



## 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. <b>Patient Identifier</b> ( <i>In confidence</i> )		2. Age		or Date of Birth ( <i>e.g., 01-Jan-1900</i> )	
		Year(s)	Week(s)		
		Month(s)	Day(s)		
3. <b>Sex:</b> Enter the patient's sex at birth ( <i>the sex that a person has or was assigned to at birth</i> ).  Male  Female		SECTION REMOVED			
4. <b>Weight</b>  lb  kg	5. <b>Ethnicity</b> ( <i>Check one</i> )  Hispanic/Latino  Not Hispanic/Latino	6. <b>Race</b> ( <i>check all that apply</i> )  American Indian/Alaska Native      Native Hawaiian/ Asian      Other Pacific Islander Black or African American      White			

## B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <b>Type of Report</b> ( <i>check all that apply</i> ) Adverse Event Product Problem ( <i>e.g., defects/malfunctions</i> )		2. <b>Outcome Attributed to Adverse Event</b> ( <i>check all that apply</i> ) Death – Date of death ( <i>01-JAN-1900</i> ): 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. <b>Date of Event</b> ( <i>01-JAN-1900</i> )	4. <b>Date of this Report</b> ( <i>01-JAN-1900</i> )		

**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 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. Treatment 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)	<b>OR</b>	Duration	Unit
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**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)*

<b>3. Dose or Amount</b>	<b>Frequency</b>	<b>Route</b>
Unit	Other Frequency	Other Route

**4. Treatment Dates/Therapy Dates** *(give best estimate of length of treatment (start/stop) or date of dose reduction.)*

Therapy started on <i>(e.g., 01-Jan-1900)</i>	Therapy stopped on <i>(e.g., 01-Jan-1900)</i>	Dose Reduced <i>(e.g., 01-Jan-1900)</i>	<b>OR</b>	Duration	Unit
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<b>5. Diagnosis for use</b> <i>(indication)</i>	<b>6. Product Type</b> <i>(check all that apply)</i>	<b>7. Expiration Date</b> <i>(e.g., 01-Jan-1900)</i>
	OTC                      Generic Compounded            Biosimilar	

<b>8. Event Abated after use Stopped or Dose Reduced?</b> Yes      No      Doesn't apply	<b>9. Event Reappeared after Reintroduction?</b> Yes      No      Doesn't apply
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**D. SUSPECT MEDICAL DEVICE**

<b>1. Brand Name</b>	<b>2a. Common Device Name</b>	<b>2b. Procode</b>
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**3. Manufacturer Name, City and State**

<b>4. Model #</b>	<b>Lot #</b>	<b>Catalog #</b>
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<b>Expiration Date</b> <i>(01-JAN-1900)</i>	<b>Serial #</b>
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<b>Unique Device Identifier (UDI) #</b>			
<b>5. Operator of Device</b> Health Professional      Patient/Consumer Other		<b>6a. If Implanted, Give Date (01-JAN-1900)</b>	<b>6b. If Explanted, Give Date (01-JAN-1900)</b>
<b>7a. Is this a single-use device that was reprocessed and reused on a patient?</b> Yes      No		<b>7b. If yes, enter the name and address of the reprocessor</b>	
<b>8. Was this device ever serviced by a third-party servicer?</b> Yes      No      Unknown		<b>9. Is this Device Available for Evaluation? (Do not send to FDA)</b> Yes      No Returned to manufacturer on (01-JAN-1900)	
<b>10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)</b>			
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**

<b>1. Name and Address</b>			
Last Name		First Name	
Address			
City	State/Province/Region	ZIP/Postal Code	Country
Phone #		Email	
<b>2. Health Professional?</b> Yes      No	<b>3. Occupation (Select from list)</b>	<b>4. Initial reporter also sent report to FDA</b> Yes      No      Unknown	

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

<b>1. Check One</b> User Facility      Importer		<b>2. User Facility/Importer Report Number</b>		
<b>3. User Facility or Importer Name/Address</b>		<b>4. Contact Person</b>		<b>5. Phone Number</b>
		<b>6. Date User Facility or Importer Became Aware of Event (01-JAN-1900)</b>		<b>7. Type of Report</b>
<b>8. Date of This Report (01-JAN-1900)</b>		<b>9. Approximate Age of Device</b>		
<b>10. Adverse Event Problem (Refer to coding manual)</b>				
Health Effect – Clinical Code		Health Effect – Impact Code		Medical Device Problem Code      Component Code
<b>11. Report Sent to FDA?</b> (If Yes, enter date (01-JAN-1900)) Yes      No		<b>12. Location Where Event Occurred</b> Ambulatory Surgical Facility      Outpatient Treatment Facility      Other (Specify) Home      Outpatient Diagnostic Facility Hospital      Nursing Home		
<b>13. Report Sent to Manufacturer?</b> (If Yes, enter date (01-JAN-1900)) Yes No		<b>14. Manufacturer Name/Address</b>		

**G. ALL MANUFACTURERS**

<b>1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility</b>				
Name		Email Address		Phone Number
Address				
Compounding Outsourcing Facility 503B? Check box if applicable		Outsourcing Facility		
<b>2. Report Source (check all that apply)</b> Foreign      Literature      Health Professional      Company Representative Study      Consumer      Use Facility      Distributor/Importer      Other (Please list)				<b>3. Date Received by Manufacturer (01-JAN-1900)</b>
<b>4. NDA #</b>	<b>ANDA #</b>	<b>IND #</b>	<b>BLA #</b>	<b>PMA/510(k) #</b>
<b>Check all that apply:</b> Combination product      Pre-ANDA      Pre-1938      OTC      Compounded Product				
<b>5. If IND/Pre-ANDA, Give Protocol #</b>		<b>6. Type of Report (Check all that apply)</b> 5-day      15-day      Periodic      Follow-up # 7-day      30-day      Initial		
<b>7. Adverse Event Term(s)</b>			<b>8. Manufacturer Report Number</b>	

## H. DEVICE MANUFACTURERS ONLY

<b>1. Type of Reportable Event</b> <i>(check all that apply.)</i> <div style="display: flex; justify-content: space-between;"> <div>Death</div> <div>Malfunction</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Serious Injury</div> <div>Summary Report</div> </div> <div style="text-align: center;">No. of events summarized</div>		<b>2. If Follow-up, What Type?</b> <div style="display: flex; justify-content: space-between;"> <div>Correction</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Additional Information</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Response to FDA Request</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Device Evaluation</div> </div>		<b>3. Device Evaluated by Manufacturer?</b> <div style="display: flex; justify-content: space-around;"> <div>Yes</div> <div>No</div> </div>	
<b>4. Device Manufacture Date</b> (01-JAN-1900)		<b>5. Labeled for Single Use?</b> <div style="display: flex; justify-content: space-around;"> <div>Yes</div> <div>No</div> </div>			
<b>6. Adverse Event Problem</b> <i>(Refer to coding manual)</i>					
Health Effect – Clinical Code		Health Effect – Impact Code		Medical Device Problem Code	
				Component Code	
Type of Investigation		Investigation Findings		Investigation Conclusions	
<b>7. If Remedial Action Initiated, Check Type</b> <div style="display: flex; justify-content: space-between;"> <div>Recall</div> <div>Relabeling</div> <div>Patient Monitoring</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Repair</div> <div>Notification</div> <div>Modification/Adjustment</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Replace</div> <div>Inspection</div> <div>Other:</div> </div>				<b>8. Usage of Device</b> <div style="display: flex; justify-content: space-between;"> <div>Initial Use of Device</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Reuse</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Unknown</div> </div>	
<b>9. If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:</b>		<b>10. Related Report Number</b>			
<b>11. Additional Manufacturer Narrative</b>					

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Department of Health and Human Services  
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 Office of Chief Information Officer  
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 PRAStaff@fda.hhs.gov

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