

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

Year(s)

Week(s)

Month(s)

Day(s)

3. Sex: Enter the patient's sex at birth
(the sex that a person has or was assigned to at birth).

Male

Female

SECTION REMOVED**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

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?

Yes

No

Doesn't apply

9. 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 # |

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; margin-top: 5px;"> <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; margin-top: 5px;"> <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> 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 <i>(Refer to coding manual)</i> | | | | | |
| Health Effect – Clinical Code | | Health Effect – Impact Code | | Medical Device Problem 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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 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
 PRAStaff@fda.hhs.gov

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