Reset Form

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

MEDWATCH
FORM 3500A

For use by user facilities, importers, distributors, packers and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291
Expires: 09-30-2027
See PRA statement on page 9.

Mfr report #
UF/Importer Report #
Exemption/Variance/ Alternative #

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) ☐ Month(s)
☐ Week(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 OR PRODUCT PROBLEM

1. Type of Report *(Check all that apply)*
☐ Adverse Event
☐ Product Problem *(e.g., defects/malfunctions)*

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)*
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Disability or Permanent 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)*

5. Describe Event or Problem

Characters Remaining (max. 10,000):

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

* Please see instructions

(continued on next page)

5. Describe Event or Problem *(Cont.)*

Characters Remaining (max. 10,000):

(continued on next page)

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, alcohol use, and liver/kidney problems, etc.)

Characters Remaining (max. 2,000):

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. Name, Strength, Manufacturer/Compounder

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name

Lot # | FEI # for cosmetics

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)*

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

OR

Duration

Unit

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

Product Name | Strength | Unit

NDC # or Unique ID | Manufacturer/Compounder Name

Lot # | FEI # for cosmetics

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)*

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

OR

Duration

Unit

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

(continued on next page)

9. List Medical Product and Treatment Given at the Same Time of the Event and Date *(Do not include treatment for initial event)*

	Product Name	Therapy/Usage Start Date *(e.g., 01-Jan-1900)*	Therapy/Usage Stop Date *(e.g., 01-Jan-1900)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2a. Procode

2b. Common Device Name

3. Manufacturer Name, City, State, and Country

4. Model #

Lot #

Catalog #

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

Serial #

Unique Device Identifier *(UDI) #*

Characters Remaining (max. 1,000):

(continued on next page)

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, enter the name and address of the reprocessor

8. Was this device ever serviced by a third-party servicer?

☐ Yes ☐ No ☐ Unknown

9. Is this Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No

☐ Returned to manufacturer *(01-Jan-1900)*

10. Concomitant Medical Products and Therapy/usage Dates *(Exclude treatment of event)*

	Product Name	Therapy/Usage Start Date *(e.g., 01-Jan-1900)*	Therapy/Usage End Date *(e.g., 01-Jan-1900)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

E. INITIAL REPORTER

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 (*Select list*)

--

4. Initial reporter also sent report to FDA?

☐ Yes ☐ No ☐ Unknown

(continued on next page)

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer

2. User Facility/Importer Report Number

3. User Facility or Importer Name/Address/Email

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(e.g., 01-Jan-1900)*

7. Type of Report
☐ Initial
☐ Follow-up #

8. Approximate Age of Device ☐ Year(s) ☐ Month(s)

9. Adverse Event Problem *(Refer to coding manual)*

Health Effect – Clinical Code | Health Effect – Impact Code | Medical Device Problem Code | Component Code

10. Report Sent to FDA? *(If Yes, enter date (e.g., 01-Jan-1900))*
☐ Yes ☐ No

11. Location Where Event Occurred
☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other *(Specify)*
☐ Home ☐ Outpatient Diagnostic Facility
☐ Hospital ☐ Nursing Home

12. Report Sent to Manufacturer? *(If Yes, enter date (e.g., 01-Jan-1900))*
☐ Yes
☐ No

13. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office *(and Manufacturing Site for Devices)* **or Compounding Outsourcing Facility or Responsible Person**

Name | Email Address | Phone Number

Address

Compounding Outsourcing Facility 503B?
☐ Check box if applicable

Outsourcing Facility

2. Report Source *(Check all that apply)*
☐ Foreign ☐ Literature ☐ Health Professional ☐ Company Representative
☐ Study ☐ Consumer ☐ User Facility ☐ Distributor/Importer
☐ Other (Please list)

3. Date Received by Manufacturer or Responsible Person *(e.g., 01-Jan-1900)*

4. NDA # | **ANDA/Pre-ANDA #** | **IND #** | **BLA #** | **PMA/510***(k)* **#**

Check all that apply:
☐ Combination product ☐ Pre-ANDA ☐ Pre-1938 ☐ OTC ☐ Compounded Product

5. If IND/Pre-ANDA, Give Protocol #

6. Type of Report *(Check all that apply)*
☐ 5-day ☐ 15-day ☐ Non-expedited (periodic) ☐ Follow-up #
☐ 7-day ☐ 30-day ☐ Initial

7. Adverse Event Term*(s)*

8. Manufacturer Report Number

(continued on next page)

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event *(Check all that apply)*

- ☐ Death
- ☐ Serious Injury
- ☐ Malfunction
- ☐ Summary Report
  No. of events summarized

2. If Follow-up, What Type?

- ☐ Correction
- ☐ Additional Information
- ☐ Response to FDA Request
- ☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Yes ☐ No

4. Device Manufacture Date

5. Labeled for Single Use?

☐ Yes ☐ No

6. Adverse Event Problem *(Refer to coding manual)*

Health Effect – Clinical Code

Health Effect – Impact Code

Medical Device Problem Code

Component Code

Type of Investigation Code

Investigation Findings Code

Investigation Conclusions Code

7. If Remedial Action Initiated, Check Type

- ☐ Recall
- ☐ Repair
- ☐ Replace
- ☐ Relabeling
- ☐ Notification
- ☐ Inspection
- ☐ Patient Monitoring
- ☐ Modification/Adjustment
- ☐ Other:

8. Usage of Device

- ☐ Initial Use of Device
- ☐ Reuse
- ☐ Unknown

9. If action reported to FDA under 21 USC 360i(g), list FDA-assigned recall number or include a statement:

10. Related Report Number

11. Additional Manufacturer Narrative

Characters Remaining (max. 450):

PRIVACY ACT STATEMENT

Authority: The information collected in this form is provided to comply with the Privacy Act of 1974 (P.L. 93-579) for individuals seeking non-employee student, post-graduate or senior scientist training opportunities from the Food and Drug Administration. Purpose and Uses: All information collected in this form is required to begin the Traineeship. Completed forms are used by the Staff to meet program selection and on-boarding requirements. Information is also shared with the FDA personnel authorized to administer the program. Effects of nondisclosure: Disclosure of the information is voluntary; however, collection of this information is necessary to continue with the FDA.

PRA Info

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 15 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:

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

"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."