Recall Process for FDA-Regulated Products

Cecilia Wolyniak
FDA, Office of Enforcement Recall Team
Cecilia.wolyniak@fda.hhs.gov

Recalls of FDA-Regulated Products

- Recall is an effective method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration.
- In Fiscal Year 2011 FDA monitored 3640 recalls of FDA regulated products

You will learn about

- The types of products regulated by FDA
- FDA's definition of a "recall"
- FDA's recall authority
- How FDA processes recalls
- Where to find recall information on FDA's website

What products does FDA regulate?

- FDA regulates the following types of products:
  - human drugs
  - animal drugs
  - medical devices
  - radiation-emitting products
  - vaccines
  - blood and blood products
  - transplantable human tissue
  - animal feed
  - cosmetics
  - about 80 percent of the foods eaten in the United States
  - tobacco

What is FDA’s definition of a “recall”?

- *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action.

Recall Definition

- Recalls are conducted by firms responsible for the product's manufacture and distribution
- Removal means removing a product to another location; correction means repair or destruction without moving the product to another location

Recall Definition

- All product removals and corrections do not meet FDA's recall definition. Examples of actions which FDA would not consider a "recall" include normal stock rotation of foods and routine adjustment or servicing of medical devices.

Does FDA have authority to mandate recalls?

- Most recalls are conducted voluntarily by firms
- In some situations firms must conduct recalls in a manner specified by FDA. An example of this is infant formulas that pose a risk to human health
- In other situations, FDA may order a firm to conduct a recall

FDA's Recall Authority

- FDA recently was given the authority to order recalls of food where there is a reasonable probability that an article of food is adulterated or misbranded and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals.

FDA's Recall Authority

- Another example is FDA's authority to order recalls of medical devices where there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.

Must firms report their recalls to FDA?

- In some instances firms must report actions that may be recalls to the FDA
- Example: Reportable Food Registry requires that firms report to FDA within 24 hours of learning that a food has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Must firms report their recalls to FDA?

- Example: Medical device corrections or removals must be reported to the FDA within 10 days if the correction or removal was done
  - To reduce a risk to health posed by the device; or
  - To remedy a violation of the act caused by the device which may present a risk to health

Processing recalls at FDA

- Firm reports its recall or intention to recall to FDA
- FDA advises the firm on its recall strategy including the need for a public warning
- FDA evaluates the risk posed by the product (recall classification)
- FDA monitors and audits the firm’s recall

Recall classification

- CLASS I: reasonable likelihood of serious adverse health consequences or death
- CLASS II: temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
- CLASS III: not likely to cause adverse health consequences

Recall monitoring

- Firms are requested to provide status reports on the progress of their recall
- FDA may audit a portion of the firm's customers to determine whether they received the recall notification and took appropriate action
- FDA may witness product destruction

Recall information on FDA's website

- Press releases announcing recalls are posted here: http://www.fda.gov/Safety/Recalls/default.htm
- All recalls, once they are classified, are listed in FDA's weekly Enforcement Report here: http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

In conclusion...

- Recalls protect the public's health by removing or correcting violative and sometimes harmful products from the market.