U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500B

For use by Consumer/Patient 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	

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after using a product, drug, cosmetic or a medical device.
- You used a product, drug, cosmetic product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the product, drug, cosmetic, or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov.
- Investigational drugs or medical devices (those being studied) – report problems to your doctor or to the contact person listed in the clinical trial.
- Animal Drug, Device, Pet Food and Livestock Feed Problems – report problems to FDA's Center for Veterinary Medicine.
- Tobacco product, including e-cigarettes (nicotine-containing vapes) and nicotine pouches - report health or product problems to the Safety Reporting Portal (SRP) www.safetyreporting.hhs.gov or call 1-877-287-1363
- Food or dietary supplement products – report problems to the SRP www.safetyreporting.hhs.gov.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information.
- Your name and contact information may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section F).

What types of products should I use this form for?

- Prescription and over-the-counter drugs, therapeutic biologics and biosimilars including monoclonal antibodies, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone), allergenics and gene therapies.
- Cannabinoid hemp products (such as products containing CBD)
- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Cosmetics such as moisturizers, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Including or attaching images of all sides of the product will help FDA review your report. Please do not send the products to the FDA.
- The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI). In collaboration with the National Library of Medicine, the FDA has created a portal, called Access GUDID, to make device identification information in the GUDID available for everyone. For more information regarding the UDI#, refer to the UDI webpage, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
- Your report will become part of a database so that it can be reviewed and compared to other reports by an FDA safety evaluator who will determine what steps to take.

How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088
To report online: www.fda.gov/medwatch/report.htm
For Cosmetics: Toll-free line: 1-888-723-3366

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 30 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 information collection, including suggestions for reducing this burden to the address to the right:

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 number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF ADDRESS.

FDA

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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.*

Section A – About the Problem

1. What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(Including new or worsening symptoms)*
- ☐ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

3. Date the problem occurred *(e.g., 01-Jan-1900)*

2. Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm
- ☐ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(Include date)* *(e.g., 01-Jan-1900)*:
- ☐ Other serious/important medical event

4. Tell us what happened, how it happened or why it happened. *(Include as many details as possible. FDA may reach out to you for any additional documents if necessary)*

Characters Remaining (max. 4,000):

(continued on next page)

5. Relevant Tests/Laboratory Results	Low Test Range	High Test Range	Date *(e.g., 01-Jan-1900)*

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

Section B – Product Availability

1. Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☐ Yes ☐ No

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

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- cannabinoid hemp products (such as products containing CBD)
- cosmetics

Go to Section C

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section D
(Skip Section C)

For a health or product problem with a food, dietary supplement or tobacco product

Go to
www.safetyreporting.hhs.gov

Section C – About the Products

1. Name(s) of the product as it appears on the box, bottle, or package *(Include as many names as you see)*

Place and Date of Purchase

Name

Address

City | State/Province/Region | ZIP/Postal Code

Country

Website (If purchased online) | Purchase Date

2. Check if therapy/usage is on-going ☐

3. Name(s) of the company that makes (or compounds) the product

4. 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

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

6. Lot number

7. NDC number

8. Strength *(For example, 800mg/160 mg or 20 mg)*

9. Quantity *(For example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*

10. Frequency *(For example, twice daily or at bedtime)*

11. How was it taken or used *(For example, by mouth, injection, or on the skin)*?

(continued on next page)

12a. Date the person first started taking or using the product *(e.g., 01-Jan-1900)*:

12b. Date the person stopped taking or using the product *(e.g., 01-Jan-1900)*:

12c. Date the person reduced dose of the product *(e.g., 01-Jan-1900)*:

13. Give best estimate of duration | Unit

14. Why was the person using the product? *(Such as, what condition was it supposed to treat)*

15. Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

16. Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☐ Didn't restart

Go to Section E ***(Skip Section D)***

Section D – About the Medical Device

1. Name of medical device

2. Name of the company that makes the medical device

3. Model number | 4. Catalog number | 5. Lot number | 6. Serial number

7. Unique Device Identifier (UDI) number

Characters Remaining (max. 1,000):

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

9. Was someone operating the medical device when the problem occurred? ☐ Yes ☐ No

If yes, who was operating it?

☐ The person who had the problem ☐ A health professional *(Such as a doctor, nurse, or aide)*

☐ Someone else *(Please explain who)*

10. For implanted medical devices ONLY *(Such as pacemakers, breast implants, etc.)*

Date the implant was put in *(e.g., 01-Jan-1900)*

Date the implant was taken out *(If relevant)* *(e.g., 01-Jan-1900)*

Section E – About the Person Who Had the Problem

1. Person's Initials

2. Sex

- ☐ Male
- ☐ Female

3. Age *(Specify unit of time for age)*

- ☐ Year(s)
- ☐ Month(s)
- ☐ Week(s)
- ☐ Day(s)

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

5. Weight *(Specify lbs or kg)*

- ☐ lb
- ☐ kg

6. What is your 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

7. List known medical conditions.
(Such as diabetes, high blood pressure, cancer, heart disease, or others)

Characters Remaining (max. 2,000):

8. Please list all allergies *(Such as to drugs, foods, pollen or others)*

9. List any other important information about the person *(Such as tobacco product use, pregnancy, alcohol use, etc.)*

10. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Characters Remaining (max. 2,000):

11. List all current prescription medications and medical devices being used.

Characters Remaining (max. 2,000):

Section F – About the Person Filling Out This Form

We will contact you only if we need additional information.

1. Last name	2. First name

3. Number/Street	4. City and State/Province

5. ZIP or Postal code	6. Country

7. Telephone number	8. Email address	9. Today's date *(e.g., 01-Jan-1900)*

10. Did you report this problem to the company that makes the product (The manufacturer/compounder)? ☐ Yes ☐ No

11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to: Atten: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993; FAX: 800-332-0178 (toll-free).

Thank you for helping us protect the public health.