Handling Inspections

FDA's Plans for Enforcing FSMA

Learning Objective

Recall the key elements of the FDA's strategy and plans for implementing and enforcing FSMA requirements

FDA's Goal for FSMA

- Reduce the risk of illness or injury attributed to food manufactured and distributed from facilities subject to FSMA
  - Domestic
  - Imported
- FDA's implementation mantra: "to educate before it regulates"

Topic/Section

FSMA Implementation Strategy

- Phase 1
  - Setting new standards through regulations, guidance, and policy
- Phase 2
  - Addressing planning and implementation
  - Designing strategies to gain and maintain food industry compliance with the new rules
- Phase 3
  - Monitoring implementation and evaluating success through the use of KPI's and metrics
    - Results Oriented Management (ROM)

Intent of FDA Inspections

- Inspectors will be food and feed-specific
- Heavy reliance on state inspectors
- Inspector training programs
- Violation findings will be risk-based
- Targeted inspections
- Two-tier inspections
- More aggressive inspections

Intent of FDA Inspections

- Subject matter expert availability
- Form 483s
- Use of "deficiency letter"
  - Incentives for voluntary compliance
- Inspection portal/database

Topic/Section

Questions

- What are your plans for developing programs to support FSMA compliance?
- Will you move forward immediately or wait for additional FDA guidance?

Inspections

- More assertive and comprehensive
  - FDA was insisting on access to records before FSMA rules were implemented
  - Asserting "right" to take photographs
  - Inspections have become more detailed, emphasizing:
    - Basic sanitation
    - Allergen control
    - Personnel adherence to GMPs

Inspections

- Collection of samples
  - Product
  - Labels
  - Packaging
- Finished product testing
- Interviewing employees
- Observing employee practices
- Can you support your written programs?

Inspections

- Environmental testing samples
  - Potentially hundreds of swabs
- Focusing on companies considered high-risk
- Challenging your environmental testing program
  - Frequency
  - Procedure
  - Qualified technicians
  - Corrective actions

Question

What's your policy when an inspector requests to swab the facility?

Inspection Results

- Inspection results between 10/1/12 – 9/30/13
  - Number of food F483s issued = 2,386 (47%)
- Top six issues (56% of the 2,386 issued)

1. Lack of effective pest exclusion
2. Sanitation monitoring
   - Failure to maintain hand washing, hand sanitizing, and toilet facilities
   - Failure to protect food, food packaging material, and food contact surfaces from adulteration

Inspection Results

3. Screening
   - Failure to provide adequate screening or other protection devices against pests
4. HACCP plan implementation
   - Did not implement the monitoring, verification, or record keeping procedures listed in the HACCP plan

Inspection Results

5. Food safety hazards
   - HACCP plan does not list hazards that are reasonable or likely to occur
   - Plan not written to be followed
6. Structure
   - Plant not constructed to allow adequate cleaning and kept clean

2013 FY FDA's Office of Regulatory Affairs Results

- 10 injunctions and consent decrees against food and dietary supplement firms
- 5 seizures
- Classified 309 Class 1 recalls
- Issued 1,006 import alert notices
- 14 food-related arrests
- 16 food-related convictions
- Collected US $18M in fines and restitution

Topic/Section

Responding to Form 483

What to do?

483's Increasing

- Recently released 483'S indicate plants are not prepared for more aggressive inspections
- Can you defend your written programs
- Have you prepared the employees for FDA interviews?

Responding to Form 483

- Respond in writing within 15 business days
- Report all corrective actions taken
  - Include a timetable (if necessary)
- FDA reviews response
  - Follow-up actions may include:
    - Follow-up inspection
    - Warning letter
    - Registration suspension

Topic/Section

Questions

- Are you ready?
- Are you concerned?
- Is there anything new here?

Preparing for FDA visit

- Is the PCQI identified?
- Are records electronic or hard copies?
- What is your policy on photographs?
- Are preventative control records signed and dated?
- Is your HACCP and Food Safety Plan up to date?

Preparing for FDA visit

- Who is the first line of contact?
- Is there a designated meeting area?
- Is there a designated team to handle inspections?
- Does the security guard or receptionist know what to ask when investigator arrives?
- How much time do you have them wait?
- Do you know your rights?
- When was the last time you reviewed your visitor policy for regulatory visits?

Key Takeaways

- FDA's primary goal for FSMA is to reduce injury and illness resulting from food safety failures
- Inspections will be conducted by those with training and experience related to food and feed
  - FDA will rely more on state inspectors
- FDA plans to make subject matter experts and an inspection portal/database available to facilities
- FDA will educate importers about FSVP while encouraging a greater focus on preventive controls

Key Takeaways

- FDA will issue guidance documents to clarify the rules
- Inspections are more assertive, comprehensive, and enforcement oriented
  - Penalties for noncompliance are more severe
- Develop your Food Safety Plan and prepare for regulatory inspections now

Questions?