



# Rights and Obligations During FDA Inspections

## Guidance for the Grain, Feed and Processing Industry

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# Rights and Obligations During FDA Inspections

## Guidance for the Grain, Feed and Processing Industry

### Role of FDA in Overseeing the Safety of the U.S. Food and Feed Supply

The U.S. Food and Drug Administration (FDA), as authorized by the federal Food, Drug and Cosmetic Act (FFDCA)<sup>(1)</sup> and the Public Health Service Act, regulates the safety of foods, including animal feed and pet food, other than the meat, poultry and egg products (which are under the jurisdiction of the U.S. Department of Agriculture). FDA also is responsible for the safety of human drugs, medical devices, biologics, cosmetics and radiation emitting devices.

To oversee the safety of human food, animal feed and pet food, FDA activities are divided between two centers:

- The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for promoting and protecting the public's health by ensuring that the nation's human food supply is safe, sanitary, wholesome, and honestly labeled, and that dietary supplements and cosmetic products are safe and properly labeled.
- The Center for Veterinary Medicine (CVM) is responsible for ensuring that animal drugs are safe and effective, and that food for animals – which includes animal feed, pet food, and pet treats, as well as ingredients and agricultural commodities used to produce such products – is safe, stored and made under sanitary conditions, and properly labeled.

FDA's authority to regulate human food, animal feed and pet food is provided by the FFDCA. The FFDCA defines "food" as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." As such, the term "food" encompasses human food, animal feed and pet food, and components

#### Editor's Note

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The National Grain and Feed Association (NGFA) has developed this guidance to assist the grain, feed and processing industry in understanding its rights and obligations during facility inspections conducted by the U.S. Food and Drug Administration (FDA). The topics discussed and guidance provided in this document are not intended to be formal recommendations or advice. Nor is this document intended to be a comprehensive compilation of all of FDA's regulations and policies that apply to the grain, feed and processing industry.

This guidance was developed with the assistance of the NGFA's Feed Legislative and Regulatory Affairs Committee and Feed Manufacturing and Technology Committee. Questions about the content and subject matter of this document should be directed to – and additional information is available from – NGFA Vice President for Feed Services David Fairfield at 712-243-4035, or by email at dfairfield@ngfa.org.

used to make such products, such as grains, oilseeds, animal- and plant-based ingredients, minerals, vitamins and other items.

FDA has broad authority provided under the FFDCA to establish regulations to ensure food products are not “adulterated” or “misbranded.”

- **Adulteration** is a legal term used by FDA to define a condition whereby a food is deemed to be unfit for its intended use. Among other things, FDA may deem a food to be adulterated if it: 1) is missing a valuable constituent; 2) contains a poisonous or deleterious substance that may render the food injurious to health; 3) has been prepared, packed or held under insanitary conditions; and 4) is not produced and distributed in conformance with applicable FDA regulations.
- **Misbranding** is a legal term used by FDA to define a condition whereby a food is not labeled properly. Among other things, FDA may deem a food to be misbranded if: 1) it is labeled in a false or misleading manner; 2) it is offered for sale under the name of another food; and 3) any word, statement, or other information required by FDA to appear on the label or labeling is not prominently placed thereon.

FDA’s authority provides the agency’s investigators the right to inspect facilities to evaluate whether human food, animal feed and pet food are being held (stored), processed, packed and distributed in accordance with provisions of the FFDCA.

Among relevant provisions, regulations and agency guidance associated with FDA’s authority are:

- **FDA Guidance Levels for Mycotoxins:** FDA has established action and guidance levels for aflatoxin, deoxynivalenol (vomitoxin) and fumonisin.<sup>(2)</sup>
- **Current Good Manufacturing Practices (CGMPs) for Human Food:** 21 Code of Federal Regulations (CFR) Part 110 details FDA’s CGMPs for the manufacture and distribution of human food.<sup>(3)</sup>
- **CGMPs for Medicated Animal Feed:** FDA’s CGMPs for the manufacture and distribution of medicated animal feed are found at 21 CFR Part 225.<sup>(4)</sup>
- **CGMPs for Animal Drugs:** 21 CFR Part 226 provides CGMPs for the manufacture and distribution of animal drugs.<sup>(5)</sup>
- **Prevention of Bovine Spongiform Encephalopathy (BSE):** 21 CFR Part 589.2000 and 21 CFR Part 589.2001 specifies FDA’s BSE-prevention regulations.<sup>(6)</sup>
- **Food and Drug Administration Amendments Act (FDAAA) of 2007:** This Act amended the FFDCA to provide for the Reportable Food Registry.<sup>(7)</sup> Under FDAAA, responsible parties at food facilities registered with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) are obligated to report to FDA through the agency’s electronic portal as soon as possible, but no later than 24 hours, after determining that a food is “reportable.” A food is “reportable” if it is an article of food (other than dietary supplements or infant formula) for which

there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

- **Bioterrorism Act:** The Bioterrorism Act authorizes FDA to take actions to protect the nation's food supply against the threat of intentional contamination. In accordance with the law, FDA has developed and implemented food, animal feed and pet food safety measures, including the following major regulations:
  - **Registration of Food Facilities<sup>(8)</sup>:** Domestic or foreign facilities that manufacture, process, pack, distribute, receive, or hold food for consumption by humans or animals in the United States are to register with FDA as a "food" facility. Covered facilities include those involved in grain handling, grain processing, feed manufacturing, grain exporting and others. Facilities may register through FDA's web-based electronic portal.
  - **Prior Notice of Imported Food<sup>(9)</sup>:** Beginning Dec. 12, 2003, importers were required to provide FDA advance notice of each shipment of food being offered for import into the United States.
  - **Establishment and Maintenance of Records<sup>(10)</sup>:** Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food are required to create and maintain records to identify the immediate previous sources and the immediate subsequent recipients of food (i.e., where the food came from and who received the food). The term "persons" includes individuals, partnerships, corporations and associations. In addition, the records established and maintained by facilities that manufacture, process or pack food also must include lot or code numbers or other identifiers if such information exists. The records are to include information that is reasonably available to identify the specific source of each ingredient that was used to make each lot of finished product.
  - **Administrative Detention:** FDA is authorized to administratively detain food if the agency has "credible evidence or information" that the food presents a threat of serious adverse health consequences or death to humans or animals.
- **Food Safety Modernization Act (FSMA)<sup>(11)</sup>:** This expansive law, enacted on Jan. 4, 2011, modified the FFDCA and mandates that FDA issue significant new regulations to ensure the safety of human food, animal feed and pet food. FDA's FSMA-related rulemaking process was underway at the time this guidance was published.

As well as mandating new regulations, FSMA also expanded FDA's authority in several key areas, including:

- **Food Facility Reregistration:** The law mandates that domestic and foreign facilities already required under the Bioterrorism Act to register with FDA renew and update those registrations every two years. The registration renewals are required to occur between Oct. 1 and Dec. 31 of even-numbered years, starting in 2012.

- **Suspension of Facility Registration:** FSMA authorizes FDA to suspend a facility's registration – in essence, shutting it down – if it determines there is a “reasonable probability” that its products could “cause serious adverse health consequences or death” to humans or animals. If this threshold is met, FDA has the authority to suspend the registration of: 1) the facility(ies) that created, caused or otherwise was responsible for the adulteration; or 2) any facility that packed, received or stored such products and knew of, or had reason to know, that it was handling such a product.
- **Increased Authority to Detain Food:** FSMA expands FDA’s authority to administratively detain a product when it has “reason to believe” that it is adulterated or misbranded. This is a lower standard than the Bioterrorism Act threshold that requires FDA to have “credible evidence or information” indicating that the product “presents a threat of (causing) serious adverse health consequences or death to humans or animals.”
- **Mandatory Recalls:** FDA is authorized to issue mandatory recalls if it determines there is a “reasonable probability” that an article of food (other than infant formula) is adulterated or misbranded, and that use of, or exposure to, the product would cause serious adverse health consequences or death to humans or animals.

In addition to federal requirements, states also have laws and regulations to govern the production and distribution of human food, animal feed and pet food products. Most state laws and regulations are modeled after those established by the FFDCA.

## FDA’s Authority to Inspect Facilities

FDA’s general authority to inspect human food, animal feed and pet food facilities is found within section 704 of the FFDCA.<sup>(12)</sup>

Based upon this general authority, it is a “prohibited act” for regulated facilities to refuse to permit access to or copying of any record required under FDA’s regulations, or to refuse to permit entry or inspection of a facility or vehicle. FDA is not obligated to have a warrant for conducting an inspection. Warrants may be obtained if inspection has been refused completely or when refusals have been encountered during the inspection.

Under its inspection authority, FDA is authorized to: 1) enter “any factory, warehouse, or establishment in which food [is] manufactured, processed, packed, or held ...” and “any vehicle....;” 2) inspect “at reasonable times and within reasonable limits and in a reasonable manner;” and 3) inspect “all pertinent equipment, finished and unfinished materials, containers, and labeling thereon.”

In addition, FDA has special authority to inspect facilities and access records in the event of a food, animal feed or pet food safety incident as follows:

- **Reportable Food Registry:** FDA may inspect records related to “each report received, notification made, and report submitted” to FDA through the Reportable Food Registry for up to two years. Therefore, a company should have (and FDA investigators may review) appropriate procedures governing the reporting of a reportable food.
- **Inspection Authority under the Bioterrorism Act:** If FDA has a reasonable belief that a food, animal feed or pet food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, then, in addition to its general inspection authority, FDA is allowed to have access to and copy records relating to that food, and foods that may be affected similarly. This authority applies to records: 1) pertaining to manufacture, processing, packing, distribution, receipt, holding or importation of such food; 2) associated with Reportable Food Registry reports and notifications; and 3) held in any format – including paper and electronic form.

Significantly, FDA’s records access authority under the Bioterrorism Act does not extend to: 1) recipes (formulas); 2) financial data; 3) pricing data; 4) personnel data; 5) research data; and 6) sales data – other than shipment data pertaining to sales of the food in question.

To invoke this authority, FDA is to present a special written “Notice of Inspection – Request for Records” (Form FDA 482c).

## Types of FDA Inspections

Under its authority, FDA may conduct various types of inspections, including:

- **For Cause:** For cause inspections pertain to public health concerns or animal illness and /or death.
- **Pre-Approval:** Some inspections are conducted to pre-approve a facility to manufacture and distribute certain foods or animal feeds. For example, FDA conducts pre-approval inspections at facilities that apply for a medicated feed mill license.
- **Surveillance:** FDA conducts routine surveillance inspections to evaluate compliance with its regulations. Inspections may address the following topics:
  - Current Good Manufacturing Practices (CGMPs).
  - Prevention of BSE.
  - Sanitation Inspections: Either state or FDA investigators may conduct these inspections, which generally are limited to evaluating for unsanitary conditions or conditions that have the potential to result in an adulterated product. Sanitary inspections primarily are made in the human food industry, but food as defined in the FFDCA includes feed (regardless of whether it is medicated) and raw agricultural commodities, such as grains and oilseeds.

- **Compliance:** These inspections are conducted because FDA has information that suggests problems may or do exist at a facility. Types of information that may generate a compliance inspection include sample analyses, prior inspections, reported information, etc.
- **Criminal:** FDA conducts criminal inspections when information suggests to the agency that serious willful and/or egregious violations of applicable requirements are occurring within a facility.

FDA's inspection protocol is outlined within the agency's Investigations Operations Manual.<sup>(13)</sup>

## Types of Facilities Inspected by FDA

Various types of facilities within the grain, feed and processing industry may be subject to FDA inspections, including:

- **Grain Elevators:** FDA has authority to inspect grain elevators for compliance with general FFDCA provisions. Those pertain primarily to conditions and practices associated with keeping grains and oilseeds from becoming adulterated because of unsanitary conditions.

In addition, since grains may become a component of feed for cattle or other ruminants, grain elevators are subject to inspections to determine compliance with FDA's BSE-prevention regulations.

Further, FDA may inspect a facility to ensure that grain elevators handle, store and distribute grains in conformance with guidance levels established by the agency for aflatoxin, deoxynivalenol (vomitoxin) and fumonisin.

Significantly, grain elevators storing and distributing raw agricultural commodities currently are exempt from CGMPs established for human food under 21 CFR Part 110.

- **Medicated Feed Mills:** FDA has authority to inspect medicated feed mills for compliance with applicable CGMPs requirements. The CGMPs for medicated feeds and animal drugs are set forth in 21 CFR Parts 225 and 226, respectively.

FDA uses Form FDA-2481<sup>(14)</sup> when conducting inspections of feed mills holding an approved medicated feed mill license, which is necessary for the use of Category II, Type A medicated articles. Investigators use a Non-Licensed Medicated Feed Establishment Inspection Form<sup>(15)</sup> when conducting medicated feed inspections at facilities that do not hold an approved medicated feed mill license.

The following are specific issues pertinent to FDA's inspection of medicated feed mills:

- **Volume of Business:** Form FDA-2481 used during inspections of facilities holding an approved medicated feed mill license requires investigators to ask for the annual tonnage of medicated and non-medicated feed manufactured. The purpose for the question is to inform FDA as to the relative activity of the mill within the industry, since a mill that produces a high volume of feed potentially may affect the safety of a greater quantity of animals and animal-based foods. In addition to tonnage, investigators sometimes may ask for a gross dollar sales volume of the mill's operation.

Importantly, while FDA's regulations do **not** require facilities to furnish volume data – either tonnage or dollar sales – current industry practice generally is to provide investigators with an approximate range of tonnage volume. However, mills need to be aware that under the Freedom of Information Act, it is possible for FDA inspection reports and business volume information to be made public. Mills should consider this possibility and develop an appropriate policy on responding to business-volume requests from FDA.

- **Formula Information:** The investigator has authority to review feed formulas to determine whether they contain: 1) the proper drug and amount; 2) unapproved ingredient(s); and 3) approved levels of regulated food additives (e.g., selenium). Industry practice generally has permitted investigators to copy formulas, **provided** that amounts of non-drug and other non-regulated ingredients are omitted. FDA Compliance Policy Guide 670.100<sup>(16)</sup> agrees with this practice. Nutritional information associated with formulas is considered proprietary.
- **Validation:** The CGMPs place responsibility upon the facility to demonstrate that its equipment is suitable and capable of producing a medicated feed of intended potency, safety and purity. It is advisable for mills to maintain records validating that equipment and systems essential to producing a medicated feed of intended potency, safety and purity are suitable and capable. Examples of equipment and systems for which it may be advisable to maintain validation records include:
  - o **Automated or computerized batching systems:** It may be appropriate to have records indicating that such systems will accurately scale ingredients and mix them for the proper length of time. Often, showing an investigator how such a system works is a useful way to demonstrate its capability.
  - o **Automated or computerized formulation systems:** Mills should consider establishing practices that document the accurate electronic transmission of formulas. Again, showing an investigator how such a system works often is a useful way to demonstrate its capability.
  - o **Equipment distribution systems associated with medicated feeds:** It may be advisable to develop testing methods to verify that equipment cleanout procedures – flushing,

sequencing, and/or physical cleanout – adequately prevent carryover that could result in an unsafe animal feed.

- **Complaint Files:** 21 CFR Part 225.115 requires that mills holding an approved medicated feed mill license maintain medicated feed complaint records that pertain to the drug's efficacy or safety. However, investigators during an inspection may wish to review all complaints involving medicated feed, even though the drug was not a factor in the complaint. Such requests can become a point of contention during the inspection. If the mill's investigation of a complaint involving a medicated feed clearly shows that the issue was caused by something unrelated to the drug (e.g., excessive fines, odor, etc.), current practice in the industry generally is that such files should remain proprietary to the firm.

To appropriately manage this issue, mills may wish to consider having a person that is responsible for evaluating each medicated feed complaint to determine whether the complaint relates to the efficacy or safety of the drug. Current industry practice generally is for firms to maintain a separate complaint file for medicated feed complaints that pertain to the drug's safety or efficacy. During an inspection, mills typically allow the investigator to review complaints within this separate file, but not other medicated feed complaints that do not pertain to the safety or efficacy of the drug.

FDA's general practices used when conducting medicated feed inspections are outlined within the agency's Feed Manufacturing Compliance Program Guidance Manual.<sup>(17)</sup>

- **Facilities Manufacturing and Distributing Non-Medicated Feeds and Feed Ingredients:** FDA has not promulgated CGMPs for non-medicated feeds and feed ingredients, although such requirements likely will be established as an outcome of FSMA-related rulemakings currently underway. Therefore, at this time, an FDA investigator is **not** authorized to inspect for CGMP-type issues at non-medicated feed establishments. However, FDA does have authority to inspect such facilities under the agency's general inspectional authority.
- **Facilities Affected by FDA's BSE-Prevention Regulations:** FDA routinely inspects feed manufacturing facilities and other facilities distributing raw agricultural commodities and ingredients used in animal feed and pet food for compliance with its BSE-prevention regulations – 21 CFR 589.2000, “Animal proteins prohibited in ruminant feed,” and 21 CFR 589.2001, “Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.”

Facilities should be familiar with the BSE-prevention regulations and associated compliance obligations. Inspections typically focus on the facility's practices and procedures to ensure that: 1) raw materials and feed products are not cross-contaminated with mammalian protein products that are prohibited from being fed to cattle and other ruminant animals; and 2) raw materials and feed ingredients that do contain prohibited mammalian protein products are properly labeled with the caution statement, “Do not feed to cattle or other ruminants.”

FDA utilizes a designated inspection form when conducting its BSE-related inspections.<sup>(18)</sup> In addition, FDA's general practices used when conducting BSE-related inspections are outlined within the agency's BSE/Ruminant Feed Ban Inspections Compliance Program Guidance Manual; however this manual has not been updated to reflect FDA's current BSE inspection form.<sup>(19)</sup>

## The FDA Inspection Process

An FDA-regulated facility should be prepared to undergo an inspection at any time during normal business operations. Once the FDA investigator arrives, it is too late to establish policies and procedures for the inspection process. A facility should consider developing a comprehensive plan on how to handle the inspection. The inspection plan should anticipate the scope of the inspection, questions that may be asked, how to handle requests for copies of records and policies, etc. In addition, the plan should outline the responsibilities that individuals within the facility will have during the inspection.

The following is information pertaining to FDA investigators and suggestions that facilities may wish to consider when preparing for and undergoing an FDA inspection.

- **FDA Investigators:** FDA titles a person conducting an inspection as an "investigator," which has a higher governmental ranking than "inspector." FDA investigators generally are based at local FDA District Offices, although investigators may be accompanied by other FDA employees from other District Offices or from the FDA's Washington, D.C.-area headquarters. State regulatory officials also may be credentialed to conduct inspections on behalf of FDA. Currently, state regulatory officials conduct about 75 percent of FDA inspections. FDA investigators or FDA-credentialed state officials should carry an FDA-issued badge.

FDA investigators are trained to make observations during an inspection, but not necessarily to make conclusions as to whether a condition is violative. However, FDA investigators may offer their own thoughts on what they observe during the inspection, as well as suggestions on how they believe procedures and practices could be changed at the facility to improve compliance. Facilities may wish to consider the suggestions offered, but also should be mindful that the primary purpose of the inspection is for the investigator to gather information to support findings of alleged violations.

- **Receiving the Investigator:** The FDA investigator should present a badge and credentials upon arrival at the facility. The facility should keep a record of the investigator's credentials when presented. If the investigator does not present a badge or credentials, then the facility may consider not allowing the inspection to proceed on grounds that the individual may not have authority to inspect.

Upon initiating the inspection, the FDA investigator should present the facility with a Notice of Inspection – Form FDA 482.<sup>(20)</sup> Facilities should keep a copy of this form. While presenting the Notice of Inspection, the investigator should state the purpose of the visit and/or inspection. If the investigator does not offer this information, it is appropriate for the facility to ask for it. It also is acceptable for the facility to ask how long the investigator believes the inspection will last.

If the investigator presents a warrant, facilities are obligated to comply with its content. If a warrant is presented, it strongly is recommended that the facility call its legal counsel immediately.

Facility management should ensure that the first point of contact within the facility is prepared for the investigator's arrival. The first point of contact should:

- Know who to contact at the facility when the investigator arrives.
- Request that the investigator sign the facility's Visitor's Log.
- Escort the investigator to a designated place within the facility until the person assigned to escort the investigator is available. This designated place should be a location that will not draw the investigator's attention to regulatory issues.
- Be courteous and offer the investigator coffee or water and access to restroom facilities.

The investigator should not be kept waiting unnecessarily. While it is appropriate to notify facility personnel that an inspection will be taking place, it is not realistic to try to make major improvements while the investigator is kept waiting. Facilities should treat the investigator with respect, always being mindful that the investigator is a government agent.

- **Facility Representative(s) Designated to Accompany Investigator:** It is advisable that the facility have a plan that assigns appropriate personnel to escort the investigator at all times. Frequently, the appropriate person may be the individual responsible for regulatory affairs or quality assurance at the facility. The designated person should:
  - Know the company and its operations well.
  - Not be a senior officer of the company.
  - Inform the investigator of all relevant visitor and safety policies established for the facility. The investigator should be required to use the clothing and personal protective equipment used by employees in the facility. As applicable, this may include dust masks, gloves, shoe coverings, etc.
  - Accompany the investigator at all times (except for restroom or lunch breaks).

It is recommended to have at least two trained individuals accompany the investigator, and one of the individuals should take detailed notes about questions asked, responses, corrective actions taken or promised, areas inspected, and any other relevant details.

The absence of the designated person during regular business operations generally does not provide a legitimate basis for refusing the inspection. Facilities should have a secondary individual(s) trained to accompany an investigator in the event that the primary designated person is not available.

- **Specific Inspection Issues:** Following is information pertaining to specific issues that may be encountered during an inspection.
  - **Investigator Requests to Interview Employees:** The FFDCA does not expressly provide FDA the authority to interview facility employees. Therefore, it is advisable for facilities to develop a policy on how to address this issue.

Because of the potential for employees to not provide a thorough or accurate response to requests for information, the facility may choose to establish a policy that prohibits employee interviews during inspections. In this case, the designated person should expressly inform the investigator of such a policy and that the designated person will respond to any questions posed during the inspection.

If the facility policy does allow investigators to interview employees, it is advisable for the designated escort person to be present during the interview and available to immediately correct any inadequate or incomplete response provided by an employee.

- **Access to and Copies of Records:** Facilities should have a written policy that designates those records the investigator will be allowed to see and copy, if requested. FDA generally is entitled to copies of labeling and can review and copy records required by regulations.

Generally, an investigator's authority to review and have access to records is limited by the FFDCA, which states that FDA may inspect "within reasonable limits and in a reasonable manner." This is subjective language, and the facility's inspection policies should address the extent to which the facility will provide access and copies of its records.

In addition to its general inspection authority, if FDA has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, then the agency is allowed to have access to and copy all records relating to the implicated food and those foods that FDA reasonably believes may be affected similarly.

As previously noted, this authority applies to records:

- pertaining to manufacture, processing, packing, distribution, receipt, holding (storage) or importation of such food.
- associated with Reportable Food Registry reports and notifications.

- held in any format, including paper and electronic forms.

Significantly, FDA's records access authority in such situations does **not** extend to:

- recipes (formulas);
- financial data;
- pricing data;
- personnel data;
- research data; and
- sales data, other than shipment data regarding sales.

FDA investigators also may, upon written request, have access to and copy records showing the movement in interstate commerce of any food or the holding of any food during or after such movement, and the quantity, shipper and consignee thereof.

Facilities should make two copies of whatever records are given to the investigator. One copy should be provided to the investigator, and the other retained for the facility's inspection file. Importantly, facilities should stamp confidential documents given to the investigator as "Confidential."

- **Use of Cameras and Photographs:** The use of cameras and taking of photographs by an investigator during an inspection is a difficult legal issue. FDA does not have express legal authority to take photographs during an inspection. But the agency's current position is that photographs are a reasonable part of the inspection process. Therefore, investigators may insist they have a right to use a camera. However, the use of photography is controversial because photos taken by an investigator may be misleading in that they do not show the entire context of a situation within the facility.

FDA's current inspection procedures state that if a company refuses to allow the taking of photos during an inspection, investigators are to "obtain name and contact information for the firm's legal counsel, and advise [the FDA] district management immediately."

It is advisable that facilities develop a policy that addresses the use of cameras and taking of photographs during inspections. If there is a possible hazard to using a camera within the facility – e.g., the flash might cause an explosion hazard – this provides a valid reason for the facility to not allow the taking of photographs. A written policy for photographs is advisable, so the investigator may be directed to the policy before the inspection begins.

If photographs are allowed, the facility should consider having a camera accessible and take

pictures of whatever the investigator photographs and do so from the same camera angle/point of view. Such duplicate photos should be retained in the facility's inspection file.

- **Taking Samples:** FFDCA authorizes FDA investigators to obtain samples. If samples are taken during the inspection, the facility should request the investigator, prior to leaving the premises, provide a receipt describing the samples obtained – FDA Form 484 – Receipt of Samples.<sup>(21)</sup>

If a sample is taken, the designated person should request the investigator to "split" the sample so that the facility can keep a retention sample of the regulatory sample. Typically, the investigator will do this; however, if not, the designated person should obtain a duplicate sample from the same lot of product, if possible.

If a sample is taken and if an analysis is made of the sample "for the purpose of ascertaining whether such food consists...of any filthy, putrid, or decomposed substance, or is otherwise unfit for food," FDA is obligated to provide the facility with a copy of the analysis. The facility should ask the investigator what tests will be performed on the sample and the expected timing of the test results.

The facility may request that the investigator pay for the samples' value; however, the investigator then may ask for records to substantiate what the fair value is for the samples.

- **Affidavits:** An investigator may write one or more affidavits of varying content for facility personnel to sign as part of the inspection process. There is no legal requirement for facility personnel to sign such affidavits. The facility's policy towards affidavits should reflect the degree of cooperation that it chooses to extend in this area. If affidavits are signed, a copy should be retained. Incidentally, FDA will not sign an affidavit if asked to do so by the facility.
- **Inspecting the Facility:** At the outset of an inspection, the investigator typically will request a tour of the facility. During this tour, designated personnel always should accompany the investigator. The designated person(s) should answer questions as the investigator poses them. Such personnel should never give the investigator false information. If the answer is not known, the designated person should say so and that they will obtain the requested information and provide it later.

After the initial facility tour, the investigator typically will focus on individual departments or processes. The investigator may stay hours or even several days in a particular department. The investigator has authority to conduct the inspection at "reasonable times," which correlates to normal business operating hours. However, the investigator does **not** have authority to disrupt the facility's normal operations. For example, an investigator is not authorized to mandate that the facility start or stop a production line for inspectional purposes.

If the investigator raises an issue of concern during the inspection to which the designated escort person agrees, it is appropriate for the designated person to remedy the issue immediately, if possible, in the investigator's presence.

- **Requests for Records:** If the investigator requests to review documents or records, it is advisable to have the investigator review the information in a designated space. Any copies of confidential documents or records provided to the investigator should be stamped “Confidential.” It is advisable for the facility to make the requested copies themselves – although the investigator should be allowed to observe the copying, if desired. Facilities are not required to create any documents; investigators are entitled to only relevant documents that already exist.

If an investigator desires access to an unreasonably large quantity of records, or seeks to review and copy records beyond those designated by the facility’s written policy, it is advisable to ask the investigator to provide a list in writing of the requested documents, along with reasons as to why access is desired, so that the list can be reviewed by facility management and/or legal counsel, as appropriate. This allows the facility to consider and balance FDA’s legal authority, the benefits of cooperating with the investigator, the investigator’s need for the information requested, the confidentiality of the information and other factors.

As previously noted, it is advisable that the facility develop a written inspection plan that clearly outlines those facility documents and records for which the investigator has authority to review upon request so as to minimize the need to seek review by facility management and/or legal counsel during the inspection.

- **Interacting with the Investigator:** It is advisable for the designated person to not volunteer information to the investigator during the inspection. Designated personnel should answer in a direct manner only those questions asked.

In addition, facility personnel should:

- interact with the investigator in a pleasant and professional manner.
- not become argumentative or hostile towards the investigator.
- freely ask the investigator questions to clarify the investigator’s comments or requests.
- display a cooperative attitude toward the investigator, to the degree possible. If it is perceived that the facility is being “uncooperative,” the investigator may become suspicious and more zealous during the inspection.
- attempt to limit the scope of the investigator’s inquiries. For example, if an investigator asks to review complaint files associated with medicated feed, ask the investigator for what specific time period or particular product they desire to review.
- emphasize to the investigator that the facility intends to comply with all applicable regulations.
- always provide truthful information to the investigator.

- **Inspection Exit Interview:** At the end of the inspection, the investigator will ask to meet with facility management to discuss the findings of the inspection. The designated person also should attend the exit interview.

During the exit interview, the investigator will discuss their findings and typically present a Form FDA 483 – Inspectional Observations.<sup>(22)</sup> Despite its title, Form FDA-483 is used to provide a written statement of what the investigator believes are objectionable matters. The investigator should discuss each of the objectionable conditions and provide facility management with an opportunity to comment. Facility management should inform the investigator of any corrective action taken and ask that it be included in the investigator's notes. Facility management also should carefully explain its position pertaining to any area of disagreement. The investigator likely will document any responses provided by management.

Facility management should not secretly record the exit interview meeting. If it is believed to be desirable to record the session, notify the investigator in advance and document the fact that notification was provided. Normally, the investigator will not want the inspection exit interview to be recorded.

Investigators often will request that company employees or officials sign an Affidavit or Declaration during the exit interview. However, there is no requirement for employees or officials to sign such documents. In addition, it is advisable that Affidavits or Declarations not be signed by company officials unless such documents have been reviewed by competent legal counsel. Companies should consider establishing a policy on signing Affidavits or Declarations and using this policy as the basis to respond to investigator requests.

When officials refuse to sign an Affidavit or Declaration, the investigator may read the document and ask whether it is true. In response, it is advisable that company officials not acknowledge or comment on the correctness of any information presented.

During the exit interview, facility management should specifically request a copy of the Establishment Inspection Report (EIR)<sup>(23)</sup> – the investigator's written report. Many investigators will provide this upon request, although some reports only are obtained through a Freedom of Information Act (FOIA) request. Upon receiving the EIR, facility management should review the document carefully for inaccuracies or trade secret information that should be stricken before the public potentially obtains copies.

- **After the Inspection:** Following is information pertaining to post-inspection activities and suggestions for facilities to consider:
  - The facility should compile and organize an inspection file that includes any documents, records, and samples made available to the investigator during the inspection. A detailed written report should be prepared and provided to company management.

- If a Form FDA-483 was issued, the facility should begin to prepare a response immediately. While there is no legal obligation for the facility to formally respond to a Form FDA-483, it may be beneficial to do so. In this regard, the FDA has established a policy that allows 15 days for companies to respond in writing to the agency after issuance of an observation on Form FDA-483. The company's written response must be received by FDA in the allotted time period if the company wishes to have its comments considered when FDA determines whether to initiate enforcement action based upon the observations.
- If FDA believes it is warranted based upon the inspection findings, the agency may issue either an "Untitled Letter" or "Warning Letter"<sup>(24)</sup> to the facility. FDA uses Warning Letters for violations that may lead to enforcement action if they are not corrected promptly and adequately. FDA uses Untitled Letters for violations that are not as significant as those that trigger Warning Letters. Unlike a Warning Letter, an Untitled Letter does not include a statement warning that failure to promptly correct a violation may result in an enforcement action.

If a facility receives an Untitled Letter or Warning Letter after an inspection, it is obligated to provide a formal response to FDA within the timeframe prescribed within the letter. A response to an Untitled Letter or Warning Letter should be sent to the FDA District Office, with a copy also sent to the investigator.

When an Untitled Letter or Warning Letter is received after an inspection, the facility should use all necessary resources to appropriately address the issues made in the letter and to prepare a response within the designated time frame. An unanswered or inadequately answered Untitled Letter or Warning Letter will lead almost certainly to further FDA enforcement action. It is advisable that the facility's response to an Untitled Letter or Warning Letter be reviewed by competent legal counsel before sending to FDA.

The facility should comment on each observation made on the Form FDA-483 when responding to an Untitled Letter or Warning Letter. Frequently, observations listed on the Form FDA-483 are cited as "for example," so it is advisable that the response not just address the specific example, but also address the relevant issue more broadly.

The facility should not admit to violations of the law or regulations in its response. Instead, the facility should note the observation and clearly state how it has or will address the condition or observations made. When corrective actions are taken, it is advisable for the facility to provide information in its response to demonstrate that the corrective action has been implemented effectively. In all cases, the facility should convey to FDA that it is concerned with the inspection findings and/or particular observation, and is committed to appropriately resolving issues of non-compliance.

Within its response, the facility may disagree with an observation. If so, the facility should provide the reasons it believes the observation is incorrect. Attempts to reconcile disagreements with observations should be made first with FDA District Office personnel. If an

agreement is not reached, it may be appropriate to pursue the issue with compliance personnel located at FDA's Washington, D.C.-area headquarters.

If more time is needed to remedy a condition documented within the Untitled Letter or Warning Letter, the facility should provide that response and indicate that another update on facility actions will be forthcoming. Facilities should take FDA's documented observations seriously and always follow through on actions that it indicates to FDA will be taken to remedy non-compliant conditions. Otherwise, depending upon the significance of the non-compliant condition, FDA may choose to initiate further enforcement actions, such as seizures, injunctions or consent decrees.

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