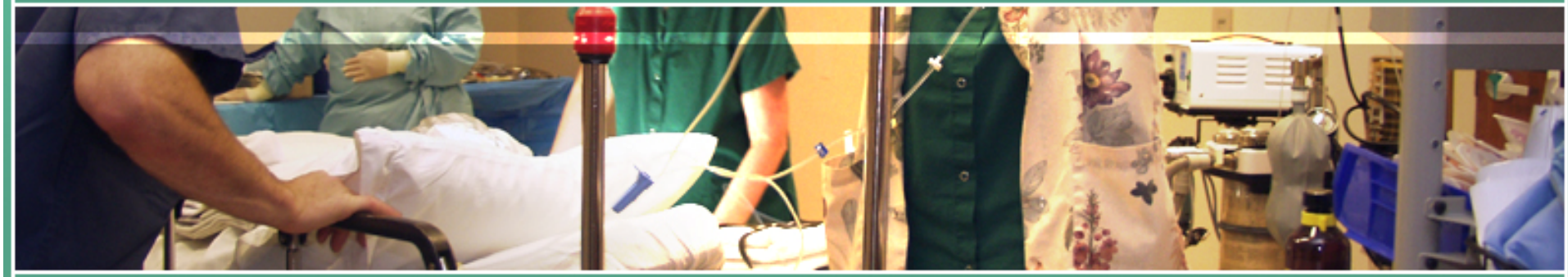
Medical Device Reporting (MDR) 21 CFR Part 803



Objectives

- Review applicable sections of 21 CFR 803 and 21 CFR 820
- Review and explain MDR reporting requirements
- Review FDA-483 observation examples

Medical Device Reporting 21 CFR 803

- §803.3 MDR Reportable Event means

- An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

Medical Device Reporting 21 CFR 803

- §803.3 MDR Reportable Event means

2. An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices;

   (i) May have caused or contributed to a death or serious injury

   (ii) Has malfunctioned and that the device or **a similar device** marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur

Medical Device Reporting 21 CFR 803

- §803.3 Becomes Aware

  An employee of the entity required to report has acquired information that reasonably suggests a reportable event has occurred

Medical Device Reporting 21 CFR 803

- §803.3 Caused or Contributed

  A death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error

Medical Device Reporting 21 CFR 803

- §803.3 Serious Injury

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
3. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure

Medical Device Reporting 21 CFR 803

- §803.3 Malfunction

  The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed…

More on Malfunctions

Guidance

- Reporters do not need to assess the likelihood that a malfunction will recur. The regulation presumes that the malfunction will recur. Furthermore, FDA believes that **once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established**. This presumption will continue until the malfunction has caused or contributed to no further deaths or serious injuries for two years, or the manufacturer can show, through valid data, that the likelihood of another death or serious injury as a result of the malfunction is remote.

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm

Who Has to Report an Event?

- User facilities
- Importers
- Manufacturers

- Distributors (maintain records only)

Manufacturer Reporting Requirements

- Individual adverse event reports no later than 30 **calendar days** after the day you become aware of a reportable death, serious injury, or malfunction
- Individual adverse event reports no later than 5 **work days** after the day that you become aware of

  (i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or

  (ii) A reportable event for which we made a written request

Manufacturer Reporting Requirements

- Supplemental reports are required if the manufacturer obtains information that was not submitted in the initial report. Must be submitted within 1 month of the day that the information was received

- Generally submitted because the information was unknown at the time of the initial report or to correct information previously submitted

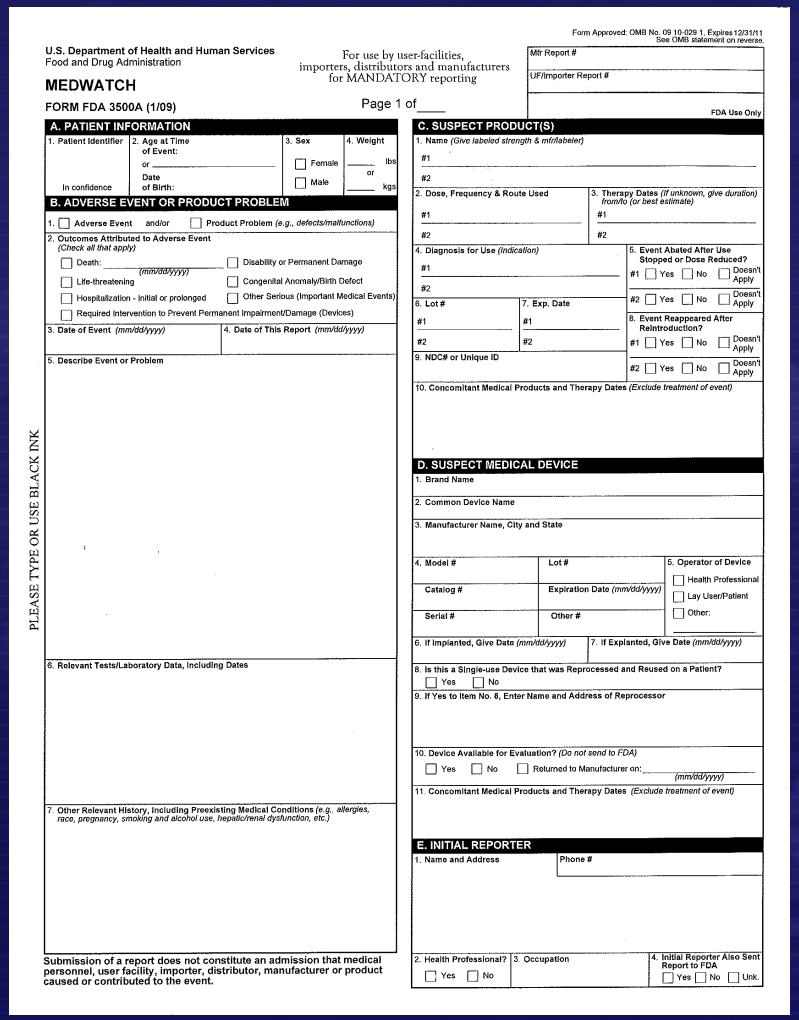
Manufacturer Reporting Requirements

- Submit required information on FDA Medwatch Form 3500A or in an electronic equivalent as approved

- Medwatch Form 3500A and instructions can be found on the internet at

  http://www.fda.gov/medwatch/getforms.htm

Medwatch Form 3500A



U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

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

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Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex — Female / Male
4. Weight — lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem *(e.g., defects/malfunctions)*
2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - Death: *(mm/dd/yyyy)*
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Required intervention to Prevent Permanent Impairment/Damage (Devices)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
3. Date of Event *(mm/dd/yyyy)*
4. Date of This Report *(mm/dd/yyyy)*
5. Describe Event or Problem
6. Relevant Tests/Laboratory Data, Including Dates
7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

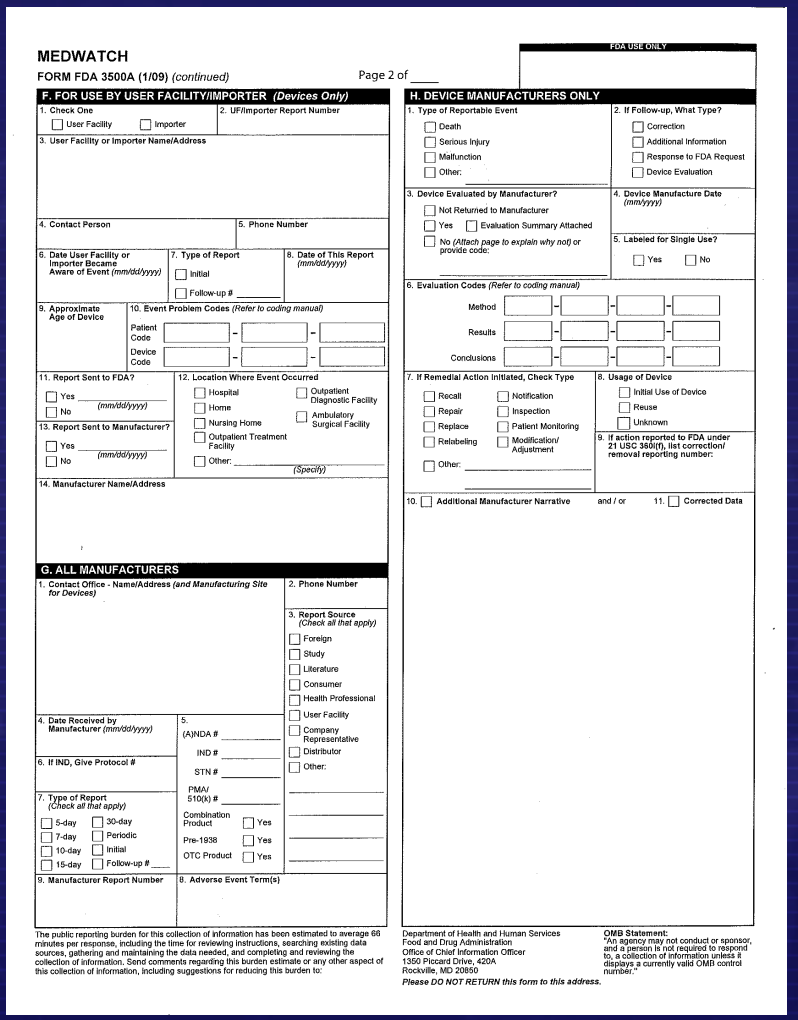
1. Name *(Give labeled strength & mfr/labeler)* — #1 / #2
2. Dose, Frequency & Route Used — #1 / #2
3. Therapy Dates *(if unknown, give duration) from/to (or best estimate)* — #1 / #2
4. Diagnosis for Use *(Indication)* — #1 / #2
5. Event Abated After Use Stopped or Dose Reduced? — #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
6. Lot # — #1 / #2
7. Exp. Date — #1 / #2
8. Event Reappeared After Reintroduction? — #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device — Health Professional / Lay User/Patient / Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* Yes No Returned to Manufacturer on: *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
   Phone #
2. Health Professional? Yes No
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes No Unk.



MEDWATCH

FORM FDA 3500A (1/09) *(continued)*

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FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER ***(Devices Only)***

1. Check One — User Facility / Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report — Initial / Follow-up # ___
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)* — Patient Code / Device Code
11. Report Sent to FDA? Yes *(mm/dd/yyyy)* / No
12. Location Where Event Occurred — Hospital / Home / Nursing Home / Outpatient Treatment Facility / Outpatient Diagnostic Facility / Ambulatory Surgical Facility / Other: *(Specify)*
13. Report Sent to Manufacturer? Yes *(mm/dd/yyyy)* / No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
2. Phone Number
3. Report Source *(Check all that apply)* — Foreign / Study / Literature / Consumer / Health Professional / User Facility / Company Representative / Distributor / Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # / IND # / STN # / PMA/510(k) # / Combination Product Yes / Pre-1938 Yes / OTC Product Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* — 5-day / 7-day / 10-day / 15-day / 30-day / Periodic / Initial / Follow-up # ___
8. Adverse Event Term(s)
9. Manufacturer Report Number

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event — Death / Serious Injury / Malfunction / Other:
2. If Follow-up, What Type? — Correction / Additional Information / Response to FDA Request / Device Evaluation
3. Device Evaluated by Manufacturer? — Not Returned to Manufacturer / Yes / Evaluation Summary Attached / No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? Yes No
6. Evaluation Codes *(Refer to coding manual)* — Method / Results / Conclusions
7. If Remedial Action Initiated, Check Type — Recall / Repair / Replace / Relabeling / Notification / Inspection / Patient Monitoring / Modification/Adjustment / Other:
8. Usage of Device — Initial Use of Device / Reuse / Unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:
10. Additional Manufacturer Narrative and / or 11. Corrected Data

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Manufacturer Requirements

- 820.198(a)(3) – Complaint procedure shall ensure that:
  - Complaints are evaluated to determine whether the complaint represents an event which is required to be reported under part 803

Manufacturer Requirements

- 820.198(d)
  - Any complaint which must be reported shall be promptly reviewed, evaluated, and investigated
  - Maintained in separate portion of complaint files or otherwise identified

Manufacturer Requirements

- 820.198(d)
- When a complaint is reportable the complaint file shall contain:
  - Information required under 820.198(e)
  - Whether device failed to meet specifications
  - Whether the device was being used for treatment or diagnosis
  - The relationship of the device to the event

Manufacturer MDR Requirements

- §803.17 Must develop, maintain, and implement written MDR procedures
  - Ensure timely and effective identification and evaluation
  - A standardized review process for reportability
  - Timely transmission of reports (5 or 30 days)
- §803.18 Must establish and maintain MDR event files
- Investigate to obtain required information and evaluate cause
- Document investigation, information and decisions in MDR event files

FDA-483 Observations

- Numerous citations in related to MDR's

  These include complaint cites, specific MDR cites, and servicing records cites

- Most used cite is 803.17

  "Written MDR procedures have not been [developed] [maintained] [implemented."

FDA-483 Observation Examples

- 21 CFR 803.50(a)(2) **Report of Malfunction**

  An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction were to recur.

  Specifically, the firm received a report of a side rail latch failing to perform as intended leading to an injury of a patient on 3/9/07. All 142 complaints of malfunctions of the side rail latch which occurred after that incident should have been reported as MDRs.

FDA-483 Observation Examples

- 21 CFR 803.50(b)(1) **Providing Incomplete or Missing Information**

  An MDR report submitted to FDA did not include all information that was reasonably known to the manufacturer.

  Specifically, your firm did not provide complete information from reports submitted by user facilities, distributors, and initial reports. The reports are: 1) Facility Report 0533000000-1993-0001 dated 1/23/94 2) Facility Report 0034030-1995-0001 dated 8/03/95

FDA-483 Observation Examples

- 820.200(c) **Servicing**

  Service reports that represent MDR reportable events were not automatically considered complaints and processed in accordance with the requirements of 21 CFR 820.198.

  Specifically, the firm performed service on a hospital bed rail which collapsed and caused a patient to fall and hit his head, resulting in a concussion and laceration requiring 15 stitches. The firm did not file a complaint or an MDR

Compliance Program Guidance Manual

- The district **should consider a Warning Letter** when the following MDR **violation**(s) was/were disclosed during the inspection. This list only provides examples and is not all-inclusive.
  - Firm fails to report, within five workdays, after becoming aware that a reportable MDR event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.
  - Firm fails to submit **an** MDR death report.
  - Firm fails to submit **an** MDR serious injury report.
  - Firm fails to develop, maintain and implement written MDR procedures.
- When the firm has already received a Warning Letter for MDR violations and still fails to comply with the MDR regulation, then the district should consider recommending a seizure, injunction, civil money penalty or prosecution.
- **All failures** to comply with MDR should be listed on the FDA-483.

Warning Letter Examples

Failure to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).

For example, your firm received information through its Service Report *****, dated October 5, 2010, of a patient that fell over the side rails of your firm's bed and sustained a broken hip. Your firm reported this event in its complaint file as ****, dated October 8, 2010. Your firm's MDR evaluation determined, "Serious injury not caused/contributed by product," and no report was submitted to FDA.

Warning Letter Examples

- Failure to submit a report to FDA no later than 30 calendar days of receiving information that reasonably suggests that your marketed devices may have caused or contributed to a death or serious injury, as required by 21 C.F.R. 803.50(a)(1). For example:

  Complaint **** contains documentation that the bone fractured after insertion of the Trial, and that the surgeon was required to use a suture on the bone, which is information your firm became aware of on May 21, 2008. This information reasonably suggests that your device may have caused or contributed to a reportable serious injury. After the inspection, you submitted a Serious Injury MedWatch report for Complaint **** on March 8, 2010. This MDR was submitted approximately 620 days late.

Warning Letter Examples

- 1. Failure to submit a report to FDA after receiving information that reasonably suggested that a marketed device may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(2).

  For example, you were notified of an occurrence, which you recorded as Complaint ****, on August 12, 2009, which involved the service loop disconnecting from the tissue mold at the distal end of the device allowing the metal helical retractor to dangle. Subsequently, your complaint report states the side of the helical retractor "caught the esophageal 1/3 of the way out" during attempted removal of the device requiring a biopsy forceps to loosen the helical retractor enough for removal of the device.

The information in the complaint files indicates that your firm was in possession of information that reasonably suggested that your marketed device malfunctioned and this device would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Your firm failed to submit this report to FDA within the required 30 day timeframe as required by 21 CFR 803.50(a)(2).

Warning Letter Examples

Failure to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report (MDR). [21 CFR 820.198(a)(3)]

Specifically, 4 of the 25 complaints reviewed by the investigator had not been evaluated to determine if they were medical device reportable events. For example, Complaint **** states that a patient claimed **[redacted]** was shocked and burned on the top of her head while being scanned in the **** system. The complaint was not evaluated to determine if it was a medical device reportable event.

Useful Links

- MDR Preamble
  - http://www.gpo.gov/fdsys/pkg/FR-1995-12-11/html/95-29906.htm
- Compliance Program Guidance Manual
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm
- CDRH Learn
  - http://www.fda.gov/Training/CDRHLearn/default.htm
- eMDR Guidance
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=MDR%20Guidance&utm_content=2

Useful Links

- MDR Guidance
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm

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Questions?