

**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 ONLYTriage 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)or **Date of Birth** (e.g., 01-Jan-1900)☐ Month(s)☐ Day(s)**3. Sex**☐ Male☐ Female**4. Weight**☐ lb☐ kg**5. Race and/or Ethnicity** (*Select all that apply*)☐ American Indian or Alaska Native☐ Middle Eastern or North African☐ Asian☐ Native Hawaiian or Pacific Islander☐ Black or African American☐ White☐ Hispanic or Latino**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

6. Relevant Test/Laboratory Data	Low Test Range	High Test Range	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? 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
<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"/>

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)

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

OR

Duration

Unit

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

Is therapy/usage still on-going? ☐ Yes ☐ No**4. 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)***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
<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"/>

Place and Date of Purchase

Name		
<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"/>		
Website (If purchased online)		Purchase Date
<input type="text"/>		<input type="text"/>

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

Is therapy/usage still on-going? ☐ Yes ☐ No

4. 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)

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 <input style="width: 95%;" type="text"/>		2a. Procode <input style="width: 95%;" type="text"/>	2b. Common Device Name <input style="width: 98%;" type="text"/>
3. Manufacturer Name, City and State <input style="width: 98%;" type="text"/>			
4. Model # <input style="width: 95%;" type="text"/>	Lot # <input style="width: 95%;" type="text"/>	Catalog # <input style="width: 98%;" type="text"/>	
Expiration Date (e.g., 01-Jan-1900) <input style="width: 95%;" type="text"/>	Serial # <input style="width: 98%;" type="text"/>		
Unique Device Identifier (UDI) #		Characters Remaining (max. 1,000):	
5. Operator of device <input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> Other		6a. If Implanted, Give Date (e.g., 01-Jan-1900) <input style="width: 95%;" type="text"/>	6b. If Explanted, Give Date (e.g., 01-Jan-1900) <input style="width: 95%;" type="text"/>
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 style="width: 98%;" 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 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
☐ 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 Spring, MD 20993
- To fax report: 1-800-FDA (332)-0178
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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
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."

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AND HUMAN SERVICES