3. Occupation	4. Also Reported to:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<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"/>			
<input type="text"/>			

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

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:

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
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