FDA Recall Activities

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Regulatory Authority

• FDA is responsible for the safety of 80% of all food consumed in the United States
  – Entire domestic and imported food supply
  – Except
    • Meat
    • Poultry
    • Frozen, dried and liquid eggs
Foods Under FDA Authority

• Dairy Products
  – Milk
  – Cheese
  – Butter
• Plant Products
  – Vegetables
  – Fruits
  – Nuts
  – Juices
• Spices
• Dietary Supplements

• Seafood
  – Finfish
  – Shellfish
  – Crustaceans
  – Surimi based
• Grain-based
  – Bread
  – Cereals
  – Flour
• Bottled Water
• Infant Formula
• Cosmetics
Code of Federal Regulations

  

- Recall is a voluntary action by a firm
- Guidance on development of recall strategy (depth, public warning, effectiveness checks)
- Guidance on recall communications with consignees
Code of Federal Regulations

- **21 CFR Part 107, Subpart E** – Infant Formula Recalls (Food and Drug Administration-required recalls of adulterated or misbranded infant formula that presents a risk to human health)
  
  [http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr107_03.html](http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr107_03.html)

- Firm must report the recall to FDA and conduct the recall in the manner specified in this part
Definition (21 CFR 7.3)

Recall means a firm’s removal or correction of a marketed product(s) 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, e.g., seizure.
FDAAA Amendments Act 2007

• The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085), Section 1005 directs the FDA to establish a Reportable Food Registry (RFR) for Industry.

• RFR involves all foods regulated by FDA except infant Formula and Dietary Supplements
Reportable Food Registry (RFR)

• Beginning September 8, 2009, the RFR requires that any Food facility that manufactures, process, packs or holds food for human or animal consumption to file a report through the RFR electronic portal when there is a reason to believe that a food will cause adverse health consequences or death to humans or animals.
Reportable Food Registry (RFR)

- Accessible at www.fda.gov home page under heading “Report a Problem” or http://rfr.fda.gov
- Mandatory Reports must be submitted within 24 hrs of a reportable situation
- Failure to report a reportable food is prohibited under the Federal Food Drug and Cosmetic act
Recall Classification

• Numerical designation (i.e., I, II, or III) is assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.
Health Hazard Evaluation

• Diseases or injuries which have already occurred
• Existing conditions that can contribute to a clinical condition
• Population
• Seriousness of hazard
• Likelihood of occurrence of hazard
• Immediate and long term consequences
Recall Classification

• **Class I** is 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.
Examples of Class I Recalls

- Pathogens in ready-to-eat food: *Salmonella*, *Listeria monocytogenes*, *E. coli O157:H7*, *Clostridium*
- Allergens: milk, eggs, peanuts, tree nuts, crustaceans, fish, soybeans
- High levels of sulfites
- High levels of heavy metals
- Choking hazards for susceptible populations
Classification

- **Class II** is 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.
Examples of Class II Recalls

- Foreign objects that pose a physical hazard
- Pathogens: *Shigella*, hepatitis A, *Cyclospora*, *Cryptosporidium*
- Allergen: wheat
Classification

- **Class III** is a situation in which use of, or exposure to, a violative product is **not** likely to cause adverse health consequences.
Examples of Class III Recalls

- “Unfit for food” where hazard is not likely
- Low levels of pesticide residue
FDA Offices Involved in Recalls

- Office of Regulatory Affairs (ORA)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Office of Public Affairs (Press Office)
Office of Regulatory Affairs (ORA)

• Consists of headquarters unit and field offices (20 district offices)
• District office has investigations and compliance branches
• Field laboratories
ORA’s Regional and District Offices

Alaska is in the Seattle District,
Hawaii, Guam and American Samoa are in the San Francisco District,
U.S. Virgin Islands are in the San Juan District.
ORA Field Role in Recalls

- Each district (except SW Import) has a recall coordinator
- Receive notification of all recalls from regulated industry in their district
- Advise firms on their recall strategy
- Monitor the progress of firm’s recalls
- Forwards information to ORA HQ, Press Office and Center for Food Safety and Applied Nutrition
ORA Headquarters Recall Unit

• Headquarters unit for recalls: Office of Enforcement, Division of Compliance Management and Operations, Recall Staff
• Mel Szymanski (CSO)
• Pete Cook (CSO)
• Cecilia Wolyniak (CSO)
• Fred Richman (Supervisor)
ORA HQ Role in Recalls

- Establish agency-wide recall policies and procedures
- Receive notification of all recalls from FDA field offices
- Advise field offices and coordinate field’s response to recalls
- Inter-agency and international coordination
Center for Food Safety and Applied Nutrition

- CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.
CFSAN Role in Recalls

- Receives information on all food recalls from district offices
- Coordinates health hazard evaluation (HHE) process within CFSAN
- Decides whether firm’s action meets the definition of a recall
- Classifies recall based on HHE (High profile Class I recalls need Center Director and Associate Commissioner for Regulatory Affairs concurrence)
- Comments on firm’s and FDA’s recall strategies
- Deborah Saville (CSO)
- Jennifer Thomas (Supervisor)
Press Office Role in Recalls

- Assists in review of firm’s press releases
- Assists in writing/clearance/issuance of FDA press releases
- Responds to media inquiries on recalls
- Posts firm’s and FDA’s press releases on FDA website, along with photos of recalled products
- Publishes weekly Enforcement Report
Responsibilities of Recalling Firm

Preparing for a Recall

• Review available recall guidance
• Develop a recall plan
• Maintain manufacturing and distribution records in a manner to facilitate a timely and effective recall
• Identify finished products with a lot number/code
Determining the scope of a recall:

- When did the problem start/end
- Can additional lots/products be affected other than the lot/product analyzed and found adulterated
- How many sizes/labels for the product
- Is the product coded with a lot number
- Shelf life of product
Determining the depth of a recall:

• Class I recalls generally to consumer/user depth via press release
• Class II generally to retail depth; some to consumer/user via press release
• Class III generally to retail depth when problem obvious to consumer
Responsibilities of Recalling Firm

Communicating with FDA

• Notify FDA District Recall Coordinator and provide information in a timely manner (A current list of FDA recall coordinators can be found on FDA’s website at: http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#Recall%20Coordinators)
Responsibilities of Recalling Firm
Communicating with FDA

• Info needed by FDA includes:
  – product (identity, size and type of containers, brand names, lot numbers, whether refrigerated/frozen/shelf stable)
  – Codes
  – amount manufactured and amount distributed
  – number of and types of consignees
  – area of distribution
  – reason for recall
Responsibilities of Recalling Firm

Communicating with FDA

- Discuss recall strategy with FDA (including disposition of recalled product)
- Let FDA review text of phone notifications, written recall notifications, press releases (follow models provided in FDA guidance)
- Provide FDA with consignee list
- Provide actual labels or clear photos of labels
Responsibilities of Recalling Firm

Communicating with Consignees

• Be brief and to the point
• Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product
• Explain concisely the reason for the recall and the hazard involved, if any
Responsibilities of Recalling Firm: Communicating with Consignees

• Provide specific instructions on what should be done with respect to the recalled products
• Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product
• Provide subrecall instructions (if necessary)
• Recontact non-responders and conduct effectiveness checks
Press Releases

• Follow FDA models as closely as possible – “fill in the blanks”
• Do not change hazard statement – don’t take out “life threatening”
• Issue press release to Associated Press
• Provide FDA with confirmation that press release was sent to AP
• FDA will issue if firm will not or if firm’s is inadequate
FDA Responsibilities:

- Monitor the recall by reviewing firm’s status reports and conducting audit checks (District)
- Discuss and approve recall strategy – including press releases (District/Center - Office of Public Affairs for press)
- Classify the recall (Center)
- Terminate the recall (District Class II and III; Center approval for class I)
Food Recalls by Class: FY 2009 – FY 1997
Reasons for Recall FY 2008
Class I

- 52 - Allergens
- 34 - *Salmonella*
- 20 - Sulfites (>10mg/eating occasion)
- 18 - *Listeria monocytogenes*
- 4 - Uneviscerated fish (botulism hazard – see CPG 540.650)
- 1 - *E. coli* O15:H7
Reasons for Recall FY 2009  
Class I

• *Salmonella*  
  326

• Undeclared allergens  
  56

• *Listeria monocytogenes*  
  25

• Undeclared sulfites  
  16

• Foreign objects  
  12
Additional information and guidance:

• Recall Guidance and Information Available through FDA Website (www.fda.gov)
• Regulatory Procedures Manual, Chapter 7
  http://www.fda.gov/ora/compliance_ref/rpm/chapter7/ch7.html
• Investigations Operations Manual, Chapter 8
  http://www.fda.gov/ora/inspect_ref/iom/contents/ch7_toc.html
Questions?

Thank you!

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