



FDA INSPECTION CHECKLIST

What to do Before, During, and After Your Next FDA Inspection

INTRODUCTION

Food Industry Counsel, LLC is pleased to provide you with the most comprehensive and useful FDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA Investigators will conduct an onsite inspection of every food facility in the U.S.¹

Here are **FDA's new enforcement priorities** during routine unannounced inspections:

- (1) To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;
- (2) To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;
- (3) To require recalls if the percentage of FDA samples testing positive for *Listeria Monocytogenes*, *Salmonella* or other pathogens exceeds FDA thresholds;
- (4) To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found; and
- (5) To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA Investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

¹ The FDA employees performing these routine onsite inspections are not referred to as "FDA Inspectors," but rather as "FDA Investigators." The concern with this terminology is that some FDA Investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.

PREPARING IN ADVANCE FOR YOUR NEXT FDA INSPECTION

PRE-INSPECTION CHECKLIST

Much of the work needed to ensure that the FDA inspection ends successfully should be completed long before the FDA Investigators arrive. All companies should begin work immediately to ensure that they have accomplished the following critical tasks:

- **Identify a Meeting Space:** Identify a space within the facility to host the FDA investigators when they arrive. This might be a conference room or a vacant office with sufficient desk space to review large amounts of records. The space selected, however, should be free of any records (in binders, boxes or on computers) which FDA Investigators could access, unsupervised, while they occupy the space.
- **Assign Designated Individuals:** Assign a primary and secondary Designated Individual (DI) for each facility to serve as the liaison with the FDA Investigators once they arrive. DIs should coordinate vacation time (and time off) to ensure that one DI will always be available in the event FDA arrives.
- **Complete PCQI Training:** Ensure that the primary DI has received FDA's Preventive Control Qualified Individual (PCQI) Training. Although the training is *not required* under FDA regulations to become a Qualified Individual, FDA Investigators will typically *expect* the training to be completed by at least one facility employee.
- **Finalize Written Food Safety Systems:** Ensure that the company's written food safety systems are finalized, and the primary and secondary DIs are familiar with each of the elements of the plans. Depending upon the size of the business and the nature of the products, this could include GMPs, Sanitation Programs, Preventive Control Plan, Recall Plan, Environmental Monitoring Program, Foreign Supplier Verification Plan, Sanitary Transportation Plan, Food Defense Plan, and Produce Safety Plan.
- **Ensure Ease of Records Access:** Ensure that the supporting records for each of the programs are organized and maintained in such a way that the DI can immediately retrieve the past *three months* of records for FDA review. Although FDA requires the majority of these records to be maintained for at least two years, the FDA investigators will typically ask only to review records for the preceding three months.
- **Document Corrective Actions Properly:** Ensure that, in the event there is a deviation, you are documenting all corrective actions *correctly*. All corrective actions should identify the root cause of the deviation, actions taken to prevent recurrence and, if product safety is not affected, a *written conclusion (supported by factual and scientific data) that the deviation "does not create an immediate food safety issue."*
- **Upgrade Sanitation Flashlights:** This may seem obvious, but many facilities are still using flashlights are severely underpowered or outdated. Be sure to equip your sanitation employees with the same high-power flashlights that the FDA Investigators will use so that your employees will be able to see (and then clean) what the FDA would observe with its own flashlights when it arrives.

- **Review Allergen Controls:** FDA is requiring companies to recall vast amounts of products if the FDA Investigators find, during their visual inspection, that the companies' allergen controls are not adequate. Make sure that your ingredient labels are accurate, and that opportunities for cross-contact are being guarded against and avoided.

- **Conduct Environmental Monitoring:** If your company processes ready-to-eat food products that are exposed to the environment prior to packaging, FDA will require you to have an environmental monitoring program. Ensure that an appropriate program is developed and implemented before FDA arrives.

- **Conduct More Environmental Sampling:** Because FDA will collect between 100 and 200 microbiological samples from your facility, it is critical to know exactly what FDA will find before it arrives. Thus, you should "Play FDA for a Day," and conduct your own FDA-style facility swabbing, to identify and immediately correct any hidden problems. If done correctly, and if your swabbing and testing plan is developed with the assistance of legal counsel, the final testing results can be kept confidential.

- **Develop a Microbiological Sample Retain Policy:** If, after reporting your testing results, your lab retains your isolates or testing materials indefinitely, create a policy requiring the lab to discard all testing material within 24 hours after testing. This is appropriate as long as the records of the final results are maintained.

- **Develop a Companion Sample Policy:** When FDA collects food product or environmental samples, some companies elect to collect companion samples at the same time. Although we typically counsel against this practice, if you choose to collect companion samples, make sure to have a policy in place governing exactly how those samples will be handled, tested and/or discarded following collection.

- **Develop a "No Photographs" Policy:** In many cases, FDA Investigators will insist on taking photographs while inspecting the processing environment. If you have a corporate policy which prevents visitors from taking photographs, you may be able to use the policy to prevent FDA from taking pictures.

- **Develop a "Do Not Sign" Policy:** Sometimes, during an FDA inspection, the FDA Investigators will insist that a company representative sign a statement or affidavit. You have no legal obligation to do so. Develop a policy that states you will neither sign nor acknowledge any written statements presented by FDA Investigators.

- **Identify an Appropriate "On Call" FDA Lawyer:** Long before your next FDA inspection, you should add an FDA lawyer familiar with the Inspection process to the company's emergency contact list who can be notified and remain "on call" once the inspection begins. This person can serve as a useful resource to help quickly answer any difficult regulatory or investigator-related questions that arise during the inspection.

- **Conduct a Mock FDA Inspection:** One of the best ways to prepare for a visit from FDA is to conduct a mock inspection. FDA consultants and/or lawyers can visit your facility and play the role of the FDA Investigator. Ask them to review your programs to identify possible regulatory shortfalls, and work with you to implement strategies that will strengthen your programs and reduce your regulatory exposure.

MANAGING THE ACTUAL FDA INSPECTION

INSPECTION CHECKLIST

When the day comes, the FDA Investigators will arrive unannounced. The FDA Investigators will present their credentials and ask to conduct an entrance meeting. During this meeting, the FDA Investigators will detail how they plan to conduct the inspection, how long they anticipate the inspection will last, and the specific tasks they intend to accomplish. These tasks will typically include the following:

- (1) a **facility inspection**, during which the FDA Investigators will tour and carefully inspect the processing and other areas of the facility;
- (2) a **records review**, during which the FDA Investigators will carefully scrutinize the company's written food safety programs, and at least three months of monitoring and verification records; and
- (3) a **swab-a-thon**, during which the FDA investigators will collect approximately 100 to 200 microbiological samples from: (a) incoming ingredients; (b) outgoing finished products, and (c) Zone 1, Zone 2, Zone 3 and Zone 4 environments.

The entire inspection process will usually take a few days and, in some cases, can last weeks. Once the inspection begins, use the following checklist to help appropriately navigate the inspection process.

- Attempt to Negotiate the Areas Being Sampled:** During the entrance meeting, the FDA Investigators will typically disclose the types of ingredients, products and/or environmental areas they intend to sample. Attempt to negotiate with the agency to limit the amounts, types or overall focus of the sampling in such a way that, if any results are positive, you can limit to the greatest extent possible the scope of any recall.
- Carefully Document the Areas Being Sampled by FDA:** While the FDA Investigators are conducting their sampling, be sure to carefully document the exact areas from which the FDA Investigators are collecting their samples. In addition, be sure to appropriately characterize the areas being sampled by the agency as Zone 1, Zone 2, Zone 3, or Zone 4. This information will be critical in the event that any samples are positive to determine the most appropriate response.
- Carefully Consider Whether to Collect "Companion Samples:"** In some instances when a company collects companion samples, the samples that the FDA collects test negative while the companion samples test positive. Because taking companion samples doubles the chances that a positive will be found (whether because of the presence of actual contamination or lab error) we generally do not recommend taking companion samples. With that said, be sure to consult with legal counsel because there may be some limited circumstances where companion sampling would be advisable.
- Hold any Product that FDA Samples:** In the event FDA collects finished product samples to test for the presence of *Listeria Monocytogenes*, *Salmonella* or any other pathogens, be sure to hold any products produced from the same lot or batch, or any products produced using the same ingredients, until the FDA results come back. If any results are positive, and the product has been held, a recall will not be necessary.

- **Hold any Product from any Lines that FDA Samples:** In the event FDA collects any Zone 1 samples from any processing lines, be sure to hold the products that were produced during the periods that FDA was sampling until the FDA results come back. Here too, if any results are positive, and the product has been held, a recall will not be necessary. To provide additional protection, the company may also consider holding any product processed on equipment where Zone 2 samples were collected as well.
- **Aggressively Clean and Sanitize all Areas Sampled by FDA:** As soon as possible after FDA has completed its sampling, be sure to aggressively clean and sanitize each of the areas that the agency sampled. This is because, in the event any sample is positive, you will be able to argue that whatever contamination existed at the time of sampling was eliminated and thus could not have affected any additional production.
- **Correct all FDA Observations Immediately:** During the course of the inspection, the FDA Investigators will likely share their findings and observations with the DI. Wherever possible, make sure to immediately correct to the satisfaction of the FDA Investigators any observations that are critical of the company. Doing so will demonstrate that the company is committed to quickly resolving any concerns, and the FDA Investigators may choose not to record those observations in the final FDA Form 483.
- **Know What Records FDA is Permitted to Review:** FDA has very broad powers to access records. Generally speaking, FDA will be able to review a company's written food safety programs and related records. The agency is not entitled, however, to review or copy any recipes, financial data, pricing data, personal data (other than to ensure that the company's employees have received training appropriate to their position and responsibilities), research data, and sales data (other than shipment information).
- **Protect the Confidentiality of any Records FDA Copies:** If FDA requests copies of any records the company deems confidential, be sure to mark those records with the following statement: THIS DOCUMENT AND THE INFORMATION CONTAINED HEREIN CONSTITUTES TRADE SECRET, CONFIDENTIAL AND PROPRIETARY COMMERCIAL INFORMATION PURSUANT TO 5 U.S.C. 552(b)(4), AND SHALL BE STRICTLY PROTECTED AS SUCH FROM ANY DISSEMINATION AND/OR DISCLOSURE. This will put the agency on notice that the information must be protected and may not be disseminated publicly.
- **Do Not Leave the FDA Investigators Unaccompanied:** Make sure that while the FDA Investigators are in your facility they remain accompanied. This way, the DI can observe and document the actions of the FDA Inspectors, and respond immediately to any concerns. Additionally, if a company employee remains present at all times, the FDA Investigators will be less inclined to develop or discuss additional "unplanned" inspection "strategies" or "goals" with each other during the course of the inspection.
- **Do Not Sign Any Statements of Affidavits:** At the conclusion of the inspection, the FDA investigators may ask you or your employees to author or sign a statement or affidavit describing the inspection, the observations and/or the conclusions. Do not sign, correct or acknowledge any documents, as you have no legal obligation to do so. If such a request is made, consult with your FDA lawyer immediately.

MANAGING THE AFTERMATH OF AN FDA INSPECTION

POST-INSPECTION CHECKLIST

Once the FDA Investigators have finished with their assigned tasks, they will conduct an exit interview and share their findings, observations and conclusions. In most cases, where violations have been identified, the FDA Investigators will issue a FORM 483, which details the specific violations observed by the FDA Investigators. In some cases, depending upon the nature of the observations and conclusions, the FDA Investigators may also ask the company to consider a recall of certain products. The following checklist can be used to help navigate the aftermath of the FDA inspection and bring all issues to closure.

- **If FDA Issues a FORM 483, Prepare a Written Response:** During the exit interview, the FDA Investigators will likely present their observations, findings and conclusions. In most cases, any regulatory or food safety violations will be documented in an FDA FORM 483. Although a response is not required by law, a company is generally expected to provide a written response *within 15 business days*. If the written response adequately addresses FDA's concerns, FDA will not pursue further regulatory action. If the response is inadequate, however, the agency may issue a "Warning Letter" threatening to withdraw the company's registration and prevent it from producing product.
- **Support Your Written Response with Documentation:** When FDA issues a FORM 483 or "Warning Letter," make sure your response is appropriately supported with adequate documentation. For instance, FDA will not be satisfied if you simply state in your response that you corrected a problem that the FDA Investigators observed by "conducting additional employee training." Rather, in addition to stating that you completed the training, FDA will expect you to attach a training log or other document to your response which provides evidencing that the training was, in fact, completed.
- **If FDA Suggests a Recall, Consult Your FDA Counsel:** Sometimes the FDA Investigators will observe conditions they believe warrant a recall. The decision whether to announce a recall in the first instance, and any determinations regarding the scope of any such recall, can vary greatly depending upon the facts and data. Any recall decisions should thus be made very carefully, and only after consultation with an experienced FDA compliance attorney. Many companies have successfully convinced FDA, based upon the availability of supporting facts, forensic analysis and scientific data, that the agency is incorrect and a recall is not needed, or the scope can be significantly limited.

Although there are countless variables which will ultimately affect the way in which your next FDA inspection unfolds, the information provided within this FDA Inspection Checklist is designed to provide some of the tools you will need to deal with the most common scenarios. We truly hope that you will find these checklists useful as you prepare for and manage your next FDA Inspection.

About the Author: *Shawn Stevens is a food safety consultant and lawyer, and the founding member of Food Industry Counsel LLC, the only law firm in the world that represents the food industry exclusively. Mr. Stevens works throughout the country and abroad with food industry clients (including the world's largest growers, food processors, national restaurant chains, and food distributors and grocery chains) helping them protect their brand by complying with FDA and USDA food safety regulations, managing recalls, and defending high-profile foodborne illness claims. Additional information about Mr. Stevens' legal and consulting practice can be found at: www.foodindustrycounsel.com.*