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Perspectives on FDA Inspections

October 10, 2012

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Presentation to the American Spice Trade Association
2012 ASTA Regulatory/Legislative Workshop

Agenda

- Culture Change at the FDA
- Factory Inspections Today
- Preparing for an FDA Inspection
- Changes Under FSMA

Audience Questions

Culture Change at the FDA

FDA Culture is Changing

- FSMA implementation is occurring just as FDA culture is changing
- FDA is rapidly becoming:
  - More inspection-oriented
  - More enforcement-minded

FDA is More Inspection-Oriented

- FDA is:
  - Conducting more domestic inspections (with the states)
  - More strategic about selecting inspection sites
  - Posting some 483s on website
  - Expanding definition of “high risk”
    - Includes spices
  - Testing more, both environmental and finished product
  - Increasing oversight of imports, especially ingredients, and conducting foreign on-site inspections

Enforcement is on the Rise

- Increase in Warning Letters for food adulteration based on food inspections/GMPs
- Increase in court injunctions
- Heightened use of Import Alerts
- Reinspection fees for repeat inspections
- New authorities for mandatory recalls and suspension of registration are now in play
- Expanded use of *Park Doctrine* on the horizon

What Does This Mean?

- FDA's expectations will change
- Inspections will change
- Testing will increase
- Imported ingredients will face particular scrutiny
- Crackdowns will increase in frequency

Food companies need to adapt to these changes.

Impact for Inspections

- Inspections have already changed:
  - FDA is energized and persistent and will note all possible violations as inspectional observations
  - FDA will demand access to records the agency lacks the legal authority to access
  - FDA will try hard to take photographs even without express legal authority
  - Inspections involve comprehensive environmental sampling (“swab-a-thon”)

Factory Inspections Today

Inspection Frequency

- Increased frequency of inspections is mandated by FSMA:
  - Domestic High-Risk Facilities: Once within 5 years after FSMA enactment and at least every 3 years thereafter
  - Domestic Non-High-Risk Facilities: Once within 7 years after FSMA enactment and at least every 5 years thereafter
  - Foreign Inspections: 600 in the first year after enactment, doubling for each of the next 5 years (e.g., 1,200 in 2012; 19,200 in 2016)

Foreign Inspections

- FDA is announcing foreign inspections in advance
  - Foreign inspections are being conducted in conjunction with foreign governments
- If you receive notice that FDA is planning to inspect a facility located overseas, it is important to prepare in advance
- Once the investigators arrive, follow the same approach you would for a domestic inspection
- Inspection results will impact ability to import:
  - Could result in Import Alerts or increased sampling at the border

Audience Questions

Environmental Sampling

- FDA has learned that it is easier to find a pathogen in the environment than in food
- FDA now will descend on a company with a team of investigators that will take environmental samples
- Dubbed a “swab-a-thon”
- Focus on *Salmonella* in a “dry” plant and *Listeria* in a “wet” plant
- Consider adopting test-and-hold policy if FDA takes environmental samples

Inspectional Observations

- 483 Inspectional Observations
  - A few years ago, investigators would note minor observations orally but would not record them
  - Today, minor observations are included in the Form 483
  - Unusual for a company to escape an inspection without receiving a 483
- FDA policy announced in August 2009 gives industry 15 business days to provide a response
- **Absolutely essential** to respond, in writing, to every 483 observation within the 15 period

Reinspection Fees

- FY 2013 reinspection fee rates (per person):
  - $221/hour domestic
  - $289/hour if foreign travel required
- Reinspection fees apply if the previous inspection was "Official Action Indicated" and the noncompliance was materially related to food safety
  - OAI = You received a Warning Letter
- Fees are being accrued, but FDA is not yet sending bills
- For foreign facilities, the U.S. agent listed on the facility registration is responsible for paying reinspection fees incurred by the foreign facility

Preparing for an Inspection

Audience Questions

Preparing for an Inspection

- Key issues to decide in advance of an inspection:
  1. Access to Records
  2. Use of Cameras
  3. Affidavits

Records Access

- For a “routine” inspection, FDA has very limited access to records:
  - List of products shipped and to where
  - Shipping records of ingredients received by company
- FDA often asks for (and frequently demands) many more records, even when no legal authority exists
- Companies should make an informed decision about whether to voluntarily release additional information

Records Access

- FDA will ask for but is not (yet) legally entitled to receive the following during routine inspections:
  - HACCP Plans
  - Food Safety Monitoring Records
  - Corrective Actions
  - Environmental and Product Testing
  - Validation Records
  - Consumer Complaints

Records Access

Options for FDA records access:

1. Only allow access to required records
2. Allow access to a pre-determined subset of discretionary records
3. Decide on a case-by-case basis, depending on the request
4. Establish a “Look but don’t copy” policy
5. Allow access and copying for any records

Photographs and Video Cameras

- Cameras are one of the most contentious issues with inspectors
- Concerns with cameras:
  1. Cameras will capture proprietary aspects of the manufacturing operation and the information could be disclosed unintentionally
     - Concerns for FOIA requests
  2. Information obtained during an inspection is evidence that will be admissible in court
  3. A picture is much more difficult to challenge than oral testimony

Photographs and Video Cameras

- Inspectors are advised to push hard on their desire to bring in cameras
- Inspectors will insist they have the right to use cameras
  - There is no definitive legal authority on this issue
- If you do not want to allow photos, you must stay calm and make it clear you are not denying the inspection, but are simply not allowing the inspector to take the camera into the manufacturing area of the facility

Photographs and Video Cameras

- Companies should establish a written policy and stick to it
  - Direct the inspector to the policy before the inspection
  - It can be difficult and it will be contentious, but if you want to keep the camera out of the facility, you typically will prevail
  - If you decide to allow photographs, take duplicates

Photographs and Video Cameras

- New IOM Procedures
  - Inspector may ask for name of senior personnel or company lawyer
  - Inspector may provide that information to District management
  - District Office may contact FDA Office of Chief Counsel
  - FDA lawyer may call company lawyer to discuss

Affidavits

- Inspectors typically will ask companies to sign affidavits (FDA 463a) during or after inspections
- You are not required to sign an affidavit
- We advise our clients that they should not sign affidavits
- At a minimum, affidavits should not be signed until they are first reviewed by your corporate or outside counsel

Changes to Come

Inspections – Changes to Come

- Historically, FDA has inspected food processing facilities for basic sanitation and to detect visible problems with the facility or the product produced
- Under FSMA, FDA also will focus on whether facilities are implementing the systems needed to make safe food
  - This “systems-based” approach is aimed at preventing problems on a continuing basis, not just when the inspector is in the facility
- This change is consistent with a main theme of FSMA: Move from reaction to prevention

Inspections – Changes to Come

- FDA will have increased access to a broad range of records, including food safety plans and implementation documents
- FDA will carefully review records, focusing on monitoring for CCPs and documentation of corrective actions
- **Complete documentation will be critical!**
  - **If you didn't document it, it didn't happen!**

Records Access Will be Central Feature of FSMA Inspections

- Records you will need to have ready:
  - Hazard Analysis
  - Food Safety Plan (with designated controls)
  - Scientific basis for preventive controls
  - Monitoring records
  - Corrective actions
  - Verification, including environmental and product testing
  - Consumer complaints related to food safety
  - Supply chain oversight (domestic and foreign)
  - Recall plan and records of any recalls conducted

Conclusion

- FDA's enforcement-minded culture is affecting the nature of inspections
  - More scrutiny and focus on finding violations
  - High emphasis on taking photographs
- It is important to be prepared for an inspection at any time
- More inspection changes are coming under FSMA

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