U.S. FOOD & DRUG ADMINISTRATION

GENERAL INSTRUCTIONS - FOR FORM FDA 3500A MEDWATCH (FOR MANDATORY REPORTING)

Contents

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

GENERAL INSTRUCTIONS

- All entries should be typed or printed in a font no smaller than 8 point.
- Complete all sections that apply. If information is unknown, not available or does not apply, the section should be left blank.
- Dates should be entered as dd-mmm-yyyy *(e.g.,12 Oct 2019)*. 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
- 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 medical device reporting, manufacturers, importers, and user facilities must prepare and submit a complete **Form FDA 3500A** for each suspect device. Each Form FDA 3500A will be given a separate 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	OEM
Device designed to be reused	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, biologic, or cosmetic product), 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 shorter form.
    - If section G is reproduced on the front of the form, it must be an identical reproduction of the original section G.
    - When reporting ONLY a cosmetic product, the sections and/or subsections/blocks that are not relevant to cosmetics should be left blank.
- All submissions must be made in English, including foreign literature reports.

- Form 3500A should not be used for the below products
    - 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.
    - Animal Drug: Persons responsible for submitting mandatory adverse event reports for animal drugs must submit them to FDA's Center for Veterinary Medicine (see CVM Veterinary Adverse Event Reporting for Manufacturers | FDA). For Device, Pet Food and Livestock Feed Problems – report problems to FDA's Center for Veterinary Medicine
    - Tobacco products: Report health or product problems to the Safety Reporting Portal (SRP) www.safetyreporting.hhs.gov or call 1-877-287-1363.
    - Food or dietary supplement products: Report to the SRP should follow the instructions at: www.safetyreporting.hhs.gov
- 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)
- Cosmetic Products: Responsible persons submitting serious adverse event reports for cosmetic products using Form FDA 3500A [Electronic submissions (Database to Database transmission and Safety Reporting Portal) are encouraged.] should include a copy of the label on or within the retail packaging of the cosmetic product, along with any information that can be provided to support the report, such as scans of labels and images of the serious adverse event. The Form 3500A along with all the supporting materials may either be sent to the email address or to the mailing address.

  Via email at: CosmeticAERS@fda.hhs.gov

  Or by mail to:

  FDA CDER Mail Center
  Attn: Cosmetics MedWatch reports
  White Oak Campus, Building 22, G0207
  10903 New Hampshire Ave.
  Silver Spring, MD 20993

FRONT PAGE

- On the top-right corner of the front page, enter the Manufacturer report number, User Facility report number, or Importer report number, as appropriate, in the corresponding labeled box. Enter all numbers, if applicable, to cross-reference this report with a report from another source on the same event. For medical devices, the cross-reference report number should be left blank in the section and instead entered in H11: Additional Manufacturer Narrative.
- **Manufacturer report # (Mfr report #):** This is the unique identifier used by the manufacturer for this report. For a follow-up report, the manufacturer report number must be identical to the number assigned to the initial report. The manufacturer report number is also entered in block G8.
    - 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, please contact reglist@cdrh.fda.gov for assistance.
    - For drug and biologics manufacturers and for responsible persons for cosmetic products: The "Mfr report #" is the number that the manufacturer or the responsible person chooses to uniquely identify the report and should conform to applicable regulations or guidance.
    - For human cell, tissue, and cellular and tissue- based product (HCT/P) manufacturers: The report number consists of three numbers separated by dashes: the 10-digit FDA Establishment Identifier (FEI) number, which was assigned to you as part of Human Cells and Tissue Establishment Registration (HCTERS), the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer. Example: 1234567890-2016-00005.
    - For cosmetic products, the User Facility/Importer Report # and Exemption/Variance # should be left blank in this section.
- **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 for devices is also entered in block F2: User Facility/Importer Report Number on the back of the form.
    - The user facility report number consists of three components: the facility's 10-digit Health Care Financing Administration (HCFA) 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 HCFA 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 HCFA number, the first report and any subsequent reports should be submitted with all zeros in the HCFA 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 HCFA 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 HCFA 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.
    - For cosmetic products, the User Facility/Importer Report # and Exemption/Variance # should be left blank in this section.
- The **Exemption/Variance/Alternative Number** identifies reports being submitted under the conditions of an FDA approved exemption or variance or alternative reporting per 21 CFR Part 803.19. If the report being submitted is not the subject of an approved exemption or variance, the field should not be completed unless instructed by the FDA to use this field for a specific purpose. For cosmetic products, the User Facility/Importer Report # and

Exemption/Variance # should be left blank in this section.

- **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. For medical device-related reporting, patients include consumers, study subjects/participants, as well as individuals who seek care, whether or not they are ill at a given time. 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, D10, 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

Enter the patient's birth date, if known, or the patient's age at the time of event onset. Provide the most precise information available if the exact age is unknown.

For age, indicate years, months, and/or 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., 34 months).
- If the patient is less than 1 month old, use day(s) (e.g., 15 day(s)).

A3: Sex

- **Sex**: Enter the patient's sex.

Choose only one response. 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.A5: Race and/or Ethnicity

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

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: Type of Report

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

Product problem (e.g., defects/malfunctions): Any report regarding the quality, performance, or safety of any regulated product.

B2: Outcomes attributed to adverse event

Indicate ALL that apply to the reported event:

Drugs, Biologics and Cosmetic Products: Only mark a box in this section if the adverse event meets the regulatory definition of serious in 21 CFR 314.80(a), 21 CFR 600.80(a) and Section 605 of the FD&C Act, respectively.

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:

- Resulted in death,
- Is life-threatening,
- Results in permanent impairment of a body function or permanent damage to body structure, or
- 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:

- 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. Permanent means irreversible impairment or damage to body structure or function, excluding trivial impairment or damage." https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803/subpart-A/section-803.3

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 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.
- 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. For cosmetic products, check if the adverse event resulted in a persistent or significant disability or incapacity.

Congenital Anomaly/Birth Defect: Check if suspected that exposure to a product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required Intervention to Prevent Permanent Impairment/ Damage: 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.
- Prevent permanent damage to a body structure.

Other Serious or Important Medical Events:

- Check when, based on appropriate medical judgment, the event may jeopardize the patient and may require medical or surgical intervention 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.
- **Cosmetic Products:** Check if the other categories are not applicable, such as when the adverse event results in an infection or significant disfigurement (including serious and persistent rashes, second- or third-degree burns, signification hair loss, or persistent or significant alteration of appearance) other than as intended, under conditions of use that are customary or usual. Describe the outcomes in the actual narrative of the event in block B5 ("Describe event or problem").
- **Devices**: Check ONLY if the other categories are not applicable to the event. Describe the outcome outcomes in the actual narrative of the event in block B5 ("Describe event or problem").

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. For device manufacturers reporting events based on literature, the date of event should be

reported as the publication date of the literature source.

B4: Date of this Report

For all mandatory reports filed for Medical Devices, Drugs, Biologics, including Human Cells, Tissues, and Cellular and Tissue- Based Products, and Cosmetic Products enter the date the report is submitted to the FDA. For device manufacturers reporting events based on literature, the date of the report should be reported as the date that the literature first came to the attention of either you or one of your employees. Dates should be entered as dd-mmm-yyyy *(e.g.,12-Oct-2020)*.

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 include any personal identifiable information (PII) or proprietary information in B5. 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 cosmetics, please describe the amount and frequency used; for which body parts the cosmetic product was used; and outcomes.

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 Test/Laboratory Data, Including Dates

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

Include:

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

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

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted.

DO NOT identify any patient, physician or institution by name. The initial's reporter's identity should be provided in full in section E.

B7: Other Relevant History, Including Preexisting Medical Conditions:

If available, provide information on:

- Other known conditions in the patient, e.g.,
    - Hypertension
    - Diabetes mellitus
    - Renal/hepatic dysfunction
    - 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 (OTC) 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
- Dietary supplements
- Cosmetic product

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.

For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.

C1: Name, Strength, Manufacturer/Compounder

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. See Appendix 1 for examples.

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.

For cosmetics: In the product name field, enter the statement of identity, as such name appears on the label. If the product names in the listing are not unique, then also include distinguishing information for identification purposes, for example brand name or a code that the responsible person uses to distinguish the product. Such information may also be included in addition to the product name even when product names in the listing are unique. If you believe certain distinguishing information is confidential, include that distinguishing information in parenthesis.

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.

For cosmetic product(s), if available, the FDA Establishment Identifier (FEI) number obtained by the owner or operator of a facility(ies), of the facility that manufactured or processed the affected cosmetic product(s). FEI is also known as the Firm or Facility Establishment Identifier.

C2: Dose, Frequency & Route Used

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

- If you select the value "Other" from the Route dropdown please use an **Structured Product Label (SPL) Acceptable Term** from the table: See Web page list of Routes of Administration.

C3: Treatment/Therapy/Usage Start and Stop Dates

Provide the date treatment/therapy administration or usage 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 treatment/therapy/usage 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.

C4: Diagnosis for Use

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

C5: Product Type

Check all boxes that best fit this suspect medical product. For cosmetic products, please check the appropriate box if the product is marked for professional use only or sold on a retail basis. If a cosmetic product belongs to other product types, multiple selections can be made.

C6: Expiration date

Include ONLY with all product problem reports and events involving human cells, tissues, and tissue and cellular-based products (HCT/Ps). For cosmetic products, if available, include best by/use by date.

C7: 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.

C8: Event Reappeared After Reintroduction

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

C9: List Medical Products and Treatment Given at the Same time of the Event and Date

In block C9 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.

List and provide therapy dates for any other products (drugs, biologics, including HCT/Ps, medical devices, etc.) that a patient was using at the time of the event. For cosmetic reports include all related cosmetic products used at the same time. Do not include products used to treat the event.

SECTION D: SUSPECT MEDICAL DEVICE

In block D10, 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. If device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, then data in GUDID must match the data submitted in this section.

For *in vitro* diagnostic products and radiation therapy products that are reported in section D, use block C4: 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. If device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, then 'Brand Name' in GUDID must match 'Brand Name' submitted here.

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

D2a: 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.

D2b: 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. For device manufacturers and importers, leave block D2b blank, and D2b will be auto-filled by eMDR based on the procode provided in block D2a.

D3: Manufacturer Name, City, State and Country

Submit the full name, city, state and country of the manufacturer of the suspected device involved in the adverse event. For user facilities and importers, enter the manufacturer name of the suspected device involved in the event and if available enter the city, state and country. If block D8 below is 'Yes', then use this field to enter the name, city, state and country of the reprocessor.

D4: Model #, Lot #, Catalog #, Expiration date, Serial #, Unique Device 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. If device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, then 'Model #' and 'Catalog #' in GUDID must match data submitted here.

- **Model #**: The exact model number found on the device label or accompanying packaging.
- **Lot #**: This number can be found on the label or packaging material.
- **Catalog #**: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging.

- **Expiration date**: If available; this date can often be found on the device itself or printed on the 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.
- **Unique Device Identifier (UDI) #**: This number can be found on the device, its label, or accompanying packaging. The number is located below the barcode and may contain numbers, letters and special characters such as (), /, $, +, = } etc. The UDI begins with one of the following three elements:

    - (01)
    - +
    - =

  Please record all numbers, letters, parentheses, and symbols included in the UDI #. Complete information will enable effective parsing of the UDI into its components for use with important public health needs.

  Please submit all applicable UDIs for a given adverse event submission. If device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, please review GUDID data for accuracy and make any corrections as necessary. For more information regarding the UDI #, refer to the UDI webpage, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system or contact the FDA UDI Helpdesk at https://www.fda.gov/medical-devices/unique-device-identification- system-udi-system/fda-udi-help-desk or by emailing GUDIDSupport@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.
- **Patient/Consumer** = person being treated, parent/ spouse/friend of the patient
- **Other** = nurses' aide, orderly, etc.

D6a: 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.

D6b: 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.

D7a: 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 H11 (Additional Manufacturer Narrative) describe the efforts made to obtain the information and any responses.

D7b: If yes, Enter Name and Address of Reprocessor

Enter the name and address of the reprocessor of the single-use device.

Please note: Any entity that reprocesses single-use devices for reuse in humans is considered the

manufacturer of the reprocessed single-use device.

D8: Is this device ever serviced by a Third Party?

Indicate “Yes”, “No” or “Unknown.”

D9: Is this 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.

D10: 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 devices, this field may also represent the location where the event occurred.

E2: Health Professional

Indicate whether the initial reporter is a health professional (e.g., physician, pharmacist, nurse, etc.) or not.

E3: Occupation

Select from the list that best indicates the initial reporter's occupation.

E4: Initial Reporter Also Sent Report to FDA

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

For Device: if report number is available, enter the report number in Block H10.

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

F1: Check one

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

F2: User Facility/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/Email

Enter the full name, address and email 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. Dates should be entered as dd-mmm-yyyy *(e.g., 12 Oct 2020)*.

F7: Type of Report

Check the appropriate box to identify the type of report being filed, i.e., an initial report of an event or a follow-up to a previously submitted report.

If a follow-up report, make sure that the UF/ Importer report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report = follow- up #1, second follow-up report = follow-up #2, and so on).

Follow-up reports should not repeat material that was submitted in the initial report but should ONLY provide additional or corrected information on the previously reported event.

F8: Approximate Age of Device

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

F9: Adverse Event Problem
(refer to the MDR Adverse Event Coding webpages)

Enter up to 3 Health Effect – Clinical Codes and 3 Medical Device Problem Codes from the Codes Manual that most accurately describes the event. Health Effect – Clinical codes indicate the effects that an event may have had on the patient, including signs, symptoms, syndromes, or diagnosis and medical device problem codes describe device failures or issues related to the device that are encountered during the event. If more than 3

Health Effect – Clinical Codes or more than 3 Medical Device Problem Codes are needed, you can enter them in block H11 and identify as additional codes for “F9”.

The CDRH Event Problem Codes can be found on the Coding Resources web page online. The codes are periodically updated, and the updated files will be found on this page.

F10: Report Sent to FDA?

In scenarios where user facilities are required to send reports of device-related deaths and serious injuries to manufacturers (21 CFR 803.30), or importers are required to send reports of device-related malfunctions or a copy of device-related deaths or serious injuries to the manufacturer (21 CFR 803.40), the user facilities or importers are required to utilize the FDA Form 3500A for these purposes. Therefore, this field is intended to alert the manufacturer that the report was also sent to FDA. In such cases, check "yes" and indicate the date sent to FDA.

F11: 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

F12: Report Sent to Manufacturer?

In scenarios where user facilities are required to send reports of device-related deaths to FDA (21 CFR 803.30), or importers are required to send reports of device-related deaths or serious injuries to FDA (21 CFR 803.40), use this field to alert FDA that the report was also sent to the manufacturer. In such cases, check "yes" and indicate the date sent to the manufacturer.

F13: 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 D7b.

SECTION G: ALL MANUFACTURERS AND RESPONSIBLE PERSONS

This section is to be filled out by all manufacturers or responsible persons (in case of cosmetic products). NOTE: If a drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P) manufacturer or responsible person (in case of cosmetic product) is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of Section D

For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.

G1: Contact Office *(and Manufacturing Site for Devices)* or Compounding Outsourcing Facility or Responsible Person (in case of cosmetic products)

Enter the full name, address, and email address of the manufacturer reporting site [contact office], including contact name. If the contact for the manufacturing site is different from the contact for the reporting site, enter the full name, address, and email of the contact for the manufacturing site after the corresponding contact information for the reporting site.

For Medical Device reports, if the contact for the manufacturing site is different from the contact for the reporting site, enter the name, address and email of the manufacturing site contact after the corresponding information for the reporting site contact.

For Cosmetic products, enter the information of the responsible person, which means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product.

Compounding Outsourcing Facility (503B)

Indicate if the manufacturer is registered as 503B facility.

G2: 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/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. For Drugs, Biologics, including HCT/ Ps and Cosmetic Products this also includes information derived from planned contacts and active solicitation of information from patients or consumers (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.

  Drugs, biologics, including HCT/ Ps and cosmetic products: A separate 3500A form must be completed for each identifiable patient described in the article or manuscript.

  Medical devices: Acceptable literature sources include published or unpublished scientific literature, clinical articles or manuscripts. Record the date of the Article as the date of the event (block B3), and provide a full literature citation in block H11. Reports from Real-World Data (RWD) sources, e.g., annual reports from registries, do not fall under this category, unless they are publicly available. Refer to https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/exemptions-variances-and-alternative-forms-adverse-event-reporting-medical-devices for additional information related to RWD sources. Please note that the attachment of literature for medical device-related events is not needed. Instead, provide a full literature citation in block H11 in lieu of the scientific literature, clinical article, or manuscript. Additionally, when submitting summary MDRs from literature sources where sufficient information about each identified patient and/or device cannot be obtained through investigation, include a .csv spreadsheet and submit it as an attachment to your summary MDR.
- Consumer (including attorneys): When this additional information is obtained, the follow- up report should check

health professional rather than consumer in block G2.

- 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/Importer**: 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. Other may also be used to identify when the source is another manufacturer— include the Manufacturer Report Number of the other manufacturer. For medical devices, this check box would be selected when submitting reports from Real Word Data (RWD) sources, such as registries, electronic health records, and medical claims, and indicate the RWD source name on the field next to Other category.

G3: Date received by manufacturer or responsible person
(in case of cosmetic product)

This means the date when the applicant, manufacturer, responsible person, corporate affiliate, etc. receives information of an adverse event that has occurred. For medical device-related adverse event reporting including events identified from literature, the date is when any employee of the device manufacturer has acquired information that reasonably suggests a reportable adverse event has occurred. This would apply to a report received anywhere in the world. Dates should be entered as dd-mmm-yyyy *(e.g., 12 Oct 2020)*.

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

G4: 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 information that 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. Additionally, for medical devices, if device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, then 'PMA/510(k)#' and "Combination Product" fields in GUDID must match data submitted here.

- **NDA #:** 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.
- **ANDA/Pre-ANDA #:** The Abbreviated New Drug Application (ANDA) number or the Pre-Abbreviated New Drug Application (Pre-ANDA) number.
- **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 appropriate regulatory approval such as 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].
    - **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-ANDA:** Check the box if the suspect product is an investigational new drug exempt BA/BE Premarket serious adverse events.
- **Pre-1938:** Check the box if the suspected product 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).
- **Compounded Product:** Check the box if the suspect medical product is compounded from one or more marketed ingredients.

G5: Give IND/Pre ANDA 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.

G6: Type of Report

Check all 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. As specified in CFR 312.32 unexpected fatal or life-threatening suspected IND suspected adverse reaction report should be reported within 7 days of the after the sponsor's initial receipt of the information.
- **15-day:** As specified in the drug, biologic, including human cell, tissue, and cellular and tissue- based product (HCT/P), and cosmetic products regulations or requirements, for reports of serious and unexpected adverse events.
- **30-day:** As specified in device regulations, for initial reports of a device that has or 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.
- **Non-expedited (Periodic):** As specified in the drug and biologic regulations, for reports of serious labeled and non-serious (labeled and unlabeled) adverse events. For cosmetic products, use this option for non-serious adverse event.
- **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, biologics, including HCT/Ps, and cosmetic products 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 G8. In the blank provided in block G6 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 G2 and enter the FDA-assigned report number there.

G7: Adverse Event Term(s)

[for use by drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P) manufacturers, and responsible persons (in case of cosmetic products)

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), a verbatim term, or the manufacturer's own terminology.

G8: 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 guidance.

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.

For cosmetics:

The manufacturer report number is the number the responsible person chooses to uniquely identify the report and should conform to any applicable regulations or guidance. The submission will not be considered complete without this information. While FDA currently does not have a mandatory format for the Manufacturer Report Number for reporting cosmetic adverse events, we strongly encourage you to use a numbering system that provides unique information of the adverse event reported, such as the year, company name, and the case report number.

SECTION H: DEVICE MANUFACTURERS ONLY

H1: Type of Reportable Event

Check all the appropriate boxes that apply to this report. These choices represent the categories of events that device manufacturers are required to report.

- **Death:** Check only if the MDR reportable event represents a device-related death.
- **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).
- **Summary Report:** Only check this box if the report is submitted as part of the Voluntary Malfunction Summary Reporting Program (see eligibility criteria here: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems#malfunction), or if you have an FDA-approved exemption/variance/alternative reporting for submitting MDRs in summary format under 21 CFR Part 803.19 (you must have a letter from FDA indicating approval of such an exemption/variance/alternative reporting), or if you summarize the MDR reportable events based on literature. Make sure you indicate the number of events being summarized as part of the Summary Report and only use the designated H.1 Summary Report Box and NOE field if the above criteria are met.

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, the event, or the circumstances surrounding the report, as it relates to compliance with MDR reporting regulations and policies, e.g., FDA requests additional information when the report is submitted late (retrospective reporting), the report is a result of an internal audit or FDA inspection, etc.
- **Device evaluation**: Evaluation/analysis of device.

H3: Device Evaluated by Manufacturer?

Check the box marked Yes if an evaluation was made of the suspect or related medical device and provide a summary of evaluation in H11: Additional Manufacturer Narrative.
If an evaluation of a returned suspect or related medical device was not conducted, check the box marked No and provide a justification to explain why not in H11: Additional Manufacturer narrative or enter the appropriate code from the codes manual in H6: Adverse Event Problem.

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. Please note that if device identification data exists in the Global Unique Device Identification Database (GUDID) for the suspect medical device, then data submitted in "For

Single Use" field in GUDID must match data submitted here.

H6: Adverse Event Problem

Space has been provided for a manufacturer to enter Health Effect – Clinical Code, Health Effect – Impact Code, and Medical Device Problem code. A manufacturer also enters codes for the categories of type of investigation, investigation findings, and investigation conclusion. Enter all applicable codes from the codes manual to depict the full event data consistent with the narrative. Reporters should code to the lowest level possible on the coding hierarchy; in other words, they should choose the most specific term(s) available in each category to describe the event or investigation. Conclusion codes must be entered even if the device was not evaluated.

H7: If Remedial Action Initiated, Check Type

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

H8: Usage of Device

Indicate whether the use of the suspect medical device was the initial use, reuse, or unknown.

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

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

Enter the correction/removal number following the format directed by 21 CFR 80 806. If a firm has submitted a correction/removal report to FDA and the corrective action has been assigned a recall number, the recall number may be used. If a firm has initiated a correction or removal, then the firm shall submit a Correction or Removal written report to FDA per 21 CFR 806.10 requirements. Instances where a firm has initiated a correction/removal, but the FDA has not assigned a recall number, include one of the following statements: 1) FDA has not acknowledged the Correction/removal. 2) Market withdrawal or Safety Alert, or device enhancement. 3) The action is still under review for recall classification and FDA has not completed classification. Please note that MDRs As Reported Do Not Satisfy All of the information required by 21 CFR 806.10 and ultimately should be worded to include the requirements of 21 CFR 806.10(c)(1-13).

H10: Related Report Number

If the same event(s) have been previously reported to the FDA from any other sources, enter the FDA's MDR report number(s) for such report(s).

H11: 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. If PII or proprietary information is critical to understand the event, that information should be included in B6 Relevant Test/Laboratory Data or B7 Other Relevant History, including Preexisting Medical Conditions. All corrections should only be reported in the specific sections of the form at the time the follow-up report is being submitted.

APPENDIX 1 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