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See PRA statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (10/15)

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

Mfr Report #
UF/Importer Report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier**	2. **Age** ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)	3. **Sex**	4. **Weight**
In Confidence	or Date of Birth *(e.g., 08 Feb 1925)*	☐ Female ☐ Male	or ____ lbs ____ kgs

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):*
☐ Life-threatening
☐ Hospitalization – initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defects

3. **Date of Event** *(dd-mmm-yyyy)*	4. **Date of this Report** *(dd-mmm-yyyy)*

5. **Describe Event or Problem**

(Continue on page 3)

6. **Relevant Tests/Laboratory Data, Including Dates**

(Continue on page 3)

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

(Continue on page 3)

C. SUSPECT PRODUCT(S)

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

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

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

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3. **Dose**	**Frequency**	**Route Used**
#1		
#2		

4. **Therapy Dates** *(If unknown, give duration)* from/to *(or best estimate))* *(dd-mmm-yyyy)*
#1
#2

5. **Diagnosis for Use** *(Indication)*
#1
#2

6. **Is the Product Compounded?**	7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No	#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No	#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 #2 __ __ - __ __ __ - __ __ __ __

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**	2b. **Procode**

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

4. **Model #**	**Lot #**	5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other
Catalog #	**Expiration Date** *(dd-mmm-yyyy)* __ __ - __ __ __ - __ __ __ __	
Serial #	**Unique Identifier (UDI) #**	

6. **If Implanted, Give Date** *(dd-mmm-yyyy)* - -	7. **If Explanted, Give Date** *(dd-mmm-yyyy)* - -

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: __ __ - __ __ __ - __ __ __ __

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

(Continue on page 3)

E. INITIAL REPORTER

1. Has a study physician investigator reviewed the information provided in this report?
☐ Yes ☐ No ☐ Pending

Was Ae serious in nature?	☐ Yes	☐ No	☐ Pending
Was AE related to medicinal product?	☐ Yes	☐ No	☐ Pending
Was AE unexpected?	☐ Yes	☐ No	☐ Pending

2. **Health Professional?**	3. **Occupation** *(Select from list)*	4. **Initial Reporter Also Sent Report to FDA**
☒ Yes ☐ No		☐ Yes ☒ No ☐ Unk

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FDA USE ONLY

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

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/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** *(dd-mmm-yyyy)* __ - ___ - ____
7. **Type of Report** ☐ Initial ☐ Follow-up # _____
8. **Date of This Report** *(dd-mmm-yyyy)* __ - ___ - ____
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
    Patient Code _____ – _____ – _____
    Device Code _____ – _____ – _____
11. **Report Sent to FDA?** *(If Yes, enter date (dd-mmm-yyyy))* ☐ Yes __ - ___ - ____ ☐ No
12. **Location Where Event Occurred**
    ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*
13. **Report Sent to Manufacturer?** *(If Yes, enter date (dd-mmm-yyyy))* ☐ Yes __ - ___ - ____ ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
   Name
   Address
   Email Address
   Compounding Outsourcing Facility 503B? ☐ Yes
2. **Phone Number**
3. **Report Source** *(Check all that apply)*
   ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(dd-mmm-yyyy)* __ - ___ - ____
5. NDA # _____ ANDA # _____ IND # _____ BLA # _____ PMA/ 510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC ☐ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)*
   ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number**

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. **Device Manufacture Date** *(dd-mmm-yyyy)* __ - ___ - ____
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Event Problem and Evaluation Codes** *(Refer to coding manual)*
   Patient Code _____ – _____ – _____
   Device Code _____ – _____ – _____
   Method _____ – _____ – _____ – _____
   Results _____ – _____ – _____ – _____
   Conclusions _____ – _____ – _____ – _____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/ Adjustment ☐ Other: _____
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

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FORM FDA 3500A (10/15) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.2 and/or D.11; please distinguish)*

Other Remarks