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Food Recall

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Institute For Thermal Processing Specialists

34th Annual Conference & General Meeting

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Food Safety Modernization Act

- A major revision of our nation's food safety laws was advanced when the President signed the FDA Food Safety Modernization Act (FSMA) into law on January 4, 2011.
- This comprehensive law has reshaped the approach taken by the FDA.
- The Agency is transitioning from one that was largely reactive to one that focuses on prevention.

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Food Safety Modernization Act

- Overall, FSMA takes lessons learned from the last decade to give the FDA enhanced tools for protecting public health.
- The law has several new and important provisions that affect the food industry.

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Food Safety Modernization Act

- These provisions impact:
  1) Recall and consumer notification
  2) Facility registration and suspension
  3) Records access
  4) Prior notice for imports
  5) Administrative detention
  6) Fees for recall and re-inspection
  7) High-risk food categories

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The 5 Major Elements of the Law

Preventive controls- For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.

Inspection and Compliance- The legislation recognizes that inspection is an important means of holding industry accountable. FDA applies its inspection resources in a risk-based manner.

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The 5 Major Elements of the Law

Imported Food Safety- FDA has new tools to ensure that imported foods meet US standards and are safe for our consumers.

Response- For the first time, FDA will have mandatory recall authority for all food products.

Enhanced Partnerships- The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies

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FSMA Recall

Under FSMA, FDA now has authority to order a mandatory recall.

How did it work before the legislation?

1) The Agency would have to request the manufacturer to voluntarily recall the product in question.

2) The Agency would need a court order to issue a mandatory recall of the product.

3) For LACF products, the Commissioner could implement Emergency Permit.

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FSMA Recall

Under FSMA, FDA now has authority to order a mandatory recall.

How does it work after the legislation?

1) Mandatory recall authority. Self-executing upon enactment of FSMA

   a) FSMA § 206; FDCA § 423; 21 U.S.C. § 3501

2) The provision requires FDA to first give companies the opportunity to conduct a voluntary recall.

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FSMA Recall

Under FSMA, FDA now has authority to order a mandatory recall.

How does it work after the legislation?

3) If a company fails to respond, FDA has the authority to order a recall.

4) The law does not require the agency to issue guidance or regulations.

5) The legislation mandates that FDA develop communications tools that will help inform consumers about recalls.

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Agency Recall Procedures

Purpose of a Food Recall

Method for removing or correcting commercially distributed products that are adulterated or misbranded and against which FDA could initiate formal legal action:

1) Voluntary
    a) Firm Initiated Recall
    b) FDA Requested Recall
2) Mandatory
    a) FDA Mandated Recall Order

Agency Recall Procedures

Classification of Food Recalls

Numerical designation to indicate the relative degree of health hazard presented by the product being recalled

A) Class I - Reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death

B) Class II - Use of or exposure to a product may cause temporary or medically reversible adverse health consequences.

C) Class III - Use of or exposure to a product is not likely to cause adverse health effects.

Agency Recall Procedures

Guidance, Regulations, Authority

1. Regulations: 21 CFR Part 7, Subpart C

2. FDA Industry Guidance: Product Recalls, Including Removals and Corrections

3. Section 206 of FSMA Amends the FD&C Act to add Section 423 giving FDA Mandatory Recall Authority for Foods

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Agency Recall Procedures

Authority and Action

FDA exercises its authority under section 423 of the Act when they have determined that there is a:

1) Reasonable probability that the article of food, other than infant formula, is adulterated under section 402 or misbranded under section 403(w) of the Act.

And

2) The use of or exposure to such article will cause serious adverse health consequences or death to humans or animals

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Agency Recall Procedures

Authority and Action

3) FDA has provided the responsible party with an opportunity to cease distribution and conduct a voluntary recall of the article of food.

And

4) The responsible party has not recalled the article of food within the time and manner specified, if prescribed, by FDA

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Agency Recall Actions

FDA has Flexed Its New Legislative Recall Muscles

- Recall notification suggests the FDA is ready and determined to use its expanded enforcement authority.
- Under the new law, FDA has authority to order the mandatory product recall where there is reasonable probability that the articles are adulterated or misbranded, and the use of or exposure to such article[s] will cause serious adverse health consequences or death to humans or animals.

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Agency Recall Action

The Kasel Notification

Background:

Kasel Associated Industries of Denver, CO produces pet food products at their Denver manufacturing facility. Inspectors had:

1) conducted tests of finished and unfinished Kasel pet treat products
2) performed environmental testing of Kasel's manufacturing facility
3) found samples tested positive for Salmonella, including food contact surfaces within the facility.

In addition, FDA investigators specifically cited cGMP issues with the Kasel facility.

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Agency Recall Action

The Kasel Notification

Kasel Associates Industries, Inc.

– 49 Pet Treat Products which included Boots & Barkley, BIXBI, Nature's Deli, Colorado Naturals, Petco, and Best Bully Stick items

– Products were distributed nationwide from 4/20 to 9/19/2012. No human illnesses were determined or reported. Some dogs were reported to be ill after treats.

– Salmonella
  • Product and Environmental Samples were Positives

– Voluntarily Recalled Sampled (+) Lots, but Not All Suspect Lots
  • October 2012

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Agency Recall Action

The Kasel Notification

Kasel Associates Industries, Inc.

– Received 423 (a) Letter: Notification of Opportunity to Cease Distribution and Conduct a Voluntary Recall

• February 13, 2013

• Notification documented that Kasel's products were adulterated under the FFDCA and a reasonable probability existed that the use of or exposure to the products would cause serious adverse health consequences or death to humans or animals.

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Agency Recall Action
The Kasel Notification

Kasel Associates Industries, Inc.

- Firm Subsequently Issued Press Recalling All Products
  - February 19, 2013

Agency Recall Action
The USPlabs Notification

Background:

USPLabs produces dietary supplements at their Dallas manufacturing facility. FDA Investigators found:

1) Epidemiological evidence showed that use of these products was associated with adverse health consequence
2) The company's weight-loss product caused 56 cases of liver damage, acute liver failure or drug-induced hepatitis
3) The supplement contained Aegeline, an unapproved dietary supplement with no safety data
4) Aegeline is a synthesized version of a natural extract from the Bael tree.

Agency Recall Action
The USPlabs Notification

USPlabs LLC.

– 3 weight loss products: OxyElite Pro Super Thermo capsules, powder and ultra-Intense capsules

– Products were distributed nationwide from March to October 2012

– Chemical Adulteration

– Warning Letter sent USPlabs October 11, 2013 – No action from firm

Agency Recall Action
The USPlabs Notification

USPlabs LLC.

– Received 423 (a) Letter: Notification of Opportunity to Cease Distribution and Conduct a Voluntary Recall on November 9, 2013

- Notification documented that USPlabs' products were deemed to be adulterated because USPlabs failed to provide the FDA with evidence, as required by law, that Aegeline was reasonably expected to be safe for use in its dietary supplements

- Predicate Rule Violation

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Agency Recall Action

The Kasel Notification

USPlabs LLC.

– Firm Subsequently Issued Press Release Recalling All Products

- November 9, 2013

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Food Recall

Company Action

1) Under FSMA, FDA has the power to demand a food company to recall, with increasing risk of criminal charges for adulteration and civil liability to consumers.

2) Companies should primarily focus their efforts on preventive controls to ensure the quality of the products they manufacture and distribute.

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Thank You

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