Introduction to Medical Device Recalls

Industry Responsibilities

Table of Contents

- Purpose
  - Explain to Industry what their role and responsibilities are in a Medical Device Recall
- Introduction to Medical Device Recalls
  - Basics of a Recall
  - Medical Device Recall Determination & Initiation
  - Medical Device Recall Reporting
  - Recall Responsibilities & Requirements
  - FDA's Role

What is a Recall

- A firm's voluntary removal or correction of a marketed product that the FDA considers to be in violation of the FD&C Act and against which FDA would initiate legal action
  - E.g., Seizure
- A voluntary action taken by a firm when they determine a device is misbranded or adulterated
  - Misbranded – includes but is not limited to a false or misleading representation

What is a Recall

- ***Adulterated*** – includes but is not limited to a device that does not meet the performance standard established under section 514 of the FD&C Act; a device that is not in conformance with any standard that is recognized under section 514 (c); a Class III device that does not have premarket approval; a banned device; a device that is not in conformance with applicable requirements under section 520(f)(1) or 520(f)(2); and if it is a device for which an exemption has been granted under section 520(g) for investigational use and the person granted the exemption fails to comply with the requirements prescribed.

What is a Recall

- An effective method to remove or correct FDA regulated products from the market place
- An alternative to FDA initiated court action for removing violative products from the market (seizure) or import detention
  - ***Violative Product*** – a product that is in violation of the applicable regulatory and statutory laws in the scope of a recall. Typically, medical device recalls occur because the device is either Adulterated, §501 or Misbranded, §502 of the Act.

Who can initiate a Medical Device Recall?

Firm Initiated

- On its own volition decides to recall
  - Recalling Firm – firm that initiates a recall or the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

Not Sure If You Have a Medical Device Recall…

How to determine if you have a Medical Device Recall

- Does it meet the following criteria:
  - A Removal - the physical confiscation (by recalling firm not government) from where it is used or sold, to some other location for:
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
  - A Removal is not part of regularly scheduled maintenance

How to determine if you have a Medical Device Recall

- Does it meet the following criteria:
  - A Correction – On site
    - Repair
    - Modification
    - Adjustment
    - Relabeling
    - Destruction
    - Inspection
    - Including patient monitoring

How to determine if you have a Medical Device Recall or ***NOT***

- A Correction or Removal Action is NOT a Recall, if it's a:
  - Market Withdrawal – firm's removal or correction of a distributed product which involves no violation or a minor violation that would not be subject to legal action by the FDA.
    - E.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
  - Stock Recovery – firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm.
  - Safety Alert – notification by responsible persons to device users that the use of a device may, in certain circumstances, pose a risk of substantial harm.

Where and What Should Be Reported

Reports of Correction and Removal

- The Center for Devices and Radiological Health requires firms to follow 21 CFR Part 806 for Reporting Medical Devices Recalls
- It requires a firm to report when there is a risk to health
- This information should be reported to a firm's FDA District Office

Recalling Firm's Responsibilities

- Submit a written report of any correction or removal of a device within 10 working days, including the following information:
  - Correction or removal report number
  - Manufacturers name and contact information, including contact person
  - Importers name and contact information
  - Device brand name, common name, and intended use

Recalling Firm's Responsibilities

- Marketing status, device model, catalog, code number, lot number, serial number, etc.
- Description of event giving rise to recall
- Corrective or removal actions that have been, and are expected to be taken
- Any related illness or injuries that have occurred with the use of the device

Recalling Firm's Responsibilities

- Total number and dates of devices manufactured and distributed that are subject to the recall, including expiration date or expected life
- Names and contact information of all domestic and foreign consignees and number of devices distributed to each
- Copy of all communications regarding the correction or removal, including name and contact information of all recipients of the communications, including recall letter or script

Recalling Firm's Responsibilities

- In the event that the required information is not immediately available, a statement must be submitted stating why it is not available and when it will be.

FDA's Enforcement Policy

- Under 21 CFR Part 7, FDA recommends that a recalling firm report the following information:
  - Product identity
  - Reason, date discovered
  - Risk Evaluation
  - Quantity manufactured and distributed
  - Distribution information for all consignees
  - Recall letter or script
  - Recall Strategy
  - Recalling firm official's contact information

Adverse Consequences or Risk to Health

Health Hazard Evaluation

A Firm's Strategy

- A planned specific course of action to be taken in conducting a recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

- An effective recall strategy takes into account:
  - The results of the risk assessment
  - Ease of identifying the affected product(s)
  - Degree to which the product's deficiency is obvious to the consumer or user
  - Degree to which the product remains unused in the market-place
  - Continued availability of essential products

A Firm's Recall Communication

- A recalling firm has a responsibility to its consignees, anyone who received, purchased, or used the product being recalled, to:
  - Promptly notify its direct accounts via a recall communication
    - e.g. By issuing press releases or providing detailed instructions

A Firm's Recall Communication

- Should supply information to help users identify the product and take steps to minimize health consequences
  - Identify product subject to recall
  - Explain reason for the recall and hazard involved
  - Further distribution or use should cease immediately
  - Direct accounts should notify its customers who received the product, where appropriate
  - Instructions should be included regarding what to do with the product

A Firm's Recall Communication

- The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.
- Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees.

A Firm's Recall Communication

- To take action to prevent the problem from happening again
- Telephone calls or other personal contacts should be confirmed by written communication and or documented in an appropriate manner.

A Firm's Recall Strategy

- The recall strategy also includes the following elements:
  - Depth – level in the distribution chain
  - Public Warning – purpose is to alert the public that the product being recalled presents a serious hazard to health
  - Effectiveness Checks – verifies that all consignees at the recall depth specified have received notification and have taken appropriate action
- The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted

Firm's Follow-up Responsibilities

Quality System Requirements

- Firms are responsible for following the Quality System Requirements found in 21 CFR Part 820.100 thru 21 CFR 820.250
  - Establishing and maintaining procedures for implementing corrective and preventative action
- This will aid in ensuring that the necessary corrective fixes are made on all units
- Additional information can be viewed at www.fda.gov/Training/CDRHLearn/ucm162015.htm

Things to Consider When Recalling Your Medical Device

- Do you recognize when you have a crisis/recall situation on your hands?
- Does your firm intend to voluntarily respond to the crisis or recall situation without FDA intervention?
- Does your firm have in place a process to contain and control the risk?
- Do you have sufficient policies, procedures, personnel and skills to bring the risk down to acceptable levels?
- Can you properly identify the affected products, problem and the cause(s) of the problem?

Things to Consider When Recalling Your Medical Device

- Device Shortage and Recalls
  - Shortages may require Recall Strategy modification based on the risk assessment of benefit vs. risk of removal
  - Verification
    - 1-Change Recall Depth or Delay
    - 2-Detailed Instructions and monitoring
  - Constant Agency re-evaluation
  - Agency Determination

Recall Status Reports

- FDA requests that a recalling firms submit recall status reports to their FDA District Office.
  - This is so the agency may assess the progress of the recall
- The frequency of these reports will be determined by the relative urgency of the recall and will be specified by the FDA.
  - Generally between 2 and 4 weeks.

Recall Status Reports

- Should contain the following information:
  - The number of consignees that were notified of the recall, along with the date and method of notification.
  - The number of consignees that responded to the recall communication and quantity of products on hand at the time it was received.
  - The number of consignees that were unresponsive.

Recall Status Reports

- The number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
- The number and results of effectiveness checks that were conducted.
- The estimated time frames for completion of the recall.

- Recall status reports are to be discontinued when the recall is terminated by the FDA.

Firm's Recall Responsibilities, in Summary

- Determine the need for a recall
- Conduct a risk assessment
- Conduct a root cause analysis, i.e. cause of the problem
- Notify the FDA District Office
- Execute appropriate recall actions
- Improve product quality for the future

FDA Expectations

- Once a decision to recall has been made, contact your District Recall Coordinator
- Conduct Effectiveness checks within 5-7 days of Recall Letter issuance
- A timeline of implementation for product returns and corrections
- Submit Termination Recommendation in a timely manner

FDA's Role

A Brief Overview

Recall Classification

Classification – is the recall classification assigned by FDA, i.e. Class I, Class II, or Class III Recall Classes, to indicate the relative degree of risk to public health of the product being recalled or considered for recall.

Recall Classification

Class I Recall - *A Situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death*

- The recalling firm notifies its customers and directs them to notify the intended recipients of the device.
- The notification usually contains the name of the device being recalled, identifying lot or serial numbers; the reason for the recall; explains concisely the risk involved; and instructions about how to correct, avoid, or minimize the problem. It should also provide a telephone number for questions related to the recall.
- The recalling firm issues a press release to notify the public, if appropriate to minimize health consequences.

Class I Recall Example

- A situation in which a catheter may kink or rupture during use leaving remnants behind in the patient that will cause serious patient injuries or death.

Recall Classification

- ***Class II Recall -*** *A situation in which 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*
  - The recalling firm notifies its customers and sometimes asks them to notify the intended recipients of the device.
  - A press release would be issued ***if*** there was a specific need to do so
    - E.g. if the device could affect the health of a large number of people, if patients need more information, or if the recalling firm could not reach every intended recipient

Class II Recall Example

- A package defect in which sterility has been compromised and could lead to contamination of the medical device and result in patient complications.

Recall Classification

- ***Class III Recall -*** *A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.*
  - The recalling firm notifies its customers
  - Press release is not usually expected

Class III Recall Example

- A labeling defect where the expiration date does not appear on the product label.
- A mislabeled package that contains one size of a particular medical device but is labeled as another size.

FDA Can Also Initiate a Medical Device Recall

FDA Recalling Medical Devices

- **FDA Requested**
  1. Based on risk of illness or injury or gross consumer deception
  2. Firm is aware of the risk but is not acting on its own initiative
  3. When necessary to protect the public health and welfare

- **FDA Ordered**
  - 21 CFR Part 810.13 and 518e of The Food, Drug & Cosmetic Act (FD&C Act)

What can FDA do when a firm is reluctant to conduct a recall?

- Conduct a Health Risk Assessment – It is CDRH's responsibility to evaluate the risk prior to discussion with the firm
- Discuss our evaluation of risk – face to face or by phone
- Issue Public Notification
- FDA Ordered/Mandatory Recall (Class I Health Hazard/Requirements (518 (e) 21 CFR 810))
- Seize product
- Injunction – Recall clause in consent agreement
- Place firm on Import alert
- Foreign Country Notification

In Review

- The firm responsible for the violative medical device should initiate a recall.
- Firm should report the recall to the FDA District Office.
- Firm should follow protocol to properly communicate the recall with consumers.
- Firm should submit up to date status reports.
- If necessary the FDA can initiate a requested or ordered recall.

Regulations/References

- Food, Drug and Cosmetic Act (FD&C Act)
- 21 CFR Part 7 (Enforcement Policy)
- 21 CFR Part 806 (Mandatory Reports of Corrections and Removals), 810 and 820
- Federal Register (June 16, 1978), Part 7
- Regulatory Procedures Manual (RPM) (Chapter 7)

References

- Medical Technology Learning Institute's Recalls from A-Z: Regulations, Decisions, Procedures, Best Practices (November 2008)
- Checklist for Reports of Correction or Removal 806.10(a)(1-13)
- FDA 101: Product Recalls, From First Alert to Effectiveness Checks
  - (http://www.fda.gov/consumer)

References

Medical Device Recalls
www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm

Guidance Documents, CDRH websites
(www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm)

and Databases