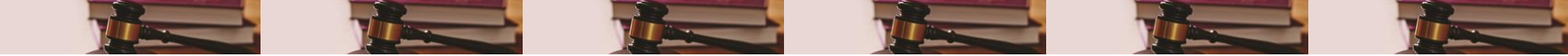

FDLI ENFORCEMENT, LITIGATION, AND COMPLIANCE CONFERENCE – DECEMBER 6 – 7, 2017

FSMA ENFORCEMENT – THE FIRST YEAR
A FEW LESSONS LEARNED FROM THE INSPECTION PROCESS

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FDLI

Inspections

- Under Section 704 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 374, an FDA inspector has the authority to enter and inspect “at reasonable times,” “within reasonable limits,” and in a “reasonable manner,” any establishment in which food is manufactured, processed, packed, or held before or after introduction to interstate commerce.

Inspections

- What is the scope of the visit?
  - Distinction between Preventive Controls and GMP inspections?
  - Significant change in approach?

Inspections

- Average inspection time—between 4-5 days, or even longer.
  - Multiple days if significant issues found.
  - Learning curve on both sides.

Inspections

- Heavy focus on records, such as corrective action logs, production schedules, sanitation records, and calibrating inspection equipment.
  - Be prepared.

Inspections

- Focus on container packaging and labeling (immediate and bulk)
  - Will review contamination risks of these products.
  - Testing.

Inspections

- Complaint investigation —
  - What do you share?
    - FDA based complaints or internally-handled complaints or complaints from other sources?

Inspections

- Written recall plan.
  - Even if no immediate need to implement, will ask to review.

Inspections

- Photographs at your facilities.
  - If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions. If management of a drug firm does not give a reasonable explanation for its objection, such as a showing that the chemical properties of products manufactured at the facility are such that taking photographs would adversely affect product quality, you may advise management that the refusal may constitute a limiting of the inspection under Section 501(j) [21 U.S.C. 551(j)] of the FD&C. **Investigation Operations Manual** §5.3.4.1.

Inspections

- **Guidance for Industry Circumstances that Constitute Delaying, Denying, Limiting or Refusing a Drug Inspection**.
  - The Guidance defines the various types of actions, inaction, and circumstances that the FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of FDCA § 501(j).
    - Impeding or resisting photography by an FDA investigator may be considered a limitation if such photographs are determined by the investigator to be necessary to effectively conduct that particular inspection.

Inspections

- Organization charts.
  - Contains proprietary data, as well as personal employee information.
  - But, can walk inspectors through the organizational chart and answers any questions inspectors may have about it.

Inspections

- The key is to be prepared.
- Ensure your policies comply with regulations.
- Support from top to bottom.
- Cooperation.