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U.S. Department of Health and Human Services

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See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

General Instructions

Page 1 of ____

FDA USE ONLY
Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION
Section A - Help

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

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Section B - Help

Check all that apply:

1. ☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*

5. **Describe Event, Problem or Product Use Error**

(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, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(Continue on page 3)

C. PRODUCT AVAILABILITY
Section C - Help

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)
Section D - Help

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

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

6. Lot #	7. Expiration Date
#1	#1
#2	#2

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

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

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE
Section E - Help

1. **Brand Name**

2. **Common Device Name**

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	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**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Section F - Help

Product names and therapy dates *(exclude treatment of event)*

(Continue on page 3)

G. REPORTER *(See confidentiality section on back)*
Section G - Help

1. **Name and Address**
Name:
Address:
City: State: ZIP:

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Combination products *(medication & medical devices)*
- Human cells, tissues, and cellular and tissue-based products
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage (devices)
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Other methods of reporting:

- 1-800-FDA-0178 - To FAX report
- 1-800-FDA-1088 - To report by phone
- www.fda.gov/medwatch/report.htm - To report online

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves a serious adverse event with a vaccine, call 1-800-822-7967 to report.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

-Fold Here-

-Fold Here-

The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

OMB statement:
"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."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (1/09) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

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

Back to Form

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

Back to Form

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

Back to Form

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

General Instructions for Completing the MedWatch Form FDA 3500

For use by health professionals and consumers for **VOLUNTARY** reporting of adverse events, product use errors and product quality problems with:

- Drugs
- Biologics (including blood components, blood derivatives, allergenics, human cells, tissues, and cellular and tissue-based products (HCT/Ps)
- Medical devices (including *in-vitro* diagnostics)
- Combination products (e.g. drug-device, biologic-device)
- Special nutritional products (dietary supplements, infant formulas, medical foods)
- Cosmetics

Adverse events involving **vaccines** should be reported to the Vaccine Adverse Event Reporting System (VAERS), http://vaers.hhs.gov/pdf/vaers_form.pdf Adverse events involving **investigational (study) drugs, such as those relating to Investigational New Drug (IND) applications**, should be reported as required in the study protocol and sent to the address and contact person listed in the study protocol. They should generally not be submitted to FDA MedWatch as voluntary reports.

Note for consumers: If possible, please take the 3500 form to your health professional (e.g., doctor or pharmacist) so that information based on your medical record that can help in the evaluation of your report will be provided. If, for whatever reason, you do not wish to have your health professional fill out the form, you are welcome to do so yourself.

GENERAL INSTRUCTIONS

- Please make sure that all entries are either typed, printed in a font no smaller than 8 point, or written using black ink.
- Please complete all sections that apply to your report.
- Dates should be entered as mm/dd/yyyy (e.g., June 3, 2005 = 06/03/2005). If exact dates are unknown, please provide the best estimate (see block **B3**).
- For narrative entries, if the fields do not provide adequate space, attach additional pages as needed.
- If attaching additional pages, please do the following:
  - Identify all attached pages as Page __ of __
  - Indicate the appropriate section and block number next to the narrative continuation.
  - Include the phrase continued at the end of each field that has additional information continued on to another page.
- **Section D,** Suspect product(s), should be used to report on special nutritional products and cosmetics as well as drugs or biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps).
- If your report involves a serious adverse event with a device and it occurred in a facility other than a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

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, please indicate the number of patients in block **B5** (Describe event or problem) and complete Section A and blocks **B2**, **B5**, **B6**, **B7**, and **F** for each patient. Enter the corresponding patient identifier in block **A1** for 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 have an adverse event that is 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, report the parent as the patient in the report.
- 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. However, the information in **Section D** would apply to the parent who was the source of exposure to the product.
- When a newborn baby is found to have a birth defect/congenital anomaly 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 have adverse events, separate reports should be submitted for each patient.

A1: Patient Identifier

Please provide the patient's initials or some other type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information. 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. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

If no patient was involved (such as may be the case with a product problem), enter none.

A2: Age at Time of Event or Date of Birth

Provide the most precise information available. Enter the patient's birth date, if known, or the patient's age at the time of event onset. For age, indicate time units used (e.g., years, months, 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 month (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/birth defect, report the sex of the child.

A4: Weight

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

SECTION B: ADVERSE EVENT, PRODUCT PROBLEM, PRODUCT USE ERROR

B1: Adverse Event, Product Problem, Product Use Error, or Problem with Different Manufacturer of Same Medicine.

Choose the appropriate box(es). If a product problem may have caused or contributed to the adverse event, check both boxes.

Adverse event: Any incident where the use of a medication (drug or biologic, including HCT/P), at any dose, a medical device (including *in-vitro* diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) is suspected to have resulted in an adverse outcome in a patient.

To report, it is not necessary to be certain of a cause/effect relationship between the adverse event and the use of the medical product(s) in question. Suspicion of an association is sufficient reason to report. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Please limit your submissions to those events that are serious. An event is classified as serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or Permanent Damage
- Congenital Anomaly/Birth Defect
- Required Medical or Surgical Intervention to Prevent Permanent Impairment or Damage (Devices)
- Other Serious (Important Medical Events)

Please see instructions for block **B2** for further information on each of these criteria.

Product problem (e.g., defects/malfunctions): Any report regarding the quality, performance, or safety of any medication, medical device or special nutritional product. In addition, please select this category when reporting device malfunctions that could lead to a death or serious injury if the malfunction were to recur. Product problems include, but are not limited to, such concerns as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Therapeutic failures (product didn't work)
- Product confusion (caused by name, labeling, design or packaging)
- Suspected superpotent or subpotent medication
- Labeling problems caused by printing errors/omissions

Product Use Error:

Medication Use Error: Any report of a medication error regardless of patient involvement or outcome. Also report circumstances or events that have the capacity to cause error (e.g., similar product appearance, similar packaging and labeling, sound-alike/look-alike names, etc.).

Medication errors can and do originate in all stages of the medication use system, which includes selecting and procuring drugs, prescribing, preparing and dispensing, administering and monitoring. A medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use."

Medical Device Use Error: Health care professionals, patients, and consumers can unintentionally cause harm to patients or to themselves when using medical devices. These problems can often arise due to problems with the design of the medical device or the manner in which the device is used. Often, use errors are caught and prevented before they can do harm (close call). Report use errors regardless of patient involvement or outcome. Also report circumstances or events that could cause use errors. Medical device use errors usually occur for one or more of the following reasons:

- Users expect devices to operate differently than they do.
- Product use is inconsistent with use's expectations or intuition.
- Product use requires physical, perceptual, or cognitive abilities that exceed those of the user.
- Devices are used in ways not anticipated by the manufacturer.
- Product labeling or packaging is confusing or inadequate.
- The environment adversely affects or influences device use.

Problem with Different Manufacturer of Same Medicine: Any incident, to include, but not be limited to, differences in noted therapeutic response, suspected to have resulted from a switch, or change, from one manufacturer to another manufacturer of the **same** medicine or drug product. This could be changes from a brand name drug product to a generic manufacturer's same product, or from a generic manufacturer's product to the same

(continued on next page)

SECTION B: ADVERSE EVENT, PRODUCT PROBLEM, PRODUCT USE ERROR *(continued)*

product as supplied by a different generic manufacturer, or from a generic manufacturer's product to a brand name manufacturer of the same product. In order to fully evaluate the incident, please include in **Section B5**, if available, specific information relative to the switch between different manufacturers of the same medicine, to include, but not be limited to, the names of the manufacturers, length of treatment on each manufacturer's product, product strength, and any relevant clinical data.

B2: Outcomes Attributed to Adverse Event: Indicate all that apply to the reported event:

Death: Check ony if you suspect that the death was an outcome of the adverse event, and include the date 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 (birth defect), 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 or other medical product 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. 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. Such would be the case if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

Congenital Anomaly/Birth Defect: Check if you suspect 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 or Damage (Devices): Check if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

Other Serious (Important Medical Events): Check when the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

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

The date the report is filled out.

B5: Describe Event, Problem or Product Use Error

For an **adverse event:**

Describe the event in detail, 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 your institution), please attach copies of these records with any confidential information deleted. **Do not identify any patient, physician, or institution by name. The reporter's identity should be provided in full in Section G.**

(continued on next page)

SECTION B: ADVERSE EVENT, PRODUCT PROBLEM, PRODUCT USE ERROR *(continued)*

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**).

If it is determined that reuse of a medical device labeled for single use may have caused or contributed to an adverse patient outcome, please report in block **B5** the facts of the incident and the perceived contribution of reuse to the occurrence.

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.
- For a medication or special nutritional product problem, please indicate if you have retained a sample that would be available to FDA.

For a product use error: Describe the sequence of events leading up to the error in sufficient detail so that the circumstances surrounding the error can be understood.

- **For Medication Use Errors:** Include a description of the error, type of staff involved, work environment in which the error occurred, indicate causes or contributing factors to the error, location of the error, names of the products involved (including the trade (proprietary) and established (proper) name), manufacturer, dosage form, strength, concentration, and type and size of container.

- **For Medical Device Use Errors:** Report circumstances or events that could cause use errors. Medical device use errors usually occur for one or more of the following reasons:

  - Users expect devices to operate differently than they do.
  - Product use is inconsistent with user's expectations or intuition.
  - Product use requires physical, perceptual, or cognitive abilities that exceed those of the user.
  - Devices are used in ways not anticipated by the manufacturer.
  - Product labeling or packaging is confusing or inadequate.
  - The environment adversely affects or influences device use.

For a problem with a different manufacturer of the same medicine:

Please include specific information relative to the switch between different manufacturers of the same medicine, to include, but not be limited to, the names of the manufacturers, length of treatment on each manufacturer's product, product strength, and any relevant clinical data.

B6: Relevant Tests/Laboratory Data, Including Dates

Please 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.

Please 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, please 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 reporter's identity should be provided in full in **Section G.**

B7: Other Relevant History, Including Preexisting Medical Conditions

Knowledge of other risk factors can help in the evaluation of a reported adverse event. If available, provide information on:

- **Other known conditions in the patient, e.g.,**
  - Hypertension (high blood pressure)
  - Diabetes mellitus
  - Liver or kidney problems

- **Significant history**
  - Race
  - Allergies
  - Pregnancy history
  - Smoking and alcohol use, drug abuse
  - Setting

SECTION C: PRODUCT AVAILABILITY

Product available for evaluation? (Do not send the product to FDA.)

To evaluate a reported problem with a medical product, it is often critical to be able to examine the product. Please indicate whether the product is available for evaluation. Also indicate if the product was returned to the manufacturer and, if so, the date of the return.

SECTION D: SUSPECT PRODUCT(S)

For adverse event reporting:

A suspect product is one that you suspect is associated with the adverse event. In **Section F** enter other concomitant medical products (drugs, biologics including human cells, tissues, and cellular and tissue-based products (HCT/Ps), medical devices, etc.) that the patient was using at the time of the event but which you do not think were 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 associated with the reported adverse event.

For product quality problem reporting:

A suspect product is the product that is the subject of the report. A separate form should be submitted for each individual product problem report.

Identification of the labeler/distributor and pharmaceutical manufacturer and labeled strength of the product is important for prescription or non-prescription products.

This section may also be used to report on special nutritional products (e.g., dietary supplements, infant formula or medical foods), cosmetics, human cells, tissues, or cellular and tissue-based products (HCT/Ps) or other products regulated by FDA.

If reporting on a special nutritional or drug product quality problem, please attach labeling/packaging if available.

If reporting on a special nutritional product only, please provide directions for use as listed on the product labeling.

D1: Name, Strength, Manufacturer

Use the trade/brand name. If the trade/brand name is not known or if there is no trade/brand name, use the generic product name and the name of the manufacturer or labeler. These names are usually found on the product packaging or labeling. Strength is the amount in each tablet or capsule, the concentration of an injectable, etc. (such as "10mg", "100 units/cc", etc.).

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 or Islet cells.

D2: Dose or Amount, Frequency, Route

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** on the next page.)

D3: Dates of Use

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, provide the date of transplant and if applicable, the date of explanation.

D4: Diagnosis or Reason for Use (Indication)

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

D5: Event Abated After Use Stopped or Dose Reduced

If available, this information is particularly useful in the evaluation of a suspected adverse event. In addition to checking the appropriate box, please provide supporting lab tests and dates, if available, in block **B6**.

D6: Lot #

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

D7: Expiration Date

Please include if available.

(continued on next page)

SECTION D: SUSPECT PRODUCT(S) *(continued)*

D8: Event Reappeared After Reintroduction

This information is particularly useful in the evaluation of a suspected adverse event. In addition to checking the appropriate box, please provide a description of what happened when the drug was stopped and then restarted in block **B5**, and any supporting lab tests and dates in block **B6**.

D9: NDC # or Unique ID

The national drug code (NDC #) is requested only when reporting a drug product problem. Zeros and dashes should be included as they appear on the label. NDC # can be found on the original product label and/or packaging, but is usually not found on dispensed pharmacy prescriptions.

If the product has a unique or distinct identification code, please provide this here. This is applicable to human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Appendix - Routes of Administration

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
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Parenteral 050
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Sublingual 059
Topical 060
Transdermal 061
Transmammary 062
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Unknown 064
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SECTION E: SUSPECT MEDICAL DEVICE

The suspect medical device is 1) the device that may have caused or contributed to the adverse event or 2) the device that malfunctioned.

In **Section F**, report other concomitant medical products (drugs, biologics including HCT/Ps, medical devices, etc.) that the patient was using at the time of the event but which you do not think were involved in the event.

If more than one suspect medical device was involved in the event, complete all of **Section E** for the first device and attach a separate completed **Section E** for each additional device.

If the suspect medical device is a single-use device that has been reprocessed, then the reprocessor is now the device manufacturer.

E1: 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. Reprocessed single-use devices may bear the Original Equipment Manufacturer (OEM) brand name. If the suspect device is a reprocessed single-use device, enter "NA".

E2: Common Device Name

The generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.). Please do not use broad generic terms such as "catheter", "valve", "screw", etc.

E3: Manufacturer Name, City and State

If available, list the full name, city and state of the manufacturer of the suspected medical device. If the answer of block **E8** is "yes", then enter the name, city and state of the reprocessor.

E4: Model #, Catalog #, Serial #, Lot #, Expiration Date, Other #

If available, provide 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 (mm/dd/yyyy):

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 bar-coded product ID, etc.)

E5: 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.

E6: If Implanted, Give Gate (mm/dd/yyyy)

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

E7: If Explanted, Give Date (mm/dd/yyyy)

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

E8: Is this a Single-use Device that was returned before Reprocessed and Reused on a Patient?

Indicate "Yes" or "No".

E9: If Yes to Item No. 8, Enter Name and Address of Reprocessor

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

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SECTION F: OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products, or provide an alternative explanation for the observed adverse event. Please list and provide product names and therapy dates for any other medical products (drugs, biologics including HCT/Ps, medical devices, etc.) that the patient was using at the time of the event. Do not include products used to treat the event.

SECTION G: REPORTER

FDA recognizes that confidentiality is an important concern in the context of adverse event reporting. The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. However, to allow for timely follow-up in serious cases, the reporter's identity may be shared with the manufacturer unless specifically requested otherwise in block G5. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

G1: Name, Address, Phone #, E-mail

Please provide the name, mailing address, phone number and E-mail address of the person who can be contacted to provide information on the event if follow-up is necessary. While optional, providing the fax number would be most helpful, if available. This person will also receive an acknowledgment letter from FDA on receipt of the report.

G2: Health Professional?

Please indicate whether you are a health professional (e.g., physician, pharmacist, nurse, etc.) or not.

G3: Occupation:

Please indicate your occupation (particularly type of health professional), and include specialty, if appropriate.

G4: Also Reported to:

Please indicate whether you have also notified or submitted a copy of this report to the manufacturer and/ or distributor of the product, or, in the case of medical device reports only, to the user facility (institution) in which the event occurred. This information helps to track duplicate reports in the FDA database.

G5: Release of reporter's Identity to the manufacturer

In the case of a serious adverse event, FDA may provide name, address and phone number of the reporter denoted in block **G1** to the manufacturer of the suspect product. If you do not want your identity released to the manufacturer, please put an X in this box.