



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 (<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. Sex: 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. Weight lb kg	5. Ethnicity (<i>Check one</i>) Hispanic/Latino Not Hispanic/Latino	6. Race (<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. Type of Report (<i>check all that apply</i>) Adverse Event Product Problem (<i>e.g., defects/malfunctions</i>)		2. Outcome Attributed to Adverse Event (<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. Date of Event (<i>01-JAN-1900</i>)	4. Date of this Report (<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)	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. 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>	OR	Duration	Unit
--	--	--	-----------	----------	------

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

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

D. SUSPECT MEDICAL DEVICE

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

3. Manufacturer Name, City and State

4. Model #	Lot #	Catalog #
-------------------	--------------	------------------

Expiration Date <i>(01-JAN-1900)</i>	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) <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 45%;">Product Name</th> <th style="width: 25%;">Therapy Start Date (01-JAN-1900)</th> <th style="width: 30%;">Therapy End Date (01-JAN-1900)</th> </tr> </thead> <tbody> <tr><td>1.</td><td></td><td></td></tr> <tr><td>2.</td><td></td><td></td></tr> <tr><td>3.</td><td></td><td></td></tr> <tr><td>4.</td><td></td><td></td></tr> <tr><td>5.</td><td></td><td></td></tr> <tr><td>6.</td><td></td><td></td></tr> <tr><td>7.</td><td></td><td></td></tr> <tr><td>8.</td><td></td><td></td></tr> <tr><td>9.</td><td></td><td></td></tr> <tr><td>10.</td><td></td><td></td></tr> </tbody> </table>				Product Name	Therapy Start Date (01-JAN-1900)	Therapy End Date (01-JAN-1900)	1.			2.			3.			4.			5.			6.			7.			8.			9.			10.		
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 <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="height: 30px; vertical-align: bottom;">Last Name</td> <td colspan="2" style="height: 30px; vertical-align: bottom;">First Name</td> </tr> <tr> <td colspan="4" style="height: 30px; vertical-align: bottom;">Address</td> </tr> <tr> <td style="width: 30%; height: 30px; vertical-align: bottom;">City</td> <td style="width: 20%; height: 30px; vertical-align: bottom;">State/Province/Region</td> <td style="width: 20%; height: 30px; vertical-align: bottom;">ZIP/Postal Code</td> <td style="width: 30%; height: 30px; vertical-align: bottom;">Country</td> </tr> <tr> <td colspan="2" style="height: 30px; vertical-align: bottom;">Phone #</td> <td colspan="2" style="height: 30px; vertical-align: bottom;">Email</td> </tr> </table>				Last Name		First Name		Address				City	State/Province/Region	ZIP/Postal Code	Country	Phone #		Email																		
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 Facility 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 <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>		2. If Follow-up, What Type? <div style="display: flex; justify-content: space-between;"> <div>Correction</div> <div>Additional Information</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Response to FDA Request</div> <div>Device Evaluation</div> </div>		3. Device Evaluated by Manufacturer? <div style="display: flex; justify-content: space-around;"> <div>Yes</div> <div>No</div> </div>	
4. Device Manufacture Date (01-JAN-1900)		5. Labeled for Single Use? <div style="display: flex; justify-content: space-around;"> <div>Yes</div> <div>No</div> </div>			
6. Adverse Event Problem <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	
7. If Remedial Action Initiated, Check Type <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>					8. Usage of Device <div style="display: flex; justify-content: space-between;"> <div>Initial Use of Device</div> <div>Reuse</div> <div>Unknown</div> </div>
9. If action reported to FDA under 21 USC 360i(g), list correction/ removal reporting number:			10. Related Report Number		
11. Additional Manufacturer Narrative					

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 73 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing 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
 Paperwork Reduction Act (PRA) Staff
 PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

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."