Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

U.S. Department of Health and Human Services

# MEDWATCH

**The FDA Safety Information and Adverse Event Reporting Program**

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

**Page ____ of ____**

Mfr Report #

UF/Importer Report #

**FDA Use Only**

## A. PATIENT INFORMATION

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

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

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mo/day/yr)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: _____

3. **Date of Event** *(mo/day/year)*

4. **Date of This Report** *(mo/day/year)*

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.)*

## C. SUSPECT MEDICATION(S)

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

7. **Exp. Date** *(if known)*
#1
#2

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

9. **NDC#** *(For product problems only)*
– –

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

## D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Type of Device**

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

4. **Model #**
**Catalog #**
**Serial #**
**Lot #**
**Expiration Date** *(mo/day/yr)*
**Other #**

5. **Operator of Device**
☐ Health Professional
☐ Lay User/Patient
☐ Other: _____

6. **If Implanted, Give Date** *(mo/day/yr)*

7. **If Explanted, Give Date** *(mo/day/yr)*

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: _____ *(mo/day/yr)*

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

## E. INITIAL REPORTER

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

**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.**

**FORM FDA 3500A (9/03)**

# Medication and Device Experience Report

*(Continued)*

*Refer to guidelines for specific instructions.*

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

**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** *(mo/day/yr)*

7. **Type of Report**
☐ Initial
☐ Follow-up # _____

8. **Date of This Report** *(mo/day/yr)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ___ – ___ – ___
Device Code ___ – ___ – ___

11. **Report Sent to FDA?**
☐ Yes _____ *(mo/day/yr)*
☐ No

12. **Location Where Event Occurred**
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?**
☐ Yes _____ *(mo/day/yr)*
☐ No

14. **Manufacturer Name/Address**

## G. ALL MANUFACTURERS

1. **Contact Office - Name/Address *(and Manufacturing Site for Devices)***

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** *(mo/day/yr)*

5.
(A)NDA # _____
IND # _____
PLA # _____
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 15-day
☐ 10-day ☐ Periodic
☐ Initial ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**

## H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: _____

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** *(mo/yr)*

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ___ – ___ – ___ – ___
Results ___ – ___ – ___ – ___
Conclusions ___ – ___ – ___ – ___

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ 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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"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."

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