Reset Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
FORM 3500A

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

Form Approved: OMB No. 0910-0291
Expires: 6-30-2025
See PRA statement on page 6.

FDA USE ONLY
Mfr report #
UF/Importer Report #
Exemption/Variance #

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 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 *(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** *(01-JAN-1900)*

4. **Date of this Report** *(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

(continued on next page)

5. **Describe Event or Problem**

6. **Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*	**Relevant Test/Laboratory Data**	**Date** *(01-JAN-1900)*

Additional comments

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, tobacco product use, alcohol use, and liver/kidney problems, etc.)*

C. SUSPECT PRODUCTS

SUSPECT PRODUCT #1

1. **Name, Strength, Manufacturer/Compounder**

Product Name	Strength	Unit
		--

NDC # or Unique ID	Manufacturer/Compounder Name	Lot #

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

3. **Dose or Amount**	**Frequency**	**Route**
	--	--
Unit	**Other Frequency**	**Other Route**
--		

4. **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 *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ 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 #

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

3. **Dose or Amount**	**Frequency**	**Route**
Unit --	**Other Frequency**	**Other Route**

4. **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 *(e.g., 01-Jan-1900)* **OR**	Duration	Unit
				--

5. **Diagnosis for use** *(indication)*	6. **Product Type** *(check all that apply)*	7. **Expiration Date** *(e.g., 01-Jan-1900)*
	☐ OTC ☐ Generic ☐ Compounded ☐ Biosimilar	

8. **Event Abated after use Stopped or Dose Reduced?**	9. **Event Reappeared after Reintroduction?**
☐ Yes ☐ No ☐ Doesn't apply	☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**	2a. **Common Device Name**	2b. **Procode**

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

4. **Model #**	**Lot #**	**Catalog #**

Expiration Date *(01-JAN-1900)*	**Serial #**

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

5. **Operator of Device** ☐ Health Professional ☐ Patient/Consumer ☐ Other	6a. **If Implanted, Give Date** *(01-JAN-1900)*	6b. **If Explanted, Give Date** *(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 on *(01-JAN-1900)*	

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

Product Name	Therapy Start Date *(01-JAN-1900)*	Therapy End Date *(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 from list)* --	4. *Initial reporter also sent report to FDA* ☐ Yes ☐ No ☐ Unknown

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**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(01-JAN-1900)*

7. **Type of Report**

8. **Date of This Report** *(01-JAN-1900)*

9. **Approximate Age of Device**

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

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

11. **Report Sent to FDA?**
(If Yes, enter date (01-JAN-1900))
☐ Yes ☐ No

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

13. **Report Sent to Manufacturer?**
(If Yes, enter date (01-JAN-1900))
☐ Yes
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

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

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 ☐ Use Faciltiy ☐ Distributor/Importer ☐ Other *(Please list)*

3. **Date Received by Manufacturer** *(01-JAN-1900)*

4. **NDA #**	**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 ☐ Periodic ☐ Follow-up #
☐ 7-day ☐ 30-day ☐ Initial

7. **Adverse Event Term***(s)*

8. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** *(check all that apply.)*
- ☐ Death
- ☐ Malfunction
- ☐ Serious Injury
- ☐ 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** *(01-JAN-1900)*

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	Investigation Findings	Investigation Conclusions

7. **If Remedial Action Initiated, Check Type**
- ☐ Recall ☐ Relabeling ☐ Patient Monitoring
- ☐ Repair ☐ Notification ☐ Modification/Adjustment
- ☐ Replace ☐ Inspection ☐ Other:

8. **Usage of Device**
- ☐ Initial Use of Device
- ☐ Reuse
- ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:**

10. **Related Report Number**

11. **Additional Manufacturer Narrative**

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Department of Health and Human Services
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