ACI's 23rd FDA Boot Camp

September 18 - 19, 2014

Recall Guidance for Drugs, Biologics, and Medical Devices: What You Need to Know

Mark Mansour

Partner

Jones Day

Tweeting about this conference?

#FDABos

What Is A Recall?

21 CFR 7.3(g)

- *Recall* means a firm's removal or correction of a marketed product that FDA considers to be in violation of its laws or regulations.

- Recall does not include a market withdrawal or stock recovery.

What Is Not A Recall?

- *Market withdrawal* means removal or correction of marketed product, but there is only a minor violation, or no violation at all. 21 CFR 7.3(j)

- *Stock recovery* means removal or correction of a product that is in violation, but has not been marketed. Product is on the premises and under control of firm and no portion of the lot has been released for sale or use.

  21 CFR 7.3(k)

FDA Recall Authority & Resources

- Authority Granted by Federal Food Drug & Cosmetic Act (FDCA) and other federal statutes

- Implementing Regulations –

  21 CFR, Part 7, Chapter C: *Recalls (Including Prouct Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility*

FDA Recall Authority & Resources (continued)

- Guidance Documents
  - *Guidance for Industry: Product Recalls, Including Removals & Corrections*

    http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm
  - *Regulatory Procedures Manual, Chapter 7: Recall Procedures*

    http://www.fda.gov/downloads/iceci/compliancemanuals/regulatoryProceduresManual/UCM074312.pdf

Mandatory Recall Authority

- Generally recalls are voluntary in nature (even if requested by FDA), however, under certain circumstances, FDA has the authority to order a firm to recall a product.

- This authority is limited to specific products, including certain devices and biological products.

- Always best to cooperate with FDA in a recall situation.

FDA Recall Policy

21 CFR 7.40

- Recalls are an effective method for removing or correcting products that present a risk of injury, deception, or are otherwise defective.

- May be initiated by firm or at the request of FDA.

- Recalls are a preferred alternative to FDA-initiated court action to seize product.

Recall Classification

- FDA will conduct a health hazard evalaution (HHE) and classify a recall based on the public health risk associated with the product defect:
  - Class I: Reasonably probability of serious adverse health consequence or death
  - Class II: May cause temporary or medically reversible adverse health consequences OR only remote chance of serious adverse health consequence
  - Class III: Unlikely to cause adverse health consequences
- The higher the risk, the greater FDA's interest and monitoring

Bases for Medical Device Recalls

Potential Recall Situations

- Product not functioning properly under normal or expected use
- Product defect discovered and requires repair for proper functioning
- Firm wants to revise labeling with new warnings or (sometimes) instructions for use

Working with FDA During a Recall

- All product recalls must be reported to FDA. 21 CFR 7.46 provides instructions and form for report.
- Generally, the FDA District Office assigns a recall coordinator for the firm to work with.
- Firm must submit recall strategy and regular status reports to FDA until recall is terminated. Effectiveness checks are required.
- Recall is terminated when FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. Firm may request termination in writing.

Other Recall Considerations

- Being prepared for the worst
  - Product identification and distribution records
  - Internal strategies and procedures
- Crisis management
  - Dealing with the press and your customers
- Effective communication with FDA
- Risks of not cooperating with FDA
  - Mandatory Recall (depending on product)
  - Court-ordered seizure or injunction
  - Fines and criminal prosecution
- Product Liability