

GENERAL INSTRUCTIONS – for Form FDA 3500A MedWatch (for Mandatory reporting)

- 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 dd-mmm-yyyy (e.g., *October 12, 2016 = 12 Oct 2016*). 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 word 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, Importer, or Manufacturer/Compounder 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, importer, or manufacturer
- If the case report involves more than two (2) suspect products attach another copy of **Form FDA 3500A**, with only section C filled in as appropriate.
- For a user facility, if more than one medical device is suspected to have caused or contributed to a patient death or serious injury, the user facility can submit one report for the event. Prepare a complete **Form FDA 3500A** for the device that is most likely to have caused or contributed to the event and a separate **Form FDA 3500A** with only section D (Suspect Medical Device) and Blocks F9, F10, F13, and F14 filled in for each additional device. Identify each report as device 1, device 2, etc.
- A user facility is required to report a device-related death or a device-related serious injury to the manufacturer and to report a device-related death to FDA.
- Manufacturers must prepare and submit a complete **Form FDA 3500A** for each suspect device. Each Form FDA 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 following table.)

Subject Device is:	Manufacturer is:
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: adverse events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS), <http://vaers.hhs.gov/index>. For additional information or assistance with filing a VAERS report, call: 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 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.

Manufacturer 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 of the form.

GENERAL INSTRUCTIONS (Continued)

- 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., 1234567-2016-00001, 1234567-2016-00002). If the manufacturing site does not have a registration number, then FDA will assign a temporary one to be used until the site is officially registered.
- For drug and biologics manufacturers: The "mfr report #" is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.
- 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: 1234567890-2016-00005
- 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/Importer report #: This is the unique identifier used by the user facility or the importer for this report. For a follow-up report, the UF/Importer report number must be identical to the number assigned to the initial report. The UF/Importer 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., 1234567890-2016-0001, 1234567890-2016-0002). 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., 0000000000-2016-0001), 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 an addendum that identifies the name, address, and CMS number for the other sites.

- The importer report number consists of three components: the FDA-assigned registration or identification number for the importer of the device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the importer (e.g., 1234567-2016-00001, 1234567-2016-00002). If an 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 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 an 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., 1234567-2016-00001, 1234567-2016-00002, and so on). For devices imported by the firm, the registration number and year would remain the same, but the 5-digit sequence number must be different (e.g., 1234567-2016-00003, 1234567-2016-00004, and so on).

SECTION A: PATIENT INFORMATION

Complete a separate form for each patient.

If you are a user facility reporting an event where multiple patients were adversely affected at the same time through the use of one device, you do not need to file a separate form FDA 3500A for each patient as long as you:

- Indicate the number of patients in block B5 (*describe event or problem*).
- Prepare a complete form FDA 3500A for one patient and attach additional 3500As with section A and blocks B2, B5, B6, B7, D11, F2 and F10 filled in for each additional patient [Be sure to identify all forms with the user facility report number].
- Enter the corresponding patient identifier in block A1 for each patient involved in the event.

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

- If the event did not affect the infant/fetus, report only on the mother
- For those cases describing fetal death, miscarriage or abortion, report the mother as the patient in the report.
- When ONLY the infant/fetus has an adverse reaction/event (other than fetal death, miscarriage or abortion), the information provided in section A applies to the infant/fetus. However, the information in section C or D would apply to the mother who was the source of exposure to the product or device.
- 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 or device used on the mother during pregnancy, the patient is the newborn baby.
- If both the mother and the infant/fetus sustain adverse events, two reports should be provided and linked using the narrative field in block B5

A1: Patient identifier

Provide the patient's initials or some other identification code number 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, medical record number or social security number.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The 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, enter 'none'.

A2: Age 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, 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.

A5a: Ethnicity

Indicate the ethnicity of the patient. Choose only one response. Please do NOT make a best guess.

A5b: Race

Indicate the race of the patient as reported by the patient. You may choose multiple answers for race. Please do NOT make a best guess.

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 product (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* diagnostic products) 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 must be reported to FDA if it involves a communicable disease and according to 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.

Medical Devices: An adverse event which must be reported to FDA is a device-related death or a device-related serious injury as defined in 21 CFR 803.3:

A serious injury means an injury or illness that:

- (1) Is life-threatening,
- (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
- (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

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 judgment, the event may jeopardize the patient and may require medical or surgical intervention

SECTION B: ADVERSE EVENT, PRODUCT PROBLEM (Continued)

to prevent one of the other outcomes. Examples include allergic bronchospasm 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.

- **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

For all mandatory reports filed for Drugs and Biologics, including Human Cells, Tissues, and Cellular and Tissue-Based Products, enter the date the report is filled out. For all mandatory Medical Device reports, enter the date the initial reporter provided the information about the event (i.e. the first person or entity who initially provided information to the user facility, manufacturer or 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.

For HCT/Ps, provide information on the type of surgical procedure and anatomical site of implantation, and the date of onset of symptoms.

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.

SECTION B: ADVERSE EVENT, PRODUCT PROBLEM (Continued)

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.
 - Recent infection
- Significant history
 - 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. Use section C to report events that involve one of the following products:

- Prescription or over-the-counter medication
- Biologic products, such as blood and blood products, human cells and tissues used for transplantation (e.g. tendons, ligaments and bone) and gene therapy
- Nutrition product, such as a vitamin or mineral, herbal remedy, infant formula, or medical food or beverage
- Cosmetic product

In block C2 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, Manufacturer/Compounder, Strength

Space provided to identify two products. Use the trade name as marketed (e.g., if there is a Structured Product Labeling (SPL) for the product, then use the Product name and/or Active ingredient as it appears in SPL; If there is no SPL and a label is attached to the report, then use the same naming convention as in the attached label). If unknown or if no trade name, use the generic name (with the manufacturer 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 and the name of the manufacturer. You can also indicate if the HCT/P has a proprietary or trade name, in addition to the common name of the HCT/P (e.g., Brand A bone chips, or Brand B skin tissue). Examples: Achilles tendon, Iliac crest bone, Islet Cells, or human skin.

Lot

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

NDC # or Unique ID

The National Drug Code (NDC #) is a universal product identifier for human drugs. NDC is a three-segment number; zeros and dashes should be included as they appear on the original manufacturer's product label and/or packaging. NDC numbers are particularly useful to the FDA in investigating drug product quality problems.

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) must have a Unique ID number to track the product. For reports involving HCT/Ps, this unique ID should be provided in this box.

C2: Concomitant Medical Products and Therapy Dates

List and provide therapy dates for any other medical products (drugs, biologics, including HCT/Ps, or medical

SECTION C: SUSPECT PRODUCT(S) (Continued)

devices, etc.) that a patient was using at the time of the event. Do not include products used to treat the event.

C3: 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

C4: 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.

NOTE: Use block C4 to record the date that a diagnostic test was performed for reports that involve an *in vitro* diagnostic product or radiation therapy.

C5: Diagnosis for Use

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

C6: Is the Product Compounded?

If the product was compounded, please check “yes.”

C7: Is the Product Over-the-Counter?

If the product is sold over the counter, please check “yes.”

C8: Expiration date

Include ONLY with all product problem reports and events involving human cells, tissues, and tissue and cellular-based products (HCT/Ps).

C9: 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.

C10: Event Reappeared After Reintroduction

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

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 that are not thought to be involved in the event.

For *in vitro* diagnostic products and radiation therapy products that are reported in section D, use block C3: Therapy Dates to record the date that diagnostic tests are performed.

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”.

D2a: 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.). Do not use broad generic terms such as “catheter”, “valve”, “screw”, etc.

D2b: Procode

Medical devices are classified under 21 CFR Parts 862-892. The assigned FDA Product Classification Code (procode) can be identified using the Product Classification Database search page at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>

Manufacturers and importers should include the procode for their devices. User facilities are encouraged to try to identify the procode for the devices reported on the form FDA 3500A. If you are unable to determine the product code, for a device, contact FDA at (800) 638-2041 for assistance.

SECTION D: SUSPECT MEDICAL DEVICE (Continued)

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, Unique Identifier (UDI)

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.
- **Unique Identifier (UDI) #:** This number can be found on the device, its label, or accompanying packaging. The number is located below the barcode and begins with one of the following three elements:
 - (01)
 - +
 - =

Record all numbers, letters, parentheses, and symbols included in the UDI #.

For more information regarding the UDI #, refer to the UDI webpage <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm> or contact the UDID Helpdesk at UDIDSupport@fda.hhs.gov.

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, importer, or manufacturer.

E1: Name and Address

Please provide the name, mailing address, phone number, and email address of the person who initially reported the adverse event to the user facility, manufacturer, or importer, and who can be contacted to provide information on the event if follow-up is necessary.

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.

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 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 Importer 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

SECTION F: FOR USE BY USER FACILITY/IMPORTER – DEVICES ONLY (Continued)

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 describes the event. Patient codes indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnosis and device codes describe device failures or issues related to the device that are encountered during the event. If more than 3 “patient” codes or more than 3 “device” codes are needed, you can enter them in block H10 and identify as additional codes for “F10”.

The CDRH Event Problem Codes have been enhanced and a link to the new [CDRH Event Problem Code](#) web

site is online. The updated codes were introduced on July 1, 2009. All inactivated and retired codes were discontinued as valid Event Problem Codes on April 2, 2010.

F11: Report Sent to FDA?

Check yes or no and indicate the date sent, if applicable. User facilities are required to send reports of device-related deaths to FDA (21 CFR 803.30). Importers are required to send reports of device-related deaths and serious injuries to FDA (21 CFR 803.40).

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. User facilities are required to send reports of device-related deaths and device-related serious injuries to manufacturers (21 CFR 803.30). Importers are required to send reports of device-related deaths and device-related serious injuries and reports of malfunctions that could cause or contribute to a death or serious injury to manufacturers (21 CFR 803.40).

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 (and manufacturing site for devices)

Enter the full name, address, and email 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.

Compounding Outsourcing Facility (503B)

Indicate if the manufacturer is registered as 503B facility

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 the source from which the information about the adverse event originated.

- **Foreign:** Foreign sources include foreign governments, foreign affiliates of the application/

SECTION G: ALL MANUFACTURERS (Continued)

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. For 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).
- **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. (dd-mmm-yyyy format)

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

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.

- **NDA #:** The new drug application (NDA) number
- **ANDA #:** 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
- **BLA:** The 6 digit Biologics Application Number (BLA). If no BLA exists, use the 4 digit U.S. License Number.
- **PMA/510(k) #:** Manufacturers should identify the pre-market application (PMA) or pre-market notification [510(k)] submission number for their approved / cleared medical device or combination product. If a product has several applicable PMAs/510(k)s and the specific one cannot be determined, then the most recently approved PMA or cleared 510(k) number for that intended use should be reported. [or most relevant to the device problem].

SECTION G: ALL MANUFACTURERS (Continued)

- **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 product or medical device was marketed prior to 1938 and does not have an application #.
- **OTC Product:** Check the box if the suspect Monograph product or medical device 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.

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

SECTION G: ALL MANUFACTURERS (Continued)

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: 1234567890-2016-00005.

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 has been removed from the form since it is not a type of report that is required by mandatory reporting regulations. 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 can still be reported to FDA using the voluntary form FDA 3500.

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 Manufacturer*, 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 dd-mmm-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: Event Problem and Evaluation Codes

Space has been provided for a manufacturer to enter patient codes and device codes (the codes that a user facility or importer enters in F10). A manufacturer also enters codes for the categories of method, results, and conclusion. Enter the applicable codes from the *codes manual* using at least one code in each 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.

SECTION H: DEVICE MANUFACTURERS ONLY (Continued)

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 correction/removal number following the format directed by 21 CFR 807. If a firm has not submitted a correction/removal report to FDA, but FDA has assigned a recall number to the corrective action, the recall number 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:

- Any information missing on the user facility or importer report. Note that a manufacturer should enter in H6 any missing or incomplete patient or device codes required by block F10
- Information corrected on the user facility or importer report form after verification, including any corrected event codes required by section D (e.g., D6: model number)
- For each event code provided in block F10, an indication of whether the type of event represented by the code is addressed in the device labeling, and
- An explanation of why any required information was not provided and the steps taken to obtain such information.

APPENDIX 1**ROUTES OF ADMINISTRATION: ICH LIST AND CODES**

For each term, read as Description – ICH-M2 Numeric Code

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

APPENDIX 2

EXAMPLES FOR POPULATING SECTION C1 SUSPECT PRODUCT(S) NAME

Examples of C1 Suspect Product Name

Correct: Miracle Wonder Drug – *The stated Trade name is the same as in the product label.*

Incorrect: Amazing Drug (paracetamol) – *If providing a foreign product name and its generic name, use the U.S. generic name (in this case, acetaminophen).*

Incorrect: MWD (APAP) – *Do not use abbreviations.*

Incorrect: Miracle Wonder DrugOTC® – *Any additional information that should be captured in other sections of the form, for example in G5, should not be added to the Suspect Product name in C1.*