Product Safety from Varied Perspectives: A Culture, Systems and Legal Approach

Feed and Pet Food Joint Conference

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Overview

I. Brief Review of Two Provisions of New FSMA "Preventive Controls" Rule
   A. Subpart E – Supply-Chain Program
   B. Subpart F – Records-Related Requirements
II. Consequences of Failing to Comply with New Requirements
III. Examples of FDA Objections During Inspections of Animal Feed and Pet Food Manufacturers
IV. Inspection Do's and Don'ts

I.A. Subpart E – Supply-Chain Program

1. History
2. Applicability
   a. Receiving facility (typically finished product manufacturer) has identified hazard at its raw material supplier that requires a supply-chain applied control. If receiving facility controls hazard, no supply-chain applied control necessary.
   b. If receiving facility is importer that complies with FSVP requirement (including documentation of verification activities) not required to conduct supplier verification activities
   c. Not applicable to animal food supplied for research and evaluation use

I.A. Subpart E – Supply-Chain Program (cont'd)

3. General Requirements
   a. Must be written
   b. Must include:
      - using approved suppliers only
      - determining appropriate supplier verification activities
      - conducting supplier verification activities
      - documenting supplier verification activities
      - when applicable, verifying a control applied by an entity other than the receiving facility's supplier
   c. Must provide assurance that hazard requiring control has been significantly minimized or prevented

I.A. Subpart E – Supply-Chain Program (cont'd)

3. General Requirements (cont'd)

d. Examples of supplier verification activities

- onsite audits
- sampling and testing raw material/ingredient
- reviewing supplier's relevant food safety records

I.B. Subpart F – Records-Related Requirements

1. Compliance is document intensive (to say the least)
2. All records must be made available to FDA for review or copying upon oral or written request
3. Records subject to FOIA, including exemptions
4. Must be maintained for ≥ 2 years after preparation (3 years for documentation of qualified facility status)
5. Food Safety Plan must be onsite
6. All other documents can be stored off-site if retrievable within 24 hours

I.B. Subpart F – Records-Related Requirements

7. Additional Requirements
   - Don't need a single set of "FSMA Records"
   - Original records, true copies, or electronic records acceptable (no Part 11 compliance required)
   - Actual values and observations
   - Accurate, indelible, and legible
   - Created concurrently with activity documented
   - As detailed as necessary to provide history of work performed
   - Must identify plant or facility
   - Dated (including time if appropriate)
   - Signature or initials of person
   - Where appropriate, identify product and lot code
   - Owner/operator/agent in charge must sign and date Food Safety Plan

"I think I've discovered where the problem is."

I.B. Subpart F – Records-Related Requirements

8. Additional Thoughts
    1. The Lorax would not like FSMA regs
    2. Insufficient to “merely” do what you say – documentation is critical
    3. Make sure you do what you say
    4. Training will be imperative
    5. Monitor enforcement

II. Consequences of Failing to Comply with New Requirements

A. Failure to comply with new GMPs may render product adulterated

B. Distribution of adulterated food is prohibited act

C. Failure to comply with Preventive Controls rule is a prohibited act

D. FDA can pursue the following remedies:
   - Administrative Detention
   - Injunction
   - Seizure
   - Civil and criminal fines and penalties

III. Examples of FDA Objections

A. Feed Mills

- Cleaning and sanitation issues throughout facility and at different places on manufacturing line
- Inadequate pest control
- Failure to screen for foreign objects
- Failure to protect finished product from contamination by raw ingredients
- Poor storage practices
- Labeling insufficiencies
- Medicated feed issues (separate GMPs)

III. Examples of FDA Objections (cont'd)

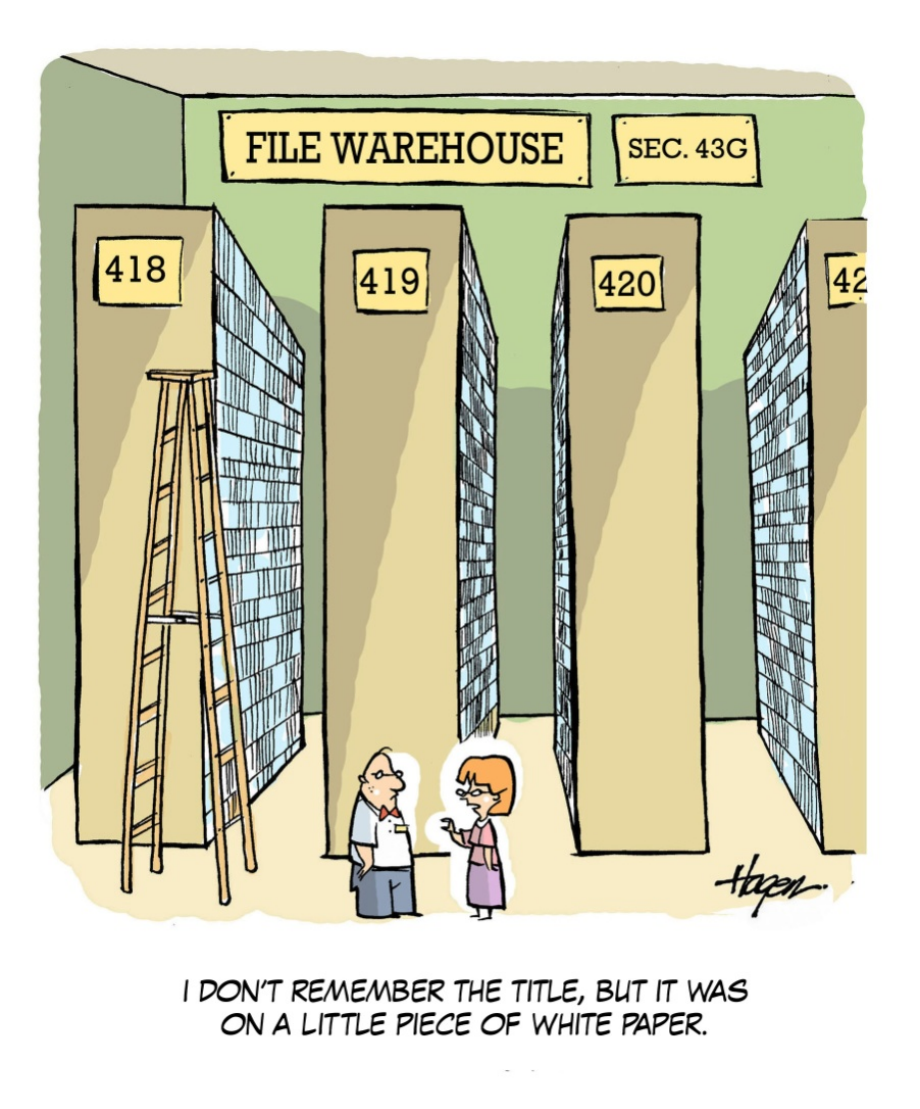
B. Pet Food Manufacturers

- Cleaning and sanitation issues
- Equipment maintenance failures leading to potential contamination
- Inadequate pest control
- Failure to protect finished product from pathogen contamination
- Low-acid canned food manufacturing violations
- Labeling violations

IV. Inspection Do's and Don'ts

A. Pre-Inspection Preparation

- Prepare inspection SOP
- Train on inspection SOP
- Review prior inspections to confirm corrective actions
- Know what records FDA has a right to inspect and where to find them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IV. Inspection Do's and Don'ts (cont'd)

B. During Inspection

- Appreciate role of inspector
- Have designated area for inspector to review dox
- Photographs?
- Correct deficiencies during inspection if appropriate and possible
- Just the facts, ma'am
- Tell the truth
- Do not sign affidavits
- If warrant presented, contact your lawyer ASAP
- Respond promptly to 483 Observations