Implementing Effective Remediation & Corrective Action Plans Post-Inspection

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Overview

- Responding to a FDA 483 Report of Investigation
- Preparing & Implementing Post-Inspection Corrective Action or Reconditioning Plans
- Lessons Learned from the Dominguez Food Case

FDA 483 Report of Observations

What is it?

- The Form FDA 483 Inspectional Observations ("483 Investigation Report") is used to provide written notice of **significant objectionable conditions** related to products and/or processes, or other violations of the FD&C Act, that were observed during an inspection.
- The 483 Investigation Reports are made when, in the **investigator's judgment**, conditions or practices are observed that indicate that any food product is adulterated or that is being prepared, packed or held under conditions that may cause the food product to become adulterated or rendered injurious to health.

The 483 Response

- There is no legal requirement to respond to the 483 Investigation Report…
- However, it is in your best interest to fully respond in writing and in a timely manner!
- As a matter of policy, the FDA expects a response.
- A well-reasoned and thoughtful response demonstrates that the company takes the lists of observations seriously and wants to bring the company into compliance.
- The goal of any response is to avoid a seizure, enforcement action or other adverse consequence.

The 483 Response

IMPORTANT – Timing Information:

- The FDA will perform a detailed review of any response to the FDA 483 Investigation Report it receives within 15 days of issuance.
- The FDA is free to issue a warning letter or to initiate an enforcement action after the 15 day response period.
- Immediate action may be initiated for egregious violations.

The 483 Response

Drafting Considerations:

- Decide whether the company intends to challenge the 483 Investigation Report's observations.
- Know and understand the inspection process and the company's rights.
- Know your audience (i.e. Investigator or District).
- Understand that a 483 Response is your opportunity to address the same FDA official that is responsible for reviewing and classifying the 483 Investigation Report.
- Understand that your 483 Response may become public.
- Understand each observation and the rationale behind said observation.

The 483 Response

Important High-Level Content:

- Leadership commitment and cooperation statement.
- Identification of individuals responsible for implementing and managing the plan.

The 483 Response

Detailed Content (response format):

- A restatement or summary of each observation to show understanding.
- A detailed response to each observation.
- A detailed description of the corrective action the firm intends to take to fix the problem or correct the non-compliance.
- Timeline for completion.

483 Response Best Practices

Best Practices:

- Set clear and obtainable completion dates.
- Allocate resources so that all corrective actions may be completed within the 15 day response window, if possible.
- The 483 Response should be complete, well organized, factually accurate and proof-read.
- Don't write anything that you do want to become public.
- Know the rules.
- Follow the observation response format.

Annotation of the FDA 483 Report

The FDA 483 Investigation Report may be Annotated!

- Annotation is voluntary on the part of the establishment.
- Annotation is proper when the establishment has promised and/or completed a corrective action to a FDA 483 observation **prior to the completion of the inspection**.

  - Annotations appear as follows:
  - Reported corrected, not verified
  - Corrected and verified
  - Promised to correct
  - Under consideration
  - Completion dates may be included in the annotations

Corrective Action Plans

483 Response vs. Corrective Action Plan:

- A proper 483 Response necessarily includes a Corrective Action Plan ("CAP").
- Unlike a 483 Response, a CAP can be, and often is, a **separate document** used strategically to influence the content of final 483 Investigation Report by addressing as many of the observations as possible before the report is forwarded to the District Office for evaluation.

Corrective Action Plans

IMPORTANT – Timing Information:

- A CAP **may** be submitted **prior to the completion** of the inspection in an effort to have the 483 Report of Investigation annotated prior to submission to the District Office.
- If the observed noncompliance issues cannot be fixed immediately, the CAP should be submitted ASAP following the FDA's tender of the 483 Investigation Report.

Corrective Action Plans

Important High-Level Content (standalone document):

- Leadership commitment and cooperation statement.
- Statement of election not to challenge the content of the 483 Investigation Report.
- Identification of individuals responsible for implementing and managing the CAP.
- Statement of key facts or disclosures, if appropriate (i.e. the planned closure of a facility).
- Resource allocation statement (i.e. how are you going to deploy resources to execute the plan?)
- Must include an employee training element.

Corrective Action Plans

Detailed Content :

- Response to each specific observation addressed in the CAP.
- Root cause analysis = ???? (do it & show it)
- Specific & detailed plan to remedy the root cause.
- Specific & detailed plan to ensure the problem will not or cannot reoccur (i.e. prepare and adopt a relevant standard operating procedure)
- Timeline for completing each remedial action contained in the CAP.

Corrective Action Plans

Best Practices:

- Be involved and in control of any FDA inspection of your establishment.
- Allocate the resources necessary to correct non-compliance observations before the completion of the inspection.
- The CAP should be complete, well organized and tailored to remedy the observed non-compliance.
- Be creative and practical.

Reconditioning Adulterated Food Products

Key Definitions:

- **Reconditioning**: the reworking, relabeling, segregation, or other manipulation which brings the product into compliance with the law.
- **Destruction**: the procedures involved in rendering a product unsalvageable.

Reconditioning Adulterated Food Products

The FDA will generally accept reconditioning proposals for foods deemed adulterated under §402(a)(4) conditions when such proposals include provisions for determining:

- Whether the food has become physically contaminated,
- The extent and type of any contamination, and
- Procedures that will result in the elimination of such contamination.

Reconditioning Adulterated Food Products

IMPORTANT FACT - a §402(a)(4) violation is considered an **environmental charge**!

- A reconditioning proposal must also provide for the removal or correction of the conditions that cause the products to be adulterated.
- The conditions addressed must include both the product itself and the environment found within the inspected facility.

Reconditioning Adulterated Food Products

Examples of Facility Corrections:

- Contracting with certified third parties to perform certain services (i.e. an exterminator).
- Performing structural modifications to the inspected facility.
- Moving the adulterated food products.
- Segregating the adulterated food products.
- Destroying the adulterated food products.

Reconditioning Adulterated Food Products

Reconditioning Plan Considerations:

- How long will it take to execute.
- Amount of labor needed to execute.
- Proper supervision provided.
- FDA/Dept. of Ag. buy-in required.
- Obtain proper authority to move and handle product.
- Document everything!!!!

Reconditioning Adulterated Food Products

Best Practices:

- Be creative and practical.
- Allocate the resources necessary to correct non-compliance observations before the completion of the inspection.
- Seek out proper oversight and verification.
- Consider involving your state's Dept. of Agriculture.
- Make sure your plan is scalable
- Maintain an element of flexibility for on the fly changes and additional authority.

Dominguez Foods

Background:

- Dominguez Foods operates a food storage and processing facility in Washington State.
- In October of 2011, the FDA inspected the facility and found evidence of widespread and active rodent activity.
- A Court Order was obtained authorizing the U.S. Marshalls to seize the food products.
- Under the FSMA, the FDA ordered the food detained until a court order could be obtained.

Dominguez Foods

Interesting Facts:

- The FDA's investigation of Dominguez lasted for 10 days.
- Evidence of a rodent infestation includes, urine stains, rodent waste, gnawing marks and a dead rodent.
- No evidence of a live mouse was found.
- No mention of the adequacy or existence of any existing pest control devices/plans.
- Complaint contained speculation about how the facility became infested (i.e. cracks or holes in the wall)

Dominguez Foods

Lessons Learned:

- The FDA will run to Court if they think there is a serious health problem.
- Don't let the FDA get to the point where everything that happens occurs under Court supervision, which is highly public.
- 10 Days is plenty of time to correct many of the FDA's observations and to get that 483 Investigation Report annotated.
- Complaint contained speculation about how the facility became infested (i.e. cracks or holes in the wall)
- If the Court makes you prepare a Reconditioning Plan they will most likely require you to hire an expert.

Continue the Discussion

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