



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**MEDWATCH**  
**FORM 3500**

For use by Health Professionals for VOLUNTARY  
reporting of adverse events, product problems and  
product use/medication errors

Form Approved: OMB No. 0910-0291

Expires: 09-30-2027

See PRA statement on page 8.

**FDA USE ONLY**

Triage unit  
sequence #

FDA Rec. Date

**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)

**3. Sex**

Male  
 Female

**4. Weight**

lb  
 kg

**5. Race and/or Ethnicity (Select all that apply)**

American Indian or Alaska Native  
 Asian  
 Black or African American  
 Hispanic or Latino

Middle Eastern or North African  
 Native Hawaiian or 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):  
 Hospitalization (Initial or prolonged)  
 Life-threatening  
 Disability or Permanent Damage  
 Required Intervention to Prevent Permanent Impairment/Damage  
 Congenital Anomaly/Birth Defects  
 Other Serious or Important Medical Events

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

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

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

\* Please see instructions

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

Characters Remaining (max. 4,000):

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

\* Please see instructions

## **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):

Characters Remaining (max. 2,000):

• The first step in the process of creating a new product is to identify the needs of the target market. This involves conducting market research to understand the wants and requirements of potential customers. The information gathered through market research can help in determining the features and benefits of the new product.

## 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? While not required, pictures of all sides of the product will help FDA review your report. (Check yes if you are including pictures.)**

Yes

**D. SUSPECT PRODUCTS****SUSPECT PRODUCT #1****1. Name, Strength, Manufacturer/Compounder (From product label).**

Product Name      Strength      Unit  
[Form fields for Product Name, Strength, and Unit]

NDC # or Unique ID      Manufacturer/Compounder Name      Lot #  
[Form fields for NDC #/Unique ID, Manufacturer/Compounder Name, and Lot #]

**Place and Date of Purchase**Name  
[Form field for Name]Address  
[Form field for Address]

City      State/Province/Region      ZIP/Postal Code  
[Form fields for City, State/Province/Region, and ZIP/Postal Code]

Country  
[Form field for Country]

Website (If purchased online)      Purchase Date  
[Form fields for Website and Purchase Date]

2. Dose or Amount	Frequency	Route
[Form field for Dose or Amount]	[Form field for Frequency]	[Form field for Route]
Unit	Other Frequency	Other Route
[Form field for Unit]	[Form field for Other Frequency]	[Form field for Other Route]

**3. Treatment/Therapy/Usage Dates (Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.)**

Therapy/Usage started on (e.g., 01-Jan-1900) [Form field]  
Therapy/Usage stopped on (e.g., 01-Jan-1900) [Form field] OR Duration [Form field]  
Dose reduced on (e.g., 01-Jan-1900) [Form field] Unit [Form field]

Is therapy/usage still on-going?  Yes  No**4. Diagnosis for use (Indication)**

[Large empty box for Diagnosis for use (Indication)]

**5. Product Type (Check all that apply)****Drug or Biologic**

- Brand
- Generic or Biosimilar
- Over-the-Counter (OTC)
- Compounded product  
*(By a Pharmacy or an Outsourcing Facility)*

**Cosmetics (Select One)**

- Cosmetics for professional use only
- Cosmetics sold on a retail basis

**Other Product Types**

- Cannabinoid hemp products  
*(Such as products containing CBD)*
- Other

**6. Expiration Date**(e.g., 01-Jan-1900)  
[Form field for Expiration Date]**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**1. Name, Strength, Manufacturer/Compounder (*From product label*).

Product Name	Strength	Unit
[ ]	[ ]	[ ]
NDC # or Unique ID	Manufacturer/Compounder Name	Lot #
[ ]	[ ]	[ ]

**Place and Date of Purchase**

Name

[ ]
-----

Address

[ ]
-----

City

State/Province/Region

ZIP/Postal Code

[ ]	[ ]	[ ]
-----	-----	-----

Country

[ ]
-----

Website (If purchased online)

Purchase Date

[ ]	[ ]
-----	-----

## 2. Dose or Amount

## Frequency

## Route

[ ]	[ ]	[ ]
-----	-----	-----

Unit

Other Frequency

Other Route

[ ]	[ ]	[ ]
-----	-----	-----

3. Treatment/Therapy/Usage Dates (*Give best estimate of length of treatment/usage (start/stop) or date of dose reduction.*)

Therapy/Usage started on (e.g., 01-Jan-1900)

[ ]
-----

Duration

[ ]
-----

Therapy/Usage stopped on (e.g., 01-Jan-1900)

[ ]
-----

OR

Unit

[ ]
-----

Dose reduced on (e.g., 01-Jan-1900)

[ ]
-----

Is therapy/usage still on-going?  Yes  No4. Diagnosis for use (*Indication*)

[ ]
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5. Product Type (*Check all that apply*)

## Drug or Biologic

- Brand
- Generic or Biosimilar
- Over-the-Counter (OTC)
- Compounded product  
*(By a Pharmacy or an Outsourcing Facility)*

Cosmetics (*Select One*)

- Cosmetics for professional use only
- Cosmetics sold on a retail basis

## Other Product Types

- Cannabinoid hemp products  
*(Such as products containing CBD)*
- Other

## 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

### E. SUSPECT MEDICAL DEVICE

1. Brand Name	2a. Procode	2b. Common Device Name
<input type="text"/>	<input type="text"/>	<input type="text"/>
3. Manufacurer Name, City and State <input type="text"/>		
4. Model # <input type="text"/>	Lot # <input type="text"/>	Catalog # <input type="text"/>
Expiration Date (e.g., 01-Jan-1900) <input type="text"/>	Serial # <input type="text"/>	
Unique Device Identifier (UDI) # <input type="text"/>		Characters Remaining (max. 1,000): <input type="text"/>
<p>5. Operator of device  <input type="checkbox"/> Health Professional   <input type="checkbox"/> Patient/Consumer   <input type="checkbox"/> Other</p> <p>6a. If Implanted, Give Date (e.g., 01-Jan-1900) <input type="text"/></p> <p>6b. If Explanted, Give Date (e.g., 01-Jan-1900) <input type="text"/></p>		
7a. Is this a single-use device that was reprocessed and reused on a patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	7b. If Yes to Item 7a, Enter Name, Address of Reprocessor <input type="text"/>	8. Was this device ever serviced by a third-party servicer? <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

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
- Packer

**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)
- Cannabinoid hemp products (such as products containing CBD)
- 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)
- Cosmetics (such as moisturizers, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)

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

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)
- Just fill in the sections that apply to your report

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To report by mail: Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Av., Silver Sprint, MD 20993
- To fax report: 1-800-FDA (332)-0178
- 

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:

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**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](mailto: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."

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AND HUMAN SERVICES