# ASSOCIATES CORNER

## Planning and Preparation: Making FDA Inspection a Positive Experience

*by Ann Peper Havelka*

Although few in the food industry may relish the thought, an inspection by Food and Drug Administration (FDA) representatives is likely in their future. Rather than dreading this experience, companies should view an FDA inspection as a positive, collaborative process. FDA has the authority to enter and inspect any establishment where food is manufactured, processed, packed or held for introduction into interstate commerce.[1]

To inspect food establishments, FDA inspectors must show their credentials and provide written notice of inspection using Form FDA 482. Because FDA is not required to give food entities advance warning of an inspection, the best course of action is to be prepared well before an inspection ever occurs. Companies should:

(1) develop written inspection policies;
(2) identify the individual(s) responsible for interacting with FDA inspectors;
(3) audit and test compliance with written inspection policies; and
(4) conscientiously respond to FDA inspectors' questions and areas of concern.

Management, legal, operations and quality assurance employees should all have input in drafting written inspection policies that take into account each business's unique operations and needs. The policies should emphasize that inspectors have a legal right to investigate and ask questions, answers should be provided (but only within an individual's scope of knowledge and authority) without becoming defensive, and all employees should treat inspectors cordially and professionally. These written policies should be communicated to all individuals who may become involved in the inspection process. In addition, written policies should identify the individual who is responsible for coordinating or "hosting" the inspection. The host should be familiar with day-to-day operations and quality-assurance policies — and able to communicate the rationale behind those decisions; understand the laws, regulations, and good manufacturing practices that govern the product(s) at issue; recognize the inspectors' right to inspect the facility — and the limits on that authority; understand the purpose of the inspection; and facilitate communication between the inspectors and company personnel.

A "cheat sheet" or summary folder of relevant information for the host may aid the inspection process. This summary could include, among other things: contact information for management, legal and quality assurance personnel; a description of plant operations; the location of records; a list of relevant regulations and good manufacturing practices; and records of past FDA inspections. The summary materials — and inspection policies in general — are only as good as their execution. They cannot be filed away, only to be pulled out when an inspector walks through the door. Rather, these materials should be updated and reviewed on a regular basis, and a company may want to consider enlisting a consultant to play the part of FDA inspector in order to test the efficacy of inspection policies and procedures — and identify any potential areas of concern *before* they become an issue.

### Inspection Process

Inspections generally begin with a walk-through of the premises. Inspectors will be judging the scale of the operation and learning about products, processes and recordkeeping during this time. Inspectors will also be on the lookout for obvious areas of concern such as general housekeeping, employee behavior and process weaknesses. The inspection will then turn to more specific areas described in the 2008 FDA

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Investigations Operations Manual for food inspections.[2] The designated host should remain with the inspectors at all times, providing a face for the inspected entity and directing inspectors to the employees best able to answer their questions.

At the end of the inspection, the FDA inspector will summarize his or her findings with the host employee and any other facility or company management present. Unless the inspection was extremely complicated and will require follow-up, the inspector will leave a completed Form FDA 483 at the end of the inspection outlining any potential violative conditions. Form 483 observations may include: practices or conditions that may lead to contamination; unsanitary conditions or practices; careless handling of poisons such as weed or pest killer; and violations of good manufacturing practices, including recordkeeping.

## Taking Corrective Actions

Inspectors may ask management what corrective actions will be taken. Although an immediate response may not be available, the company should appear to be receptive and responsive to the inspector's observations. Communicating the desire to correct any errors is more important than having answers on the spot. After the inspection, the host employee should provide a detailed report of the inspection visit, including the inspectors' questions and the answers given, documents viewed by the inspectors, and any of the inspectors' comments. The Forms FDA 482 and 483 (and 484, if samples were taken) should be attached to this report. The report should be discussed with management, legal, operations and quality control employees to determine what corrective action is needed. A timely formal written response to the Form 483 observations is usually the best course of action. The tone of the response should again be cordial and responsive, outlining all corrective actions that have been taken, and a timeline for implementing any corrective actions that have not yet been put into place. If significant operations improvements are needed, the company might want to consider hiring an outside consultant to bring the process into regulatory compliance.

### Inspection Preparation Checklist

- Draft inspection policies with input from management, legal, regulatory, operations and quality assurance employees;
- Identify an employee or position who will "host" the FDA inspection;
- Prepare inspection preparation materials that will serve as a "cheat sheet" for the inspection host;
- Update, test and audit inspection policies and procedures;
- Be responsive, courteous and professional in all interactions with FDA inspectors;
- Do not guess or estimate—it is better to identify the employee who can provide the information or ask for time to look into an issue while the investigation continues;
- Summarize the inspection for interested company personnel and draft a comprehensive and professional response to all FDA Form 483 observations;
- Provide a careful, reasoned discussion for any areas in which the organization disagrees with the 483 observations; and
- Implement all promised changes and improvements.

1 21 U.S.C. § 374.

2 *Available at* http://www.fda.gov/ora/inspect_ref/iom/ChapterText/5_4.html.