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See OMB statement on reverse.

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

PLEASE TYPE OR USE BLACK INK

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)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ 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.)*

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.

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.

Save As... | Print | Next Page | Previous Page | Reset Form

MEDWATCH

FORM FDA 3500A (10/05) *(continued)* Section F - Help **Page ____ of ____**

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** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
   Patient Code ____ - ____ - ____
   Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred**
   ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

Section G - Help

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** *(mm/dd/yyyy)*
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ 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

Section H - Help

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** *(mm/yyyy)*
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 ☐ 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**

GENERAL INSTRUCTIONS

- All entries should be typed or printed in a font no smaller than 8 point.
- Complete all sections that apply. If information is unknown, not available or does not apply, the section should be left blank.
- Dates should be entered as mm/dd/yyyy *(e.g., June 3, 2005 = 06/03/2005)*. If exact dates are unknown, provide the best estimate.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s).

The following specific information is to be incorporated:

  - Include the phrase continued at the end of each field of FDA Form 3500A that has additional information continued onto another page
  - Identify all attached pages as *Page __ of __*
  - Indicate the appropriate section and block number next to the narrative continuation
  - Display the User Facility, Distributor (Importer), or Manufacturer report number in the upper right corner as applicable
  - Include the firm's or facility's name in the upper right corner as well, if the report is from a user facility, distributor (importer), or manufacturer

- If the case report involves more than two (2) suspect medications attach another copy of **Form FDA 3500A**, with only section C or section D filled in as appropriate.
- If the event involves more than one suspect medical device, complete all applicable sections of **Form FDA 3500A** for the first device and a separate section D (Suspect Medical Device) and Blocks F9, F10, F13, and F14 for each additional device. Identify each report as *device 1*, *device 2*, etc.
- Manufacturers must complete and submit a separate **Form FDA 3500A** for each different suspect device. Each 3500A will be given a separate Manufacturer Report Number.
- If the suspect medical device is a single use device that has been reprocessed for use in humans, then the reprocessor is the manufacturer. The manufacturer can be either an Original Equipment Manufacturer (OEM), or a Reprocessor of Single-Use Devices, which also can be a User Facility that reprocesses Single-Use Devices. *(See the table below)*

Subject Device	Manufacturer
Single Use Device	Original Equipment Manufacturer (OEM)
Device designed to be reused	Original Equipment Manufacturer (OEM)
Single Use Device, reprocessed for reuse	Reprocessor
Single Use Device, reprocessed by Hospital or Health Care Facility	Hospital or Health Care Facility

- If no suspect medical device is involved in a reported adverse event (i.e., when reporting ONLY a suspect drug or biologic), ONLY sections A, B, C, E, and G are to be filled out:
  - Section G (All manufacturers) may be substituted for section D (Suspect medical device) on the front of the form to enable the submission of a one page form
  - If section G is reproduced on the front of the form it must be an identical reproduction of the original section G
- All submissions must be made in English, including foreign literature reports.
- Vaccines: Events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS) on form VAERS-1 (PDF format), available at http://vaers.hhs.gov or by calling 1-800-822-7967.
- Devices: Federal law provides that user facility reports that are required by law may not be used in private civil litigation actions unless the party who made the report had knowledge the report contained false information. 21 USC 360i(b)(3).

FRONT PAGE

At the top of the front page:

Enter the page number and total number of pages submitted (include attachments in the total) where the words *Page __ of __* are indicated.

On the top-right corner of the front page:

Enter the Manufacturer report number, User Facility report number, or Distributor (Importer) report number in the correspondingly labeled box Enter both report numbers, if applicable, to cross-reference this report with a report from another source on the same event.

Mfr report #:

This is the unique identifier used by the manufacturer for this report. For a follow-up report, the manufacturer report number must be identical to the number assigned to the initial report. The manufacturer report number is also entered in block G9 on the back ofthe form.

For device manufacturers: The report number consists of three components: the manufacturer's FDA registration number for the manufacturing site of the reported device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer (e.g., 1234567-1997-00001,1234567-1997-00002).

(continued on next page)

GENERAL INSTRUCTIONS *(continued)*

For drug and biologics, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturers: The "mfr report #" is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.

If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer Program , check the other box in block G3 and enter the FDA-assigned report number there.

UF/Dist report #:

This is the unique identifier used by the user facility or the distributor (importer) for this report. For a follow-up report, the UF/Dist report number must be identical to the number assigned to the initial report. The UF/Dist report number is also entered in block F2 on the back of the form.

The user facility report number consists of three components: the facility's 10-digit Centers for Medicare & Medicaid Services (CMS) number, the 4-digit calendar year, and a consecutive 4-digit number for each report filed during the year by the facility (e.g., 1234567890-1997-0001,1234567890-1997-0002). If the CMS number has fewer than 10 digits, enter ONLY these numbers, leaving the remainder blank (zeros will be automatically filled in by the system). If a facility does not have a CMS number, the first report and any subsequent reports should be submitted with all zeros in the CMS space (e.g., 0000000000-1997-0001), and FDA will assign a number to be used in future reports. If a facility has more than one CMS number, the facility must select one of those numbers as the primary number and use it for subsequent submissions.

If a user facility has multiple sites, the primary site can report centrally and use one reporting number for all sites IF the primary site provides the name, address, and CMS number for each respective site.

The distributor (importer) report number consists of three components: the FDA-assigned registration or identification number for the distributor (importer) of the device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the distributor (importer) (e.g.,1234567-1997-00001, 1234567-1997-00002). If a distributor (importer) does not have an assigned identification number, it should use all zeros in the appropriate space on the initial report, and continue to use zeros on subsequent reports until the FDA-assigned number is received. The distributor (importer) would still enter the 4-digit calendar year and 5-digit sequence number.

Note: In cases where a reporting site is registered as both a manufacturer and a distributor (importer), and the registration and/or FDA-assigned identification numbers are identical for both, then the 5-digit sequence number for reports submitted during the year by either one may NOT be duplicated. For example, for devices manufactured by the firm, the report number would consist of the registration number, calendar year, and a consecutive 5-digit number (e.g., 1234567-1997-00001, 1234567-1997-00002, and so on). For devices distributed (imported) by the firm, the registration number and year would remain the same, but the 5-digit sequence number must be different (e.g., 1234567-1997-00003, 1234567-1997-00004, and so on).

BACK PAGE

At the top of the back page, enter the page number and total number of pages submitted (include attachments in the total) where the words *Page __ of __* are indicated.

SECTION A: PATIENT INFORMATION

Complete a separate form for each patient, unless the report involves a medical device where multiple patients were adversely affected through the use of the same device.

In that case:

- Indicate the number of patients in block B5 *(Describe event or problem)*
- Complete separate section A and blocks B2, B5, B6, B7, D11, F2 and F10 for each additional patient
- Enter the corresponding patient identifier in block A1for each patient involved in the event

Parent-child/fetus report(s) are those cases in which either a fetus/breast feeding infant or the mother, or both, sustain an adverse event that the initial reporter considers possibly associated with a product administered to the mother during pregnancy. Several general principles are used for filing these reports:

- If there has been no event affecting the child/fetus, report only on the parent
- For those cases describing fetal death, miscarriage or abortion, only a parent report is applicable
- When ONLY the child/fetus has an adverse reaction/event (other than fetal death, miscarriage or abortion), the information provided in section A applies to the child/ fetus, and characteristics concerning the parent who was the source of exposure to the product is to be provided in section C.

- When a newborn baby is found to have a congenital anomaly/birth defect that the initial reporter considers possibly associated with a product administered to the mother during pregnancy, the patient is the newborn baby.

- If both the parent and the child/fetus sustain adverse events, two reports should be provided and linked using the narrative *(include the manufacturer control #'s in block B5)*

A1: Patient identifier

Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different) to locate the case if contacted for follow-up. Do not use the patient's name or social security number.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. If no patient was involved, enter *none*.

A2: Age at Time of Event or Date of Birth

Provide the most precise information available. Enter the patient's birthdate, if known, or the patient's age at the time of event onset. For age, indicate time units used (e.g., years, months, and days).

- If the patient is 3 years or older, use years (e.g., 4 years)
- If the patient is less than 3 years old, use months (e.g., 24 months)
- If the patient is less than 1 month old, use days (e.g., 5 days)
- Provide the best estimate if exact age is unknown

A3: Sex

Enter the patient's gender.

If the adverse event is a congenital anomaly, report the sex of the child.

A4: Weight

Indicate whether the weight is in pounds (lbs.) or kilograms (kgs). Make a best estimate if exact weight is unknown.

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: Adverse event *and/or* Product problem

Choose the appropriate box. Both boxes should be checked if a product problem may have caused or contributed to the adverse event.

Adverse event:

Any incident where the use of a medication (drug or biologic, including human cell, tissue, or cellular or tissue-based product (HCT/P), at any dose, or a medical device (including *in vitro* diagnostics) is suspected to have resulted in an adverse outcome in a patient.

Product problem (e.g., defects/malfunctions):

Any report regarding the quality, performance, or safety of any medical product. This category is selected when reporting device malfunctions that could lead to a death or serious injury if the malfunction were to recur.

B2: Outcomes attributed to adverse event:

Indicate ALL that apply to the reported event:

Drugs and Biologics: Only mark a box in this section if the adverse event meets the regulatory definition of serious in 21 CFR 314.80(a) and 600.80(a).

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): An adverse reaction which is required to be reported to FDA is an adverse reaction which involves a communicable disease and by 21 CFR 1271.350a:

(i) Is fatal;

(ii) Is life-threatening;

(iii) Results in permanent impairment of a body function or permanent damage to body structure;

or

(iv) Necessitates medical or surgical intervention, including hospitalization.

Death: Check if death was an outcome of the adverse event, or if the cause of the death is unknown. Include the date of death, if known.

***DO NOT* check if:**

- The patient died while using a medical product, but there was no suspected association between the death and the use of the product
- A fetus is aborted because of a congenital anomaly, or is miscarried

Life-threatening: Check if suspected that:

- The patient was at substantial risk of dying at the time of the adverse event, or
- Use or continued use of the device might have resulted in the death of the patient

Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.

***DO NOT* check if:**

- A patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event, UNLESS the adverse event prolonged the hospital stay

***DO* check if:**

- A patient is admitted to the hospital for one or more days, even if released on the same day
- An emergency room visit results in admission to the hospital

Note: Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious (medically important event)

Disability or Permanent Damage: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions. Congenital anomaly/Birth Defect: Check if suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required Intervention to Prevent Permanent Impairment/Damage (Devices): if either situation may be due to the use of a medical device and medical or surgical intervention was necessary to:

- Preclude permanent impairment of a body function, or
- Prevent permanent damage to a body structure.

Other Serious (Important Medical Events):

- Check when, based on appropriate medical judgement, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes. Examples include allergic brochospasm requiring emergency treatment, blood dyscrasias or convulsions that do not result in hospitalization, or the development of drug dependency or drug abuse. For human cells, tissues, and cellular and tissue-based products (HCT/P's), such interventions could include antibiotics in response to a positive culture or clinical suspicion of an infection, but not as prophylaxis for infection.

(continued on next page)

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM *(continued)*

Devices: Check ONLY if the other categories are not applicable to the event. Describe the patient outcome in the actual narrative of the event in block B5.

B3: Date of Event

Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

- When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child
- When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated.

If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.

B4: Date of this Report

- **Drugs and Biologics, including Human Cells, Tissues, and Cellular and Tissue-Based Products:** The date the report is filled out.
- **Devices:** The date the initial reporter provided the information about the event [i.e., the first person or entity who initially provided the information to the user facility, manufacturer, or distributor (importer)].

B5: Describe Event or Problem

For an adverse event: Describe the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), attach copies of these records with any confidential information deleted. DO NOT identify any patient, physician, or institution by name. The initial reporter's identity should be provided in full in section E. Information as to any environmental conditions that may have influenced the event should be included, particularly when (but not exclusive to) reporting about a device.

- Results of relevant tests and laboratory data should be entered in block B6. *(see instructions for B6)*.
- Preexisting medical conditions and other relevant history belong in block B7. Be as complete as possible, including time courses for preexisting diagnoses *(see instructions for B7)*.

For a product problem: Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section.

B6: Relevant Tests/Laboratory Data, Including Dates:

Provide all appropriate information, including relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.

Include:

- Any relevant baseline laboratory data prior to the administration or use of the medical product
- All laboratory data used in diagnosing the event
- Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, include:

- Any pre- and post-event medication levels and dates (if applicable)
- Synopses of any relevant autopsy, pathology, engineering, or lab reports

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. **DO NOT** identify any patient, physician or institution by name. The initial's reporter's identity should be provided in full in section E.

B7: Other Relevant History, Including Preexisting Medical Conditions:

If available, provide information on:

- Other known conditions in the patient, e.g.,
  - Hypertension
  - Diabetes mellitus
  - Renal/hepatic dysfunction, etc
- Significant history
  - Race
  - Allergies
  - Pregnancy history
  - Smoking and alcohol use
  - Drug abuse, etc.

SECTION C: SUSPECT PRODUCT(S)

For adverse event reporting, a suspect product is one that the initial reporter suspected was associated with the adverse event. In block C10 enter other concomitant medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), and medical devices, etc.) that the patient was using at the time of the event but are NOT thought by the initial reporter to be involved in the event.

Up to two (2) suspect products may be reported on one form (#1=first suspect product, #2=second suspect product). Attach an additional form if there were more than two suspect products for the reported adverse event.

C1: Name:

Use the trade name as marketed. If unknown or if no trade name, use the generic name (with the manu- facturer or labeler's name, if known). For foreign reports, use both the foreign trade name and the U.S. generic name.

For human cells, tissues, and cellular and tissue-based products (HCT/Ps), please provide the common name of the HCT/P. You can also indicate if the HCT/P has a proprietary or trade name. Examples: Achilles tendon, Iliac crest bone, Islet Cells , or Brand X Bone Chips.

C2: Dose, Frequency & Route Used:

Describe how the product was used by the patient (e.g., 500 mg QID orally or 10 mg every other day IV). For reports involving overdoses, the amount of product used in the overdose should be listed, NOT the prescribed amount.

- See **APPENDIX** for list of Routes of Administration

C3: Therapy Dates:

Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g., 2 years) or, if therapy was less than one day, then duration is appropriate (e.g., 1 dose or 1 hour for an IV).

For human cells, tissues, and cellular and tissue-based products HCT/Ps, provide the date of transplant and if applicable, the date of explantation.

C4: Diagnosis for Use

Provide the indication for which the product was prescribed or used in this particular patient.

C5: Event Abated After Use Stopped or Dose Reduced:

In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C6: Lot #:

If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication.

C7: Expiration date:

Include with all product problem reports ONLY.

C8: Event Reappeared After Reintroduction:

In addition to checking the appropriate box, provide supporting lab tests and dates, if available, in block B6.

C9: NDC # or Unique ID:

The national drug code is required ONLY when reporting a drug product problem. It can be found on the product label and/or packaging. Zeros and dashes should be included as they appear on the label.

If the product has a unique or distinct identification code, please provide this here. Please provide the appropriate tracking code for all human cells, tissues, and cellular and tissue-based products (HCT/Ps)

C10: Concomitant Medical Products and Therapy Dates:

List and provide therapy dates for any other medical products (drugs, biologics, including HCT/Ps, or medical devices, etc.) that a patient was using at the time of the event. **DO NOT** include products used to treat the event.

APPENDIX - ROUTES OF ADMINISTRATION: ICH LIST AND CODES

Description ICH-M2 Numeric Codes

Auricular (otic) 001
Buccal 002
Cutaneous 003
Dental 004
Endocervical 005
Endosinusial 006
Endotracheal 007
Epidural 008
Extra-amniotic 009
Hemodialysis 010
Intra corpus cavernosum 011
Intra-amniotic 012
Intra-arterial 013
Intra-articular 014
Intra-uterine 015
Intracardiac 016
Intracavernous 017
Intracerebral 018
Intracervical 019
Intracisternal 020
Intracorneal 021
Intracoronary 022
Intradermal 023
Intradiscal (intraspinal) 024
Intrahepatic 025
Intralesional 026
Intralymphatic 027
Intramedullar (bone marrow) 028
Intrameningeal 029
Intramuscular 030
Intraocular 031
Intrapericardial 032
Intraperitoneal 033
Intrapleural 034
Intrasynovial 035
Intratumor 036
Intrathecal 037
Intrathoracic 038
Intratracheal 039
Intravenous bolus 040
Intravenous drip 041
Intravenous (not otherwise specified) 042
Intravesical 043
Iontophoresis 044
Occlusive dressing technique 045
Ophthalmic 046
Oral 047
Oropharingeal 048
Other 049
Parenteral 050
Periarticular 051
Perineural 052
Rectal 053
Respiratory (inhalation) 054
Retrobulbar 055
Sunconjunctival 056
Subcutaneous 057
Subdermal 058
Sublingual 059
Topical 060
Transdermal 061
Transmammary 062
Transplacental 063
Unknown 064
Urethral 065
Vaginal 066

SECTION D: SUSPECT MEDICAL DEVICE

In block D11, report other concomitant medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), or medical devices, etc.) that the patient was using at the time of the event but are not thought to be involved in the event.

D1: Brand Name:

The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g., Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device.

Single use reprocessed devices may bear the OEM's brand name. If the suspect device is a reprocessed single-use device, enter "NA".

D2: Common Device Name:

Use the Product Code assigned to the device based upon the medical device product classification designated under 21 CFR Parts 862-892. Product codes may be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm

If the product code is cannot be determined, use the generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.). Do not use broad generic terms such as "catheter", "valve", "screw", etc.

D3: Manufacturer Name, City and State

If available, enter the full name, city, and state of the manufacturer of the suspect medical device. If Block D8 below is 'Yes", enter the name, city and state of the reprocessor.

D4: Model #, Catalog #, Serial #, Lot #, Expiration date

If available, provide any expiration date or any or all identification numbers associated with the suspect medical device exactly as they appear on the device or device labeling. This includes spaces, hyphens, etc.

Model #: The exact model number found on the device label or accompanying packaging

Catalog #: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging

Serial #: This number can be found on the device label or accompanying packaging; it is assigned by the manufacturer and should be specific to each device

Lot #: This number can be found on the label or packaging material

Expiration date: If available; this date can often be found on the device itself or printed on the accompanying packaging.

Other #: Any other applicable identification number (e.g., component number, product number, part number, barcoded product ID, etc.)

D5: Operator of Device:

Indicate the type (not the name) of person operating or using the suspect medical device on the patient at the time of the event as follows:

- Health professional = physician, nurse, respiratory therapist, etc.
- Lay user/patient = person being treated, parent/ spouse/friend of the patient
- Other = nurses aide, orderly, etc.

D6: If Implanted, Give Date:

For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D7: If Explanted, Give Date:

If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: Is this a Single-use Device that was Reprocessed and Reused on a Patient?

Indicate "Yes" or "No"

If the original equipment manufacturer (OEM) is unable to determine if their single use device was reprocessed and reused on a patient, then the OEM should enter 'UNK' in Block D8 and in Block H10 (Additional Manufacturer Narrative) describe the efforts made to obtain the information and any responses.

D9: If Item No.8 is "Yes", Enter Name and Address of Reprocessor:

Enter the name and address of the reprocessor of the single-use device. Any entity that reprocesses single-use devices for reuse in humans is the manufacturer of the reprocessed single-use device.

D10 : Device Available for Evaluation?

Indicate whether the device is available for evaluation by the manufacturer. Indicate if the device was returned to the manufacturer and, if so, the date of the return. Do not send the device to FDA.

D11 : Concomitant Medical Products and Therapy Dates:

List and provide product names and therapy dates for any other medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), or medical devices, etc.) that the patient was using at the time of the event. **DO NOT** include products used to treat the event.

SECTION E: INITIAL REPORTER

Indicate the person who initially reported the adverse event to the user facility, distributor (importer), or manufacturer.

E1: Name, Address & Phone #:

Please provide the name, mailing address, and phone number of the person who initially reported the adverse event to the user facility, manufacturer, or distributor (importer), and who can be contacted to provide information on the event if follow-up is necessary. If available, provide reporter's E-mail address and/or fax number.

For medical device reporting by user facilities, this person may or may not be the designated medical device reporting (MDR) contact.

E2: Health Professional?:

Indicate whether the initial reporter is a health professional (e.g., physician, pharmacist, nurse, etc.) or not. If not a health professional, complete block E3 by filling in NA.

E3: Occupation:

Indicate the initial reporter's occupation (particularly type of health professional), and include specialty if appropriate.

E4: Initial Reporter Also Sent Report to FDA:

Indicate whether the initial reporter also notified or submitted a copy of this report to FDA.

SECTION F: FOR USE BY USER FACILITY/IMPORTER - DEVICES ONLY

F1: Check one:

Indicate whether the report is from a user facility or importer.

F2: UF/Importer Report Number:

Enter the complete number of the report exactly as entered in the upper right corner of the front page. For a follow-up report, the UF/Importer report number must be identical to the number assigned to the initial report. See instructions on front page for further explanation of UF/Importer report number.

F3: User Facility or Iimporter Name/Address:

Enter the full name and address of the user facility or importer reporting site.

F4: Contact Person:

Enter the full name of the medical device reporting (MDR) contact person. This is the person designated by the facility's most responsible person as the device user facility/importer contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with the MDR requirements.

F5: Phone Number:

Enter the phone number of the MDR contact person.

F6: Date User Facility or Importer Became Aware of Event:

Enter the date that the user facility's medical personnel or the importer became aware that the device has or may have caused or contributed to the reported event.

F7: Type of Report:

Check the appropriate box to identify the type of report being filed, i.e., an initial report of an event or a follow-up to a previously submitted report. If a follow-up report, make sure that the UF/ Importer report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2, and so on). Follow-up reports should not repeat material that was submitted in the initial report, but should ONLY provide additional or corrected information on the previously reported event.

F8: Date of this Report:

Enter the date that the report was forwarded to the manufacturer and/or the FDA.

F9: Approximate Age of Device:

Enter the age of the device or a best estimate (include unit of time used: e.g., month, year).

F10: Event Problem Codes *(refer to Device Coding Manual for Form 3500A)*:

Enter up to 3 "patient" and 3 "device" codes from the Codes Manual that most accurately describe the event. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems encountered during the event. If more than 3 "patient" codes or more than 3 "device" codes are needed, record them on a separate sheet, mark it "F10", and provide the report number and page number.

If a user facility or an importer has reason to believe that a reused device has or may have caused or contributed to an adverse event, the device problem code 1537 ("Reuse") should be entered in F10 along with any other applicable device and/or patient-related codes.

F11: Report Sent to FDA?:

Check yes or no and indicate the date sent, if applicable.

F12: Location Where Event Occurred:

Check the location of the actual occurrence of the event. If none of the designated location options apply, check the other box and provide the location.

F13: Report Sent to Manufacturer?:

Check yes or no and indicate the date sent, if applicable.

F14: Manufacturer Name/Address:

Enter full name and address of the device manufacturer, if available. If the manufacturer is a reprocessor of a single-use device, the name and address should be identical to the information in Block D9.

SECTION G: ALL MANUFACTURERS

This section is to be filled out by all manufacturers.

NOTE: If a drug or biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D on the front of the form so that a one page form may be submitted.

G1: Contact Office - Name/Address (and manufacturing site for devices):

Enter the full name and address of the manufacturer reporting site [contact office], including contact name. If the manufacturing site of the device is not the same as the contact office, enter **site** and the name and address of the manufacturing site after the contact office name and address.

G2: Phone Number:

Enter the telephone number of the contact office (devices) or a representative knowledgeable about the report *(drugs; biologics, including HCT/Ps)*.

G3: Report Source:

Check the box(es) that most accurately describe(s) how the manufacturer [contact office] became aware of the reported adverse event or from where the information about the adverse event originated.

- **Foreign:** Foreign sources include foreign governments, foreign affiliates of the application/license holder, foreign licensors and licensees, foreign medical facilities, etc. The country of origin should be included.

- **Study:** Postmarketing, clinical trial, surveillance, or other study that involves a systematic collection of adverse events from a protocol designed specifically to investigate product safety.

  - **Drugs and Biologics, including HCT/Ps:** This also includes information derived from planned contacts and active solicitation of information from patients (e.g., company-sponsored patient support programs and disease management programs). Applicants, manufacturers, and licensed manufacturers should not report safety information obtained through these types of patient contacts unless the adverse event meets the regulatory definitions of **serious** and **unexpected** and there is a reasonable possibility that the drug or biological product caused the adverse experience. In addition, manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) are only required to report any adverse reaction involving a communicable disease, if the adverse reaction is fatal, life-threatening, results in permanent impairment to body structure or necessitates medical or surgical intervention including hospitalization (effective May 25,2005).

- **Literature:** If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated into English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10. **Drugs and Biologics, including HCT/Ps:** A separate 3500A form must be completed for each identifiable patient described in the article or manuscript.

- **Consumer (including attorneys):** Additional information, whenever possible, should be sought from the treating healthcare provider. A determined effort should be made to obtain additional detailed information from health professionals for all serious reactions, adverse events & product problems initially reported by consumers. When this additional information is obtained, the follow-up report should check health professional rather than consumer in block G3.

- **Health professional:** Physician, pharmacist, nurse, etc.

- **User facility:** User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as identified in section F. The health professional should be listed as the initial reporter on the front page of the form.

- **Company representative:** This check box would be selected if a company representative reported the event to the contact office based on information received from a health professional. The health professional should be listed as the initial reporter in Section E.

- **Distributor:** This check box would be selected for a report received from the distributor (importer) of the suspect product. The health professional or other reporter should be listed as the initial reporter on the front page of the form.

- **Other:** Any source not covered by the previous categories. For **drug or biologic, including HCT/P manufacturers,** this check box would be selected when submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, and the FDA-assigned report number entered into the space provided. **Other** may also be used to identify when the source is another manufacturer - include the Manufacturer Report Number of the other manufacturer.

G4: Date received by manufacturer: This means the date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred. This would apply to a report received anywhere in the world. *(mm/dd/yyyy format)*

- **Follow-up reports:** Use the date that the follow-up information was received.

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SECTION G: ALL MANUFACTURERS *(continued)*

G5:

This block is for use by all manufacturers of drug, device, biological products [including cell, tissue, and cellular and tissue-based products (HCT/P)] and combination products.

Provide whatever information is applicable to the suspect product identified in section C or suspect medical device identified in Section D.

If the report lists two products by the same applicant as suspect, the report should be submitted to the application file of the product thought by the initial reporter to be the more likely cause of the adverse event. If they are equally suspect, the report should be submitted to the application file of the product that is first alphabetically.

- **(A)NDA #:** The abbreviated new drug application or the new drug application (NDA) number. The report should be filed to the first approved NDA if a product has several NDAs and the specific one cannot be determined.
- **IND #:** The investigational new drug (IND) application number
- **STN:** The 6 digit product submission tracking number (STN). If no STN exists, use the 4 digit U.S. License Number.
- **PMA/510(k) #:** The pre-market application (PMA) or pre-market notification [510(k)] submission number for the approved / cleared medical device or combination product. If a product has several applicable PMA/ 510(k)'s and the specific one cannot be determined, then the first approved / cleared PMA or 510(k) number should be reported.
- **Combination Product:** Check the box if the suspect product is comprised of a drug-device, device-biological, drug-biological, or a drug-device-biological product,
- **Pre-1938:** Check the box if the suspect medication was marketed prior to 1938 and does not have an NDA #.
- OTC Check the box if the suspect medication can be purchased over-the-counter (without a prescription).

G6: If IND, Protocol #: This block is for use by drug and biologic, including HCT/P manufacturers ONLY. If the form is being used as a written IND safety report, enter the protocol number.

G7: Type of Report: Select ALL the check boxes that apply to reported event:

- **5-day:** As specified in the device regulations, for reports of adverse events that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health, or are required by FDA by written notice.
- **7-day:** As specified in 21 CFR 606.170(b), blood collection or blood transfusion fatalities should be reported within 7 days of the fatality.
- **10-day:** As specified in the device regulations, for adverse event reports of death and serious injury from user facilities.
- **15-day:** As specified in the drug and biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P) regulations, for reports of serious and unexpected adverse events.
- **30-day:** As specified in device regulations, for initial reports of a device that may have caused or contributed to a death or serious injury or for a device malfunction that would be likely to contribute to a death or serious injury if it were to recur.
- **Periodic:** As specified in the drug and biologic regulations, for reports of serious labeled and non-serious (labeled and unlabeled) adverse events.
- **Initial:** Check if the report is the first submission of a manufacturer report. For devices, this is the 30-day report.
- **Follow-up:** Check if the report is a follow-up to a previously submitted report.
  - Follow-up reports on devices should **NOT** repeat material that was submitted in the initial report, but should **ONLY** provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics, including HCT/Ps, should contain information that was submitted in the original report if the information is still correct.
  - If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report is recorded in block G9. In the blank provided in block G7 after follow-up, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2, and so on).
  - **For drug and biologic, including HCT/P manufacturers:** If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the other box in block G3 and enter the FDA-assigned report number there.

G8: Adverse Event Term(s) *[for use by drug and biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), manufacturers only]*:

Include a list of adverse event terms that most accurately characterize the adverse event described in narrative format in block B5. Terms should be listed with the most important term(s) first. The terminology may be an accepted standard (e.g., MEDDRA or WHOART), a verbatim term, or the manufacturer's own terminology.

(continued on next page)

SECTION G: ALL MANUFACTURERS *(continued)*

G9. Manufacturer Report Number

For all manufacturers:

Enter the Manufacturer report number exactly as it appears in the "Mfr Report #" field in the upper right corner of the first page. For a follow-up report, the Manufacturer report number must be identical to the number assigned to the initial report .

For drug and biologic manufacturers:

The manufacturer report number is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances. If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the **other** box in block G3 and enter the FDA-assigned report number there.

For human cell, tissue, and cellular and tissue-based product (HCT/P) manufacturers:

The report number should consist of three numbers separated by dashes. The first number will be the 10-digit FDA Establishment Identifier (FEI) number, which was assigned to you as part of the Human Cells and Tissue Establishment Registration (HCTERS). The second number should be the year that you are submitting the report. The last number should be a consecutive 5-digit number for each report filed during the year by the manufacturer. Example: 1234567890-2005-00005.

Save As... Print Previous Page Reset Form

Go Back to Form

SECTION H: DEVICE MANUFACTURERS ONLY

H1: Type of Reportable Event:

Check the appropriate box. These choices represent the categories of events that device manufacturers are required to report.

Death: Check **ONLY** if the death was an **OUTCOME** of the adverse event.

Serious injury: An adverse event that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Malfunction: See the guidelines. ("See the guidelines" refers to the applicable sections in 21 CFR Part 803 reporting guidelines associated with device malfunctions).

Other: This option is intended to capture reports that the manufacturer believes the agency should be aware of that are not covered by death, serious injury, or malfunction as these terms are defined by the statute, regulation, or guidelines. This type of event category should be rarely used

H2: If Follow-up, What Type?:

Check the box(es) that most accurately describes the nature of the follow-up report.

Correction: Changes to previously submitted information.

Additional information: Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.

Response to FDA request: Additional information requested by FDA concerning the device/event.

Device evaluation: Evaluation/analysis of device.

H3: Device Evaluated by Manufacturer?:

Check the box marked **not returned to mfr.** if an evaluation could not be made because the device was not returned to, or made available to, the manufacturer. Check the box marked yes if an evaluation was made of the suspect or related medical device. If an evaluation was conducted, attach a summary of the evaluation and check the box marked **evaluation summary attached**. If an evaluation of a returned suspect or related medical device was not conducted, check the box marked no and attach a page to explain why not or provide the appropriate code from the codes manual in the space provided.

H4: Device Manufacture Date:

Enter the month and year of manufacture of the suspect medical device using a *MM/YYYY* date format.

H5: Labeled for Single Use?:

Indicate whether the device was labeled for single use or not. If the question is not relevant to the device being reported (e.g., an X-ray machine), check no.

H6: Evaluation Codes:

Enter the applicable codes from the codes manual for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated.

If the reuse of a device may have caused or contributed to the adverse event, then the appropriate manufacturer Result codes are to be entered from the codes manual. Applicable reuse codes are 230-233 and may be used alone or with any other applicable results codes. *(see H8).*

H7: If Remedial Action Initiated, Check Type:

Indicate the applicable action(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the Act or in the FDA regulations concerning remedial action (see 21 USC 360h and 21 CFR Parts 7, 803 and 806).

H8: Usage of Device:

Indicate whether the use of the suspect medical device was the initial use, reuse, or unknown. If a manufacturer receives an adverse event report that indicates that the event was caused by or contributed to by reuse of a single use device they manufactured, this block is to be appropriately marked and the facts of the firm's investigation provided with an explanation of how the reuse of the product contributed to the outcome. The appropriate manufacturer Result codes for reuse are also to be entered into H6.

H9: If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

Enter the number that FDA assigned to the corrective action. If a number has not yet been assigned by FDA, the number assigned by the firm for the action may be used.

H10: Additional Manufacturer Narrative:

Enter any additional information, evaluation, or clarification of data presented in previous sections. Do **NOT** duplicate information that has already been provided elsewhere.

H11: Corrected Data:

Provide the following additional, corrected, or missing information, identifying each data item by the applicable section and block number:

1. Any information missing on the user facility or distributor (importer) report, including any missing or incomplete event codes required by block F10

2. Information corrected on the user facility or distributor (importer) report form after verification, including any corrected event codes required by section D (e.g., D6: model number)

3. For each event provided in block F10, an indication of whether the type of event represented by the code is addressed in the device labeling, and

4. An explanation of why any required information was not provided and the steps taken to obtain such information.