Food Recalls

Recall Initiation, Implementation, Effectiveness, and Costs:

Enhancing Communication Between Industry, Regulators and Public Health

Overview of Recall Activities from the FDA Perspective

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Nashville, TN
February 19, 2009

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Objectives

- Importance of Recalls
- FDA Recall Policies
- Overview of FDA Responsibilities
- FDA Expectations of Recalling Firms

FDA believes that the cooperation of manufacturers and distributors in expediting recall activities is vital upon determining that a distributed product is potentially hazardous to the public and/or is in violation of the laws that it administers

What is a Recall?

- **Recall** - a firm's removal or correction of a distributed product that FDA considers to be in violation of laws that it administers and against which the agency would initiate legal action, e.g., seizure.
  - Title 21, Code of Federal Regulations, Part 7.3(g)

Types of Recalls

- Firm-initiated
  - Most common type
  - Voluntary
- FDA-Requested
  - Urgent situation
  - Risk of illness or injury or gross consumer deception
  - Necessary to protect public health and welfare
  - Firm has not voluntarily initiated a recall
- FDA-Ordered
  - Initiated by a firm in response to an order for such an action
    - Infant formula

Why are Recalls Important?

- An FDA-regulated product that is either defective or potentially harmful and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) needs to be removed from the market or the problem corrected

Why are Recalls Important?

- Effective
  - Recall is the most effective means in removing potentially harmful products from the market or correcting the problem in the interest of protecting the public

Why are Recalls Important?

- Efficient & Timely
  - Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or civil actions, especially when the product has been widely distributed

Why Should Firms Conduct Recalls?

- Sense of responsibility
- Obligation to prevent harm to the public health and welfare
- Desire to avoid an FDA-initiated legal action
- Desire to minimize civil liability

FDA Recall Policy

- FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in 21 CFR Part 7
  - These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful.

FDA Responsibilities

- Assurance to the public that violative products are removed from the market place.
  - By recall
  - By legal action

FDA Responsibilities - Recalls

- Oversee a company's strategy and assess the adequacy of the recall
- Strategy and Classification
  - Formalize the recall action by:
    - Reviewing recall information, including the recall strategy provided by the firm;
    - Assessing the health hazard presented by the recalled product; and
    - Classifying the recall

FDA Responsibilities - Recalls

- Notification and Public Warning
  - Notify the firm of the classification and necessary changes in its recall strategy, including the need for press releases as appropriate
  - Publish all recalls on the FDA Internet site and ensures that the public is warned about products that are hazardous to health
  - Provide recall information to other federal and state government agencies and to foreign governments.

FDA Responsibilities - Recalls

- Monitoring and Auditing the Recall
  - Develop and implement a recall audit program to ensure that the recall action has been effective
- Termination of a Recall
  - Determine when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm

FDA Responsibilities

- FDA will take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails
  - Firm refuses to recall or sub-recall after being requested to do so by the FDA;
  - Firm fails to complete a recall in a timely fashion;
  - FDA has reason to believe that a recall strategy is not effective

When Do I Initiate a Recall?

- Manufacturers and/or distributors may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective.
- Firms may also initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, or as ordered by FDA.

How Does a Recall Get Initiated?

- A company discovers a problem and recalls a product on its own (most common)
- FDA inspects a manufacturing facility and determines the potential for a recall
- FDA receives reports of health problems through various reporting systems
- FDA formally requests that a firm recall
  - Firm has not voluntarily initiated a recall

Next Step After Deciding to Recall

- Notify your local FDA District Recall Coordinator as soon as possible after the decision to recall
- Begin preparing and assembling your recall information
  - "Early" notification will allow FDA the opportunity to review and comment on your written notification and to offer guidance and assistance in your recall process

Recall Strategy (21 CFR 7.42)

- Develop a recall strategy
  - A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall
  - Developed by the recalling firm
  - FDA develops for an FDA-requested recall
- Each recall is unique and requires its own recall strategy

Recall Strategy

- Depending on the circumstances of the particular recall, a recall strategy may take into consideration factors such as:
  - Results of a health hazard evaluation;
  - Ease in identifying the product;
  - 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

Elements of a Recall Strategy

- Depth of the recall
  - Level in the distribution chain to which the recall is to extend
  - Depends on the product's degree of hazard and the extent of distribution
    - i.e., consumer or user level; retail level; or wholesale level

Elements of a Recall Strategy

- Public warning
  - Purpose is to alert the public that a product being recalled presents a serious hazard to health
  - Reserved for urgent situations
    - General public warning, i.e. press release
    - Public warning through specialized news media, e.g.. professional or trade press, or to specific segments of the population such **as** physicians, hospitals, etc.

Elements of a Recall Strategy

- Effectiveness Check
  - The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action
  - The responsibility of the recalling firm
  - May be accomplished by personal visit, telephone, letter, or a combination thereof.

Recall Communications

- Purpose is to convey:
  - Product in question is subject to recall
  - Further distribution or use of any remaining product should cease immediately
  - Where appropriate, that the direct account should conduct a sub-recall
  - Instruction regarding what to do with the product
- 21 CFR 7.49(a)

Recall Communications

- Contents:
  - Should be brief and to the point
  - Clearly identify the product
  - Concisely explain the reason for the recall and the hazard involved
  - Provide specific instructions on what should be done with respect to the recalled product(s)
  - Provide a means for the recipient to report back to the recalling firm
- 21 CFR 7.49 (c)(1)

Recall Communications

- Should not be diluted or camouflaged by irrelevant qualifications, promotional materials, or any other statement or information that may detract from the message
- 21 CFR 7.49 (c)(2)

FDA Recall Audit Check Program

- Audit checks determine the adequacy of the firm's effectiveness checks
- Audit checks are decided upon after evaluating the recalling firm's strategy
- Audit checks are conducted by:
  - Personal visits
  - Telephone calls

FDA's Expectations For Firm-Initiated Recalls

- Promptly notify FDA when a decision is made to recall, including providing information pertaining to the recall action

FDA's Expectations For Firm-Initiated Recalls

- Conduct a health hazard assessment
  - Provides an assessment of the health risk associated with the deficiency
  - Assessment should provide an evaluation of the potential risk to the population at risk

FDA's Expectations For Firm-Initiated Recalls

- Develop and follow a recall strategy
  - A planned specific course of action to be taken in conducting a specific recall
    - Address the depth or level of distribution in which the recall will be extended
    - Outline the method and mode of notification
    - Provide recall instructions to consignees
    - Provide the extent of the effectiveness of the recall action

FDA's Expectations For Firm-Initiated Recalls

- Notify all consignees of the recall action
  - Various methods acceptable (mail, telephone, facsimile, electronic mail, personal visit)
    - However, inclusion of a written notification to consignees as documentation of the recall is advisable
  - Details of mode of notification
    - If by letter, how was it sent (e.g. overnight mail, first class mail, facsimile)
    - If by telephone, provide copy of phone script

FDA's Expectations For Firm-Initiated Recalls

- Perform effectiveness checks
  - Verification that recall notification was received by consignees, including assurance that it reached the appropriate level in the distribution chain
  - Verification that consignees read and followed the recall instructions
  - Verification that consignees understand the nature of the problem and reason for recall

FDA's Expectations For Firm-Initiated Recalls

- Determine root cause and implement corrective action to prevent recurrence
- Provide FDA with the recall status or progress including product disposition

FDA's Recommendation

- Develop a contingency plan for recalls
  - Provides facets of the recall process that a firm can establish in advance of an actual recall including, but not limited to:
    - Point of contact(s)
    - Communication techniques
    - Health hazard assessment procedures
    - Investigation procedures

In Summary

- Recalls are an effective method of removing or correcting a potentially hazardous product
- Recalls benefit all parties involved (i.e., firm, consignee, public, FDA)
- Formalize or develop procedures of the recall process
- Establish communication with your local FDA district office

References

- 21 CFR, Part 7.1 - 7.59
- Guidance for Industry: Product Recalls, Including Removals and Corrections, issued November 3, 2003, http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm
- FDA Enforcement Report, http://www.fda.gov/opacom/Enforce.html