Introduction to Medical Device Recalls

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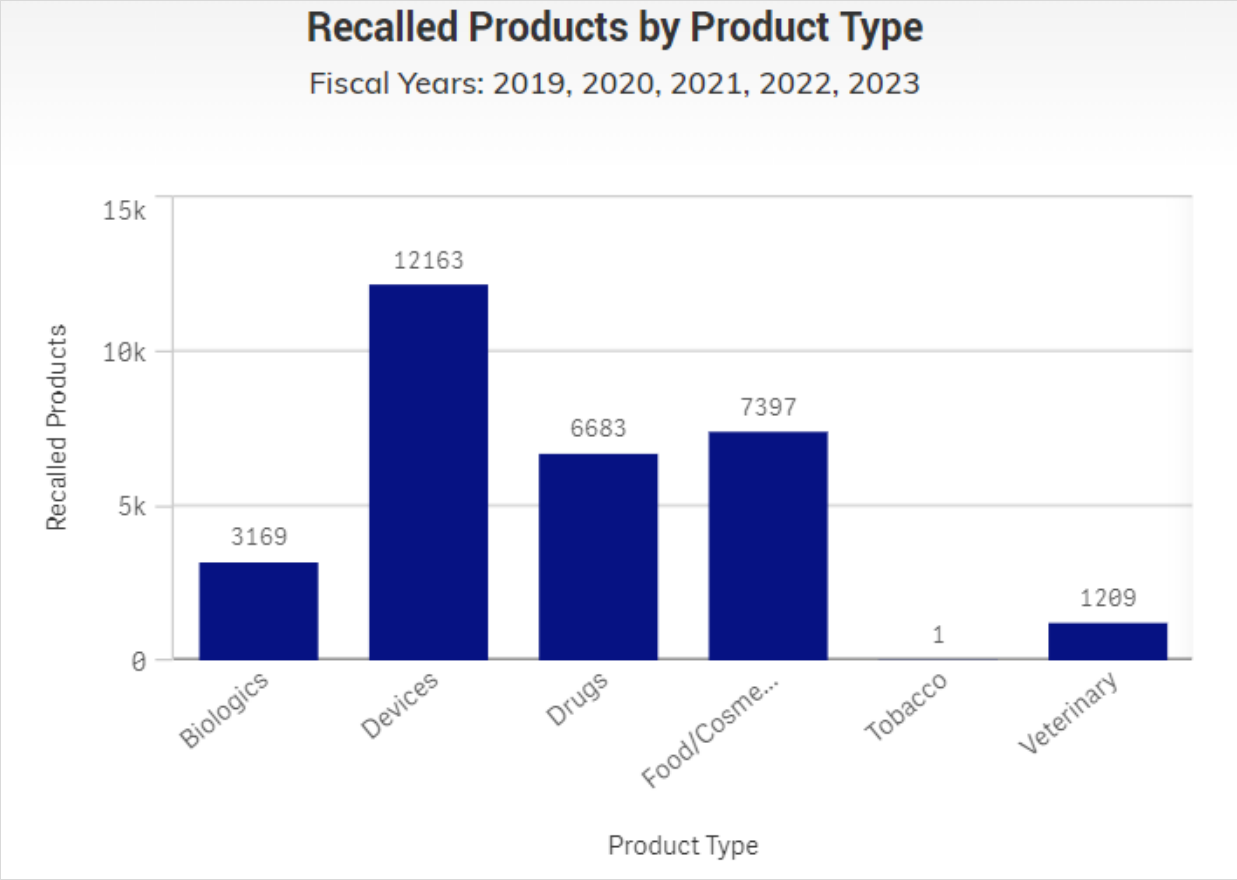
U.S. Food and Drug Administration


Recalled Products by Product Type
Fiscal Years: 2019, 2020, 2021, 2022, 2023
15k
10k
5k
0
Recalled Products
12163
6683
7397
3169
1
1209
Biologics
Devices
Drugs
Food/Cosme...
Tobacco
Veterinary
Product Type

Learning Objectives

- Review Basics of a Medical Device Recall
- Discuss Recall Classifications
- Describe Firm's Recall Responsibilities
- Review CDRH's Responsibilities in Medical Device Recall Process

Medical Device Recall Basics

Recall Regulations and Law

- 21 CFR Part 7 Subpart C Recalls (Including Product Corrections)
- 21 CFR Part 806 Medical Devices; Reports of Corrections and Removals
- Mandatory Device Recall Authority Section 518(e) Food, Drug, and Cosmetics (FD&C) Act
  - 21 CFR Part 810 Medical Device Recall Authority

Definitions

Recall:

- Removal or correction of a marketed product in violation of the FD&C Act
- Does not include market withdrawal or stock recovery

21 CFR 7.3(g)

Definitions

Removal:

- The physical removal of a device from its point of use to some other location
- For the purpose of repair, modification, adjustment, relabeling, destruction, or inspection

21 CFR 806.2 (j)

Examples of a Recall: Removal

- Firm gives “return material authorization”, and user ships the device back

- Firm instructs user to destroy and dispose of the device

Definitions

Correction:

- Repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device
  - Without physical removal from its point of use

21 CFR 7.3(h)

Examples of Recall: Correction

- On-site field service correction of a problem with an MRI device
- Additional monitoring of patient with implanted device
- Providing an addition to labeling to user to reduce potential for a device malfunction

Note: Adjustments that are regularly scheduled maintenance are not corrections

Recall Basics

- **A Correction or Removal action is not a Recall, if it is a:**
  - Market Withdrawal
  - Stock Recovery
  - Routine Servicing
  - Medical Device Enhancement
  - Safety Alert

Recall Basics

- **Types of Medical Device Recalls**
  - Voluntary by the manufacturer
  - FDA-Requested
  - FDA-Ordered/Mandatory

Recall Classification

Recall Classification

Recall Class	Definition
Class I	***Reasonable probability*** *that use of or exposure to a violative device* ***will cause serious adverse health consequences or death***
Class II	*Use of or exposure to a violative device* ***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 device is* ***not likely to cause adverse health consequences****.*

Firm’s Recall Responsibilities

Firm's Recall Responsibilities

- Identify need for recall
- Cease distribution, shipment and/or sale as needed
- Report to FDA's Medical Device Division Recall Coordinator (DRC)

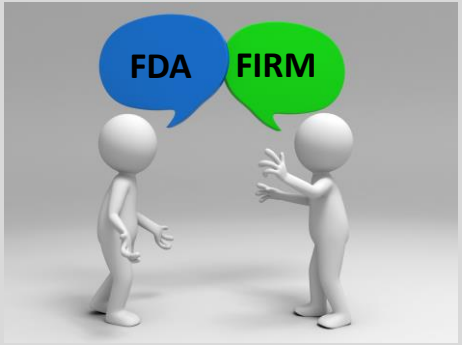
21 CFR 7.42

Firm's Recall Responsibilities

- Identify recall strategy to suit circumstances
- Draft and issuing recall communication
- Notify public when appropriate
- Conduct follow-up activities

21 CFR 7.42

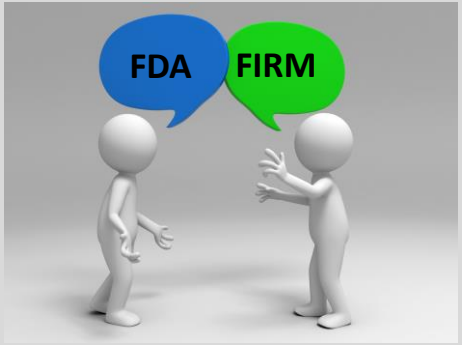
Recall Strategy



Factors considered:

- Results of risk assessment
- Ease of identifying product
- Degree to which deficiency is obvious
- Degree to which the product remains unused
- Continued availability of products if needed

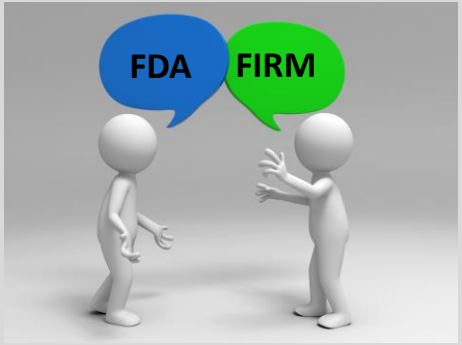
Recall Strategy



Other factors considered:

- Specification of Depth of recall in distribution chain
- Issuance of a Public Warning if necessary
- Specification of the method and level of effectiveness checks
- Conduct Effectiveness checks

Recall Communication



- Promptly notify direct accounts
  - ➢For example, mail, telephone call, email, etc…
    - Document communication
- Instruct distributors to notify their customers
- Follow up communications sent to those who fail to respond to initial communication

21 CFR 7.49

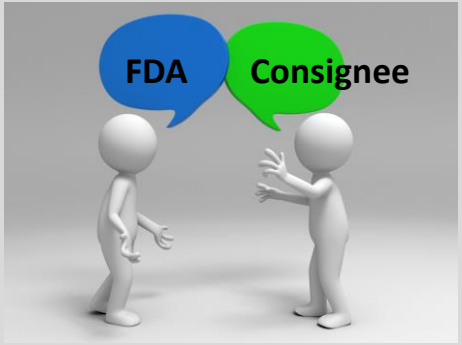
Recall Communication

Includes:

- Clear identification of product
- Steps to take to minimize health consequences
- Recall reason and hazard involved
- Instructions on what to do with product
- A ready means for recipient to report to recalling firm

Should not include:

- Irrelevant qualifications
- Promotional materials
- Any other statement that detracts from message



21 CFR 7.49

Public Warning/Notification

- When appropriate, alert public that recalled product presents a serious health hazard
- Either issued by FDA in consultation with firm, or submitted to FDA for review and comment
- Issued as:
  - General public warning through general news media (national or local news)
  - Public warning through specialized news media (professional or trade press)

Recall Follow-Up Activities

- Submit Report of Corrections and Removals
- Implement requirements of 21 CFR 820
- Submit recall status report
- Request Recall Termination

Report of Corrections and Removals

- Described in 21 CFR 806, Medical Devices, Reports of Corrections and Removals (806 Report)
  - Electronic Submission of 806 Reports of Corrections and Removals module is located in CDRH Learn
- Mandatory report when there is a violation or a risk to health
- Report to the FDA's Medical Device Division Recall Coordinator (DRC) by:
  - email or
  - eSubmitter

Implement Quality System regulation requirements

- Most relevant to recalls are the following requirements in 21 CFR Part 820:
  - Implement procedures to address nonconforming product
  - Review complaint files
  - Identify action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems

21 CFR 820

Submit Recall Status Reports to Include:

- Number of consignees notified
- Method of notification and date
- Number of responses received and quantity of devices on hand
- Unresponsive consignees

21 CFR 7.53

Submit Recall Status Reports to Include:

- Number of products returned or corrected and the quantity
- Number and results of effectiveness checks
- Estimated recall completion time frame

21 CFR 7.53

Recall Termination

- Recalling firm may request in writing
  - ➢ Accompanied with most current recall status report and product disposition
- Determined by FDA
- Termination letter issued by FDA
  - ➢ Once recall activities have been completed and verified

21 CFR 7.55

Considerations in 21 CFR 7.59

- Possible Device Shortages
  - May modify recall strategy
- Verification of each notification in a multi-step recall process
- Product Identification
  - Lot #, serial #, date
  - Unique Device Identifier (UDI)
- Effectiveness Checks
  - Right person received notification and has taken appropriate action

CDRH's Responsibilities

CDRH's Recall Responsibilities

- Evaluate health hazard
- Classify recall
- Review firm's recall communication
- Review firm's recall strategy

CDRH's Recall Responsibilities

- Evaluate if press release is needed
- Post recall on FDA.gov and in weekly FDA Enforcement Report
- Terminate Recalls

CDRH's Recall Responsibilities

Mandatory Recalls: CDRH

- Conducts a Health Risk Assessment
  - Reasonable probability the device would cause serious, adverse health consequences or death (section 518(e) of the FD&C Act; 21 CFR 810.2)
- Discusses risk evaluation with firm
- Issues Cease Distribution and Notification Order

Possible Enforcement Actions

- Injunction
- Import alert
- Foreign Country Notification
- Seize product

Summary

The recalling firm should:

- Develop and implement recall strategy
- Notify consignees
- Report to the FDA's Medical Device Division Recall Coordinator (DRC)
- Submit 806 Report, if required
- Submit up-to-date status reports

Summary

FDA will:

- Review recall information
- Classify recall
- Post recall information
- Request or Order a Recall if needed

Resources

Slide Number	Cited Resource	URL
5, 16, 17, 20, 21	21 CFR 7- Enforcement Policy	www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7
5, 7, 24	21 CFR 806 - Medical Devices; Reports of Corrections and Removals	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806
5, 33	21 CFR 810 - Medical Device Recall Authority	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-810
5	Federal Food, Drug, and Cosmetic Act	www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdb
6, 9	21 CFR 7.3 Definitions	ecfr.io/Title-21/Section-7.3

Resources

Slide Number	Cited Resource	URL
	Recalls, Corrections and Removals (Devices)	www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices
	Device Correction/Removal Report for Industry Fillable Form	file:///C:/Users/TAW/AppData/Local/Temp/1/Microsoft EdgeDownloads/f6dd2050-ba4b-43ef-b915-3646af30a188/FDA-5072%2011-30-2023.pdf
	FDA Recall Coordinators	www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators
25	21 CFR 820	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
	Regulatory Procedures Manual, Chapter 7 Recall Procedures	www.fda.gov/media/71814/download
	Recalls, Market Withdrawals, & Safety Alerts	www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, audio recordings, PowerPoint presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4:30 pm ET)

Your Call to Action

- Be prepared and plan for your recall
- Make sure you properly identify the affected products, problems, and its possible cause
- Plan your actions to address the risk related to the recall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