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

MEDWATCH

FORM FDA 3500A (10/05)

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

General Instructions

Page ____ of ____

Mfr Report #

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION — Section A - Help

1. **Patient Identifier** — In confidence
2. **Age at Time of Event:** or **Date of Birth:**
3. **Sex** — ☐ Female ☐ Male
4. **Weight** — ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM — Section B - Help

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

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

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*

5. **Describe Event or Problem**

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

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

Was AE serious in nature? ___Yes ___No
Was AE related to medicinal product? ___Yes ___No
Was AE unexpected? ___Yes ___No

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.

FAX TO:

C. SUSPECT PRODUCT(S) — Section C - Help

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1
   #2

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

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

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

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

9. **NDC# or Unique ID**

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

D. SUSPECT MEDICAL DEVICE — Section D - Help

1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State**
4. **Model #** | **Lot #**
   Catalog # | **Expiration Date** *(mm/dd/yyyy)*
   Serial # | **Other #**
5. **Operator of Device**
   - ☐ Health Professional
   - ☐ Lay User/Patient
   - ☐ Other:
6. **If Implanted, Give Date** *(mm/dd/yyyy)*
7. **If Explanted, Give Date** *(mm/dd/yyyy)*
8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
   ☐ Yes ☐ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**
10. **Device Available for Evaluation?** *(Do not send to FDA)*
    ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*
11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

E. INITIAL REPORTER — Section E - Help

1. **Name and Address**

Phone #

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

PLEASE TYPE OR USE BLACK INK