

FDA Recalls

Risk Communication Advisory Committee

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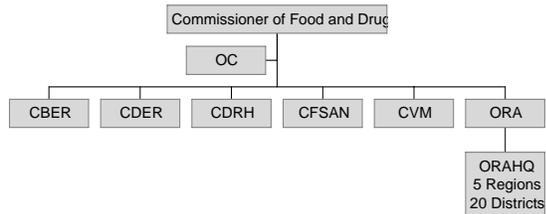


FDA Overview

- Regulates about 25% of all consumer purchases
- Mission summary: protect and advance public health
- Products: food, cosmetics, drugs, biologics, medical devices
- Pre-market and post-market responsibilities and operations
- About 10,000 employees operating in product Centers, OC, and ORA



FDA Organizational Structure



What is a Recall?

Recall – a firm’s removal or correction of a marketed product that is in violation of the law, and against which FDA would initiate legal action.

Reference: 21 CFR 7.3(g)



FDA Sample Collection & Analysis

Other Health Agencies

Firm Testing

FDA inspection

How Does FDA Learn About a Problem with a Regulated Product?

Adverse Event Reports

NDA Field Reports

3rd party information

CDC Epidemiological Information

What Does a Firm Do When a Problem is Detected in a Marketed Product?

- Review, analyze, discuss, debate
- Often get to the decision point: ‘remove the product from the market’
- Then: scope, strategy, notification, execution, verification, and analysis



Steps Taken By a Firm When Conducting a Recall

- Scope – the specific products to recall
- Strategy – the plan to execute the removal or correction to minimize risk of illness/injury from recalled product
- Notification – inform FDA* of the planned recall; offering the opportunity to comment on the scope and strategy.



Steps Taken By a Firm When Conducting a Recall (cont'd)

- Execution - make the recall happen; calls, emails, faxes, letters, visits, internet posting, press releases
- Verification - ensure execution of the strategy was performed effectively
- Analysis - review overall effort and identify opportunities for improvement



Steps Taken By FDA in the Recall Process

- Assess situation & obtain recall related information (e.g. labeling, distribution, testing)
- Investigate - What went wrong? What steps were taken to prevent recurrence?
- Evaluate scope and strategy - Is it appropriate in light of the risk? Adjustments needed? Other steps needed? Additional public notice necessary?



Steps Taken By FDA in the Recall Process (cont'd)

- Health hazard evaluation and classification of the recall; publication in the Enforcement Report
- Recall audit checks; level is set based on risk to verify the effectiveness of the recall efforts



How is a Recall Classified?

- Class 1 - highest risk; reasonable probability of serious adverse health consequences or death
- Class 2 - medium risk; may cause temporary or medically reversible adverse health consequences and probability of serious adverse health consequences is remote
- Class 3 – low risk; adverse health consequences are unlikely

Classification is a legal determination based on the health hazard evaluation. FDA oversight is commensurate with risk and therefore proportional to classification

Reference: 21 CFR 7.3(m)



When is a Recall Classified?

- Upon receipt and review of all pertinent information relevant to the recall
- After an assessment of the health hazard associated with the recalled product has been made
- As soon as reasonably possible



What Are the Practical Implications of a Recall Classification?

Class 1 & 2 Recalls May Require Additional Actions Be Undertaken:

- Option for FDA to issue a public warning per 21 CFR 7.42(b)(2)
- Guidance to Industry recommends procedures for issuing Public Notifications (Press Releases) in certain situations



Public Communication

Class 1 Recall:

- Prompt, clear, accurate communication reduces the risk of serious injury or death
- Press Releases are usually issued to enhance the consumer's awareness of the recall and the steps that should be taken



Public Communication (cont'd)

Class 1 Recall:

- Press releases also post to the FDA internet site and are sent to all state health agencies, foreign governments, and various other stakeholders
- There are several hundred Class 1 recalls per year across all FDA regulated products
- Look how The Washington Post now presents product recall notices...



Daily Washington Post Notices

2/16/2008
PRODUCT RECALLS

Dried Pachyrhizus

DETAILS: Lion Pavilion is recalling 2,340 eight-ounce packages of Grassplot-brand dried Pachyrhizus, imported from China.

DEFECT: They contain undeclared sulfites.

WHAT TO DO: Call 718-384-6951.

SOURCE: Associated Press



Daily Washington Post Notices

2/13/2008
PRODUCT RECALLS

Vehicles

DETAILS: Ford is recalling about 124,000 Ford Expedition and Lincoln Navigator sport-utility vehicles from the 2007-08 model years.

DEFECT: A spring system in the inside door handles could break.

WHAT TO DO: Dealers will replace the interior handle spring on all side doors. Call 800-392-3673 for more information.



Daily Washington Post Notices

Vinaigrette

DETAILS: Giant said that, following a voluntary recall by Annie's Naturals, it has removed all eight-ounce bottles of Annie's Naturals Shitake Sesame Vinaigrette from its shelves. The product recalled by Annie's has a UPC code of 0-92325-33319-2 and "Best By" date codes of 02/20/09/1/E and 02/20/09/2/E.

DEFECT: It may contain soy sauce and sesame that were not listed as ingredients.

WHAT TO DO: Call Annie's Naturals consumer relations at 800-288-1089 or Giant Customer Service at 888-469-4428, or go to www.giantfood.com.

SOURCE: Associated Press



Daily Washington Post Notices

2/15/2008

PRODUCT RECALLS

Drug Patches

DETAILS: All 25-microgram-per-hour fentanyl patches with expiration dates on or before December 2009 sold under the brand name Duragesic by Prit-Cara and generically by Sandoz.

DEFECT: Some of the patches may have a cut in the lining of the internal reservoir, where the drug is stored in gel form. If the fentanyl gel leaks into the drug's packaging, it could cause a patient or caregiver to come into direct contact with the powerful opioid drug.

WHAT TO DO: Damaged packages should be flushed down the toilet and not handled. Skin that has been exposed to the gel should be thoroughly rinsed with water but not washed with soap. For details on Duragesic patches sold by Prit-Cara, call 800-647-6446. For details on generic fentanyl patches sold by Sandoz, call 800-901-7236.



Legislation and New Initiatives

- FDAAA Section 1003
 - Enhance the quality and speed of communication with the public
 - Post information that is easily accessed and understood by the public
- Food Protection Plan
 - Improve the food protection communication process to increase timeliness of food protection messages
 - Better inform consumers and other stakeholders during food related emergencies

Legislation and New Initiatives (cont'd)

- Import Safety Action Plan
 - Provide FDA with mandatory food recall authority
 - Develop best practices for the use of technologies to expedite consumer notification of recalls



Oversight and Evaluations

Congressional, HHS Office of the Inspector General, Government Accountability Office
Concerns:

- Timely, clear, effective communication
- Interagency cooperation and collaboration
- Prompt and complete execution of recalls (ensuring all recalled product is removed from distribution channels)



How Can RCAC Help?

In light of legislation, initiatives, oversight, evaluations and FDA intent to seek process improvements:

- Provide feedback on draft Press Release template
- Assist us in applying risk communication principles to improve the timeliness, clarity, accuracy, consistency, and ultimately, the effectiveness, of this method of public communication



Help by Answering Key Questions

- Standardization of the draft template in FDA
- Substance and format (blocking, information mapping) of the draft template
- Incorporating other Recommended Communication Practices into the template
- Other advice for Recommended Communication Practices beyond the use of the Press Release template

