FDA Recalls: Office of Regulatory Affairs & Center for Devices and Radiological Health

MedCon 2019
FDA/Xavier University
Cincinnati, OH

ORA Recall Coordinators: Meredith Andress, Cynthia Aycock, Andrew Lang, and CDR Melinda Ruiz
CDRH: Shumaya Ali, MPH Assistant Director

www.fda.gov
Outline

• Structure within FDA
  – ORA
  – CDRH

• Customer Notification Letter & 806 Report Exercise

• CDRH - Review & Classification

• Status Reports

• Terminations
Office of Medical Device and Radiological Health Operations

Jan Welch
Director, Office of Medical Device and Radiological Health
# Office of Medical Device and Radiological Health Operations

## Division I

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Coverage</th>
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<tbody>
<tr>
<td>Program Division Director/District Director</td>
<td>Joseph S. Matrisciano Jr</td>
<td>CT, DC, DE, IN, KY, MA, MD, ME, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV</td>
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<tr>
<td>Compliance Branch Director</td>
<td>Gina Brackett</td>
<td>CT, DC, DE, IN, KY, MA, MD, ME, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV</td>
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<tr>
<td>Investigations Branch Director</td>
<td>Arduino Frankovic</td>
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<td>Recall Coordinators</td>
<td>Melinda Ruiz, Cynthia Aycock, Andrew Lang</td>
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### Office of Medical Device and Radiological Health Operations
#### Division II

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<tr>
<td>Program Division Director</td>
<td>Blake Bevill</td>
<td>NC, SC, GA, FL, MS, AL, LA, TN, IL, MN, WI, SD, ND, KS, MO, NE, IA, San Juan, US Virgin Islands</td>
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<tr>
<td>Compliance Branch Director</td>
<td>Melissa Michurski</td>
<td>NC, SC, GA, FL, MS, AL, LA, TN, IL, MN, WI, SD, ND, KS, MO, NE, IA, San Juan, US Virgin Islands</td>
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<tr>
<td>Investigations Branch Director</td>
<td>Kathleen Sinninger</td>
<td>NC, SC, GA, FL, MS, AL, LA, TN, IL, MN, WI, SD, ND, KS, MO, NE, IA, San Juan, US Virgin Islands</td>
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<tr>
<td>Recall Coordinators</td>
<td>Neisa Alonso</td>
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<td>Meredith Andress</td>
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<td>Marie Fink</td>
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**Office of Medical Device and Radiological Health Operations**  
**Division III**

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<tr>
<td>Program Division Director</td>
<td>Shari Shambaugh</td>
<td>TX, OK, AR, CO, UT, NM, WY, CA, NV, HI, WA, OR, MT, ID, AK</td>
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<tr>
<td>Compliance Branch Director</td>
<td>Vacant</td>
<td>TX, OK, AR, CO, UT, NM, WY, CA, NV, HI, WA, OR, MT, ID, AK</td>
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<tr>
<td>Investigations Branch Director</td>
<td>Eric Anderson</td>
<td>TX, OK, AR, CO, UT, NM, WY, CA, NV, HI, WA, OR, MT, ID, AK</td>
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<tr>
<td>Recall Coordinator</td>
<td>Theresa Kirkham</td>
<td>TX, OK, AR, CO, UT, NM, WY, CA, NV, HI, WA, OR, MT, ID, AK</td>
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Division Contact Info

• General:
  https://www.fda.gov/AboutFDA/CentersOffices/Office ofGlobalRegulatoryOperationsandPolicy/ORA/Contact ORA/ucm604350.htm#OMDRHO

• Recalls: general inquiries, new recall submissions, status reports, requests for termination, etc.
  – Division 1: oradevices1recalls@fda.hhs.gov
  – Division 2: oradevices2recalls@fda.hhs.gov
  – Division 3: oradevices3recalls@fda.hhs.gov
Recall Coordinator Duties

• Each Division Recall Coordinator is responsible for:
  – Receiving and triaging new recalls
  – Communicating with industry and CDRH
  – Recording new recalls
  – Preparing and sending classification letters
  – Issue recall audit checks
  – Reviewing status reports
  – Processing termination requests
  – Preparing and sending termination letters
Miscellaneous Info & Workload

• 7 full-time DRCs process the recalls for the entire Country
• 984 recalls 2018
• Class I recalls take precedence
• Ensure submissions are complete to expedite processing - include labeling, consignee list (Excel), HHE, CAPA, etc.
• We will notify you if there’s any information missing
CDRH Organizational Structure
Office of the Center Director (OCD)

- Office of Policy (OP)
- Office of Strategic Partnership and Technology Innovation (OSPTI)
- Office of Product Evaluation and Quality (OPEQ)
- Office of Communication and Education (OCE)
- Office of Management (OM)
- Office of Science and Engineering Laboratories (OSEL)

Re-organization effective date = May 1, 2019
Office of Product Evaluation and Quality (OPEQ)

Recall review & classification

Recall Process & Policy owner
PART 806 – Medical Devices; Reports of Corrections and Removals

TITLE 21 Sec. 806.10
Sec. 806.10 (a)

• Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
  – (1) To reduce a risk to health posed by the device; or
  – (2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set forth in paragraph (f) of this section or is exempt.
Sec. 806.10 (b)

• The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.
The manufacturer or importer shall include the following information in the report:

- The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R".
Sec. 806.10 (c)(5)

• The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

Compliance Dates Established by FDA in Conjunction with UDI Final Rule

• https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm
Sec. 806.10 (c)(7)

• A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
Sec. 806.10 (c)(8)

• Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.
Sec. 806.10 (c)(9)

• The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.
Sec. 806.10 (c)(11)

- The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.
  - Consignee format (easy data analysis)
  - List & Flag U.S.A. Government accounts

<table>
<thead>
<tr>
<th>Consignees</th>
<th>Approx. Number</th>
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<th>Approx. Number</th>
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<tr>
<td>Distributor</td>
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<td>Repacker/Relabeler</td>
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<tr>
<td>Retailer</td>
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<td>Direct Accounts</td>
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<tr>
<td>Institution</td>
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<td>Veterans Admin.</td>
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<td>Medical Facility</td>
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<td>Department of Defense</td>
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<tr>
<td>Internet Sales</td>
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<td>Manufacturer</td>
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<td>Physician</td>
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<td>USDA</td>
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<tr>
<td>Consumer/ Patient</td>
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<td>Other</td>
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806.10 Letter & Packet Exercise
Diagnostics ‘R’ US

Recall Letter and 806 Submission Exercise
The Scenario

• Diagnostics ‘R’ Us recently was inspected by the FDA
• The investigator believes that one of the unreported correction/removal activities should have been reported to the FDA
• Firm’s original customer notification was insufficient, so they’ll need to send a new one
• FDA provided a template for both the customer letter and the 806 submission
Be the recall coordinator

• You’ve received the proposed customer letter from the firm
• What feedback do you give them on the letter?
• What information is missing?
• What about the letter (content, format, etc.) could be improved?
• Remember: The letter’s audience is the customer!
What was missing?

• Who is the letter addressed to?
• Product information: lot numbers, expiration dates, manufacturing/distribution dates, quantities
• What is the health risk?
• How to recognize the device may fail?
• When will the firm’s corrective action be enacted?
• Who to contact with questions?
• What if adverse reactions or quality problems encountered?
What could be improved?

• “Customer Bulletin” should say “Urgent Medical Device Recall”
• Font should be larger overall
• Make it concise!
• Encourage customers to complete and return the form even if they do not have product on hand. Better yet, provide a due date
Now for the 806...

- With the help of the 806 template, the firm has submitted an 806 Report of Corrections and Removals
- Review the 806 submission
- What information should be omitted?
- What information is missing?
- What questions would you ask the firm?
What should be omitted?

• The opening letter
  (pages 1-2)

• The customer notification & response form
  (pages 3-6)
What was missing?

- Report Number
- Recalling firm
- Top Firm Official/Recall contact
- Manufacturer
- Unique Device Identifier (UDI)
- Lot codes
- Reason for recall
What was missing? (cont’d)

• Recall initiation date
• Description of event giving rise to report
• Root cause
• Total quantities manufactured and distributed
• Date ranges for manufacturing and distribution
• Distribution details (list of consignees, types of accounts)
What was missing? (cont’d)

• Recall strategy
  – How are you planning on notifying customers?
  – How will you verify that customers were notified?
  – What will you do about nonresponding customers?

• Final product disposition

• CAPA
What could be improved?

• If unsure whether an action is reportable to the FDA, still provide all requested information
• REF #’s in Customer Bulletin are unmatched to 806 report
• Provide summaries of complaints in 806
• Provide summary of HHE in 806
Questions?
Venous Medical Products

Recall Letter and 806 Submission Exercise
The Scenario

- Venous Medical Products received multiple complaints regarding their Central Venous Catheter kits
- Customers reported that the incorrect length of guide wire was included in the kits
- Firm’s investigation identified a packaging mix-up issue involving two lots of CVC kits
- FDA provided a template for both the customer letter and the 806 submission
Be the recall coordinator

• You’ve received the proposed customer letter from the firm
• What feedback do you give them on the letter?
• What information is missing?
• What about the letter (content, format, etc.) could be improved?
• Remember: The letter’s audience is the customer!
What is missing from the draft letter?

• “Field Safety Notice” should say “Urgent Medical Device Recall”
• A specific date, rather than month and year, should be included
• Organization of the Product Name, Model Number, and Lot numbers is difficult to follow
• The hazard statement is inadequate
• No clear instructions for what to do with recalled product
• No instruction to forward the letter in the event the products were further distributed
• Contact info should include days/hours available to receive calls
806 Report and Consignee List

• With the help of the 806 template, the firm has submitted an 806 Report of Corrections and Removals as well as a Consignee List
• Review the 806 report and consignee list
• What information is missing?
• What questions would you ask the firm?
What is missing from the 806 report?

- No C/R number
- Recalled products, model numbers, and lot codes unclear
- Inadequate Manufacturing and Distribution date ranges
- Quantities of each recalled product is not specified
- Firm awareness date and Initiation date are the same. Draft notification letter indicates an initiation date of in April
- Complaint info should include summaries at a minimum
- MDR number not included
- Delivery confirmations are not an adequate form of effectiveness checks
- Additional details required for non-responding customers. When will letters be sent? When will phone calls be made? How many of each?
What is missing from the Consignee List?

• This is more of a detailed distribution list rather than a consignee list
• Street address is required
• Contact info (i.e. email, telephone number)
• Multiple ship dates of product listed for same customers
• VA/DoD customers not separated from others (also not identified in the 806)
• List should identify quantities of each lot distributed to each consignee
CDRH Transparency: Recall Review

Shumaya Ali, MPH
Assistant Director

Fracture Fixation, Bone Growth Stimulator & Stereotaxic Devices Team (2)
Division of Health Technology 6C
Office of Health Technology 6 (Orthopedic Devices)
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

FDA/Xavier MedCon Conference
May 2, 2019
Objective

To provide visibility into CDRH’s review of Reports of Correction and Removal (806 Report)

- Electronic Products are not within the scope of this presentation
Talking Points

• Initial Triage
• Health Hazard/Risk Evaluation
• Recall Classification
• Recall Strategy Review
• Recall Communication
• Reasons for delay in review
Initial Triage

• Is there a violation?
  – 806 Report is not required for safety alert, market withdrawal, a stock recovery, product enhancement or routine servicing
Health Hazard Evaluation

**Input**
- 806 report, clinical and technical knowledge, precedent recalls, etc.

**Product Description**
- # Adverse Events, complaints & MDRs

**Injury Description**
- Conditions that may alter risk of injury
- Affected population/subpopulation

**Hazard Evaluation**
- Likelihood of injury/adverse health consequences

**Output**
- Risk mitigation strategy & recall classification

* evaluation factors disclosed in this slide are not intended to be all inclusive
Recall Classification

• **Class I**
  – There is a **reasonable probability** that the use of or exposure to a violative product **will cause** serious adverse health consequences or death.

• **Class II**
  – Use of or exposure to a violative product **may cause temporary or medically reversible** adverse health consequences, or where the probability of serious adverse health consequences is **remote**.

• **Class III**
  – Use of or exposure to a violative product is **not likely to cause** adverse health consequences.
Recall Strategy Review

• Determine whether the firm has adequately characterized the device failure and risk
• Ensure that the recall strategy can adequately remedy the violation and mitigate risk
• Ensure that the proposed corrective and preventive actions are effective
• Identify any follow-up actions or concerns
Recall Communication Review

• Evaluate the firm’s Communication Letter for adequacy
• Coordinate with the firm and ORA to address any gaps in the communication letter
• Determine if FDA communication/press is needed
Reasons for Delay in Review

• Incomplete 806 Report
• Inadequate risk information
• Inadequate corrective actions
• Inadequate customer notification
• Missing supporting documents
Things to Consider

• Put patient first
• Understand the trend and broader view of the issue
  – Isolated event vs. problem common across all device areas
• Establish an improved system for identifying and controlling potential recall situations
• Take systemic approach in addressing the issue
  – Ensure compliance with other regulatory requirements
Additional Resources

• CDRH Recall Team:
  – CDRHRecallTeam2@fda.hhs.gov

• Division of Industry and Consumer Education
  – DICE@fda.hhs.gov

• CDRH Learn
  – Medical Device Recall Modules https://www.fda.gov/Training/CDRHLearn/default.htm

• Regulations
  – 21 CFR part 7 (Enforcement Policy)
  – 21 CFR part 806 (Reports of Corrections & Removal)

• Regulatory Procedures Manual (Chapter 7)
FDA RECALLS:
STATUS UPDATES

MedCon
Cincinnati, OH
Meredith Andress
Recall Coordinator
FDA’s Recall Process

Recall Situation

Firm initiates correction or removal

Division Recall Coordinator (DRC) works with firm on recall action

CDRH Reviews and Classifies Recall

Division Office Monitors Recall and conducts follow up as necessary

Terminate recall
Classification Letter

March 29, 2019

Dear Mr. [Redacted],

We agree with your firm’s decision to recall the [Redacted] because the...

[Redacted] Lot Numbers [Redacted]

We have reviewed your action and conclude that it meets the formal definition of a “Recall.” This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. This recall was reported in an issue of the weekly FDA Enforcement Report...

It is suggested that you follow the FDA’s “Enforcement Policy: Recalls (including Product Corrections) – Guidelines on Policy, Procedures and Industry Responsibilities” issued April 1, 2011 as conducting your recall...

Examples of an effectiveness check letter, response form, and questionnaire can be found at:...

This recall should be conducted by the Consumer/User and that Level A Effectiveness checks should be conducted by your firm. Level A Effectiveness Checks are 100 percent of the total number of consignees to be contacted.

In addition to your recall effort, it is equally important to ensure that any returned merchandise is promptly inventoried, handled and stored in such a manner as to assure its separation from acceptable materials so it will not be inadvertently used or shipped.

One experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse...

We, therefore, urge you to develop and begin steps to recondition the product...

We request that you retain a copy of your recall notification, the steps you have taken to ensure that the recalled merchandise is properly inspected and that steps be taken to prevent unсанctioned use or shipment and provide details of all recondition actions, to our office before implementation for our review and concurrence...

In addition, we request that you submit to our office a recall status report at monthly intervals...

These recall status reports should contain the following information:

1. Number of consignees notified of the recall, and date and method of notification
2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was initiated
3. Number of consignees that did not respond
4. Number of products returned or corrected by each consignee contacted and the quantity of products corrected for
5. Number and results of effectiveness checks that were made
6. Estimated time frame for completion of the recall
7. Final disposition of recalled products
8. Root cause of the recall
9. Action(s) taken to prevent similar problems in the future

These periodic status reports should be sent via e-mail...

Audits regarding the effectiveness of your recall will likely be used in the determination of the recall...

Please be advised that this letter represents an enforcement action.
Elements in a Status Report

21 CFR Part 7.53

1. Number of consignees notified of the recall, and date and method of notification

2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received

3. Number of consignees that did not respond

4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for
Elements in a Status Report (Cont’d)

5. Number and results of effectiveness checks that were made
6. Estimated time frames for completion of the recall
7. Final Disposition of recalled products
8. Root cause of the recall
9. Action(s) taken to prevent similar problems in the future
Take Home

• Think cumulative - we should not have to reference past reports to add up the numbers
• Delivery receipts do not count as a customer response
• Effectiveness checks – at least 3 ADDITIONAL attempts using VARIOUS methods
• Please make sure the numbers make sense!
PART 7 - Correction/Removal Terminations

MedCon
Cincinnati, OH
CDR Melinda Ruiz, PA-C
Recall Coordinator
PART 7 Enforcement Policy

• Subpart C-- Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

• Sec. 7.55 – Termination of a recall (Correction/Removal)
PART 7 Sec. 7.55 (a)

- A recall will be terminated when the Food and Drug Administration determines that:
  - All reasonable efforts have been made to remove or correct the product in accordance with the recall strategy;
  - It is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product.
PART 7 Sec. 7.55 (b)

• A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration division stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.
Termination Points

- Quantity Recovered / Number of Units Corrected
- Product Disposition (destruction records/photos or FDA witnessed)
- Number of Consignees Responding to Notification
- Assessing Effectiveness (consignee responses/results)
- Root Cause
- Preventative Action Taken by Firm
Assessing Effectiveness

• Has the consignee received the notification?
• If the recall notification was received, were the instructions read/followed?
• If not followed/received, were necessary steps taken?
• These steps may involve sending out a follow up notification
Root Cause/Corrective Action

- **Root Cause**
  - Report to FDA division once it has been established

- **Corrective Action**
  - Explain corrective actions planned or underway
Termination of the Recall

• Goal

All possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed.
Overview

• Structure within FDA
  – ORA
  – CDRH
• Customer Notification Letter & 806 Report Exercise
• CDRH - Review & Classification
• Status Reports
• Terminations
Resources

- Industry Guidance for Medical Device Recalls: https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/recallscorrectionsandremovals/default.htm
- Part 7: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7
- Part 806.10: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=806.10
- Device Correction Removal Report Model for Industry
Questions?