Reset Form

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)*

2. Age ☐ Year(s) ☐ Week(s) ☐ Month(s) ☐ Day(s)

or Date of Birth *(e.g., 01-Jan-1900)*

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)
☐ Cisgender woman/girl (gender corresponds with birth sex)
☐ Transgender man/trans man/ female-to-male (FTM)
☐ Transgender woman/trans woman/ male-to-female (MTF)
☐ Other gender category; please specify:
☐ 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 ☐ Asian ☐ Black or African American ☐ Native Hawaiian/ Other Pacific Islander ☐ White

## 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
☐ Hospitalization (initial or prolonged)
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent Damage
☐ 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

| 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 |
|---|---|---|
| | | |

| NDC # or Unique ID | Manufacturer/ Compounder Name | Lot # |
|---|---|---|
| | | |

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

**Unit** | **Other Frequency** | **Other Route**

3. **Treament 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 |
|---|---|---|---|---|---|
| | | | | | |

Is therapy still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(indication)*

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

6. **Expiration Date** *(e.g., 01-Jan-1900)*

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 |
|---|---|---|
| | | |

| NDC # or Unique ID | Manufacturer/ Compounder Name | Lot # |
|---|---|---|
| | | |

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

**Unit** | **Other Frequency** | **Other Route**

3. **Treament 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 |
|---|---|---|---|---|---|
| | | | | | |

Is therapy still on-going? ☐ Yes ☐ No

4. **Diagnosis for use** *(indication)*

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

6. **Expiration Date** *(e.g., 01-Jan-1900)*

7. **Event Abated after use Stopped or Dose Reduced?**
☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply


*(continued on next page)*

## E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2a. **Common Device Name**

2b. **Procode**

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

4. **Model #**

**Lot #**

**Catalog #**

**Expiration Date** *(e.g., 01-Jan-1900)*

**Serial #**

**Unique Identifier** *(UDI)* **#**

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

6a. **If Implanted, Give Date** *(e.g., 01-Jan-1900)*

6b. **If Explanted, Give Date** *(e.g., 01-Jan-1900)*

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, Address of Reprocessor**

8. **Was this deviced ever serviced by a third-party servicer?**
☐ Yes ☐ No ☐ 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. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |
| 7. | | | |
| 8. | | | |
| 9. | | | |
| 10. | | | |

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

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:** ☐

# 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
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