

What to Do When FDA Knocks At your Door?

(From the Industry's Perspective)



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Agenda

- Your “Bill of Rights”

What are the FDA legal/regulatory requirements?

- Cameras
- Samples
- Logistics of Handling an Inspection

Factory Inspections



- My informal, anecdotal experience indicates FDA is inspecting facilities with more frequency and the inspections are much more rigorous
- FDA has been much more forceful in demanding access to records regardless of legal authority
- FDA is more critical and more inclined to identify/find issues
- The times have changed.....
- You need to know your rights

Know Your Rights

- The Federal Food, Drug, and Cosmetic Act (FFDCA) and implementing regulations specifically address the records that FDA legally is entitled receive during an inspection
- FDA can ask (and frequently demands) it has the right to records when no such authority exists
- Companies should know their rights and then make informed decisions on whether they will voluntarily release additional information

Know Your Rights

- The scope of records access will depend on the type of product and the type of inspection FDA is conducting
 - Regular Inspections
 - LACF/Acidified Food
 - Seafood HACCP
 - Juice HACCP
 - Bioterrorism
- The type of inspection will dictate the scope of FDA's records access authority

Records Access General Inspections

- List of products shipped
- Product samples
- Pesticide use information
- Label information
- Shipping records of products received by company
- Open access to the manufacturing environment

Records Access General Inspections

- FDA may ask for, but does not have express authority to receive:
 1. Production figures
 2. Product cost/pricing information
 3. Description of manufacturing process
 4. Quality control records
 5. Organizational charts
 6. Product development records
 7. Consumer complaints

Records Access for Low Acid Canned Foods

- The LACF regulations provide FDA with expanded records access to:
 1. Process and production records
 2. Records required for different retort processing systems
 3. Recording thermometer charts
 4. Container closure examination records
 5. Initial distribution records
 6. Must retain records for 3 years

Records Access for Acidified Foods

- The acidified food regulations provide FDA with expanded records access to:
 1. Raw materials, finished products, and suppliers' guarantees
 2. Processing and production records
 3. Records regarding departures from scheduled process (if has a bearing on public health)
 4. Initial distribution
 5. Must keep records for 3 years

Records Access Under Juice HACCP

- Under the juice HACCP regulations, FDA can access:
 1. Sanitation records
 2. Hazard analysis
 3. HACCP records
 4. CCP records (monitoring)
 5. Corrective actions
 6. Verification and validation of HACCP plan
 7. Records must be retained for 1 year (perishable) and 2 years for all others
- Expanded access also exists under seafood HACCP

Bioterrorism Act

- Significantly expands FDA's access to records in limited instances
- FDA must have “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death”
- FDA can invoke the Bioterrorism Act expanded records access when it is investigating an incident involving a Class I recall
- Expanded records access is not limited to instances when FDA is investigating acts of Bioterrorism

Bioterrorism Act

- How do you know if FDA is invoking the Bioterrorism Act?
 - FDA must provide written notice
 - FDA must obtain written authorization signed from a high ranking official (such as a District Director) before the statute can be invoked
 - The FDA inspector does not have the authority to invoke the expanded records access

Bioterrorism Act

- What records can FDA access?
 1. Manufacturing records
 2. Packing records
 3. Distribution records
 4. Product receipt records
 5. Holding records
 6. Importation records
 7. And most likely, consumer complaint files
 8. In essence, FDA can access many of the key/important records that are maintained during your manufacturing operation

Bioterrorism Act

- FDA cannot access
 1. Recipes
 2. Financial data
 3. Pricing data
 4. Personnel data
 5. Sales data (other than shipping data related to sales)
- FDA must be given access to these records within 24 hours

Photographs and Video Cameras

- The issue of cameras is one of the most contentious issues with inspectors
- Concerns with cameras
 1. Cameras will capture proprietary aspects of the manufacturing operation and the information could be disclosed unintentionally
 2. Information obtained during an inspection is evidence that will be admissible in court

Photographs and Video Cameras

- Inspectors frequently insist he/she has the RIGHT to use
- There is no definitive legal authority on this issue
 1. The FFDCA does not address it
 2. Nor have the courts
- Your company should establish a policy and stick to it
 1. Many companies do not allow cameras
 2. Some companies do not object

Photographs and Video Cameras

- Inspectors are advised to push hard on their right to bring in cameras
 1. They will say they have clear legal authority
 2. They will threaten to call headquarters
 3. They will storm out of the room and have been known to leave the facility for hours
- You must make it clear you are not denying the inspection, you simply are not allowing the inspector to take the camera into the manufacturing area of the facility

Photographs and Video Cameras

- Provide FDA reasons for not allowing:
 1. Plant manufacturing process is proprietary and we do not allow anyone to take cameras inside
 2. While we understand proprietary information is protected under the Freedom of Information Act, proprietary information has been released by the agency unintentionally in the past. If it is ever released, our competitors will know our process
 3. Our lawyers won't let us
 4. If necessary, contact corporate or outside legal counsel and have them be the "bad guy"

Photographs and Video Cameras

- It has been our experience that if the company holds firm, in most instances the inspector will conduct the inspection without the camera
- It can be difficult and it will be contentious

Affidavits

- Inspectors typically will ask companies to sign affidavits
- You are NOT required to sign an affidavit
- Affidavits should NOT be signed until they are first reviewed by your corporate or outside counsel
- Why—once an affidavit is signed, the content is treated as evidence regardless if it is accurate

Affidavits

- We typically advise our clients that they should not sign affidavits, although we have made exceptions to this general policy on a case-by-case basis
- FDA will insist the company official is required to sign----hold firm, blame it on your “lawyers,” and good luck

Samples

- Inspectors are authorized to take samples
- The company can seek reimbursement for samples taken but typically will not do so unless the sample is particularly expensive
- When the inspector takes samples, the company should
 1. Obtain at least three duplicate samples
 2. Ask the inspector to identify the analyses that will be performed
 3. Let the inspector know that you would like to receive a copy of the analyses when it is completed

Environmental Samples

- While the statute does not specifically address the issue, we believe FDA has the legal authority to take environmental samples
- Environmental samples will present valuable information on status of the manufacturing environment, but the location and prevalence of the sample are important
 1. Location
 1. Zone 1 or 2?
 2. Zone 3 or 4?
 2. Prevalence
 1. Isolated
 2. Consistently present

Environmental Samples

- Remember the legal standard—a food is deemed adulterated under 402(a)(4) if it is manufactured in a facility whereby it may have become adulterated
- Mere finding of pathogen in the environment does not necessarily mean the food is manufactured in an environment whereby it may have become contaminated
- As FDA collects more information on environmental samples, stay tuned for precedent established by findings in zone 1, 2, 3, or 4

Samples

- Label the samples after they have been taken
- Establish a chain of custody that tracks where the samples have been taken after the inspection
- Store the samples under conditions that will maintain the integrity of the sample
- At least one of the samples should be analyzed
- All inventory from the sampled lot should be placed on hold until the FDA results are obtained
- FDA will provide results of its analysis on FD-1551 (typically within a few weeks)

Samples

- After the inspection, stay in communication with FDA regarding the results from the agency analysis
- We are seeing delays in the analytical results which places companies in a difficult situation because product frequently is on hold
- For perishable products, companies have very difficult decisions to make—if you release the product and it is found violative there will be a recall—if you hold onto the product it will perish before the results are obtained by FDA
- Know your plant, know your product, and make reasoned decisions on whether product should be released

Samples

- FDA is required to provide company with the results when it collects samples of food products
- Surprisingly, FDA is not required to provide companies with the results from environmental testing
- Some district offices provide the results; others do not (consistency would be nice)

Handling Inspections

- Advance Planning
 1. Dust off your inspection procedure manuals
 2. If you don't have one, consider making one
 3. Know in advance how you will handle an inspection
 4. Allocate responsibilities from "a" to "z"
 5. Advance planning is crucial

Pre-Inspection Procedures

- Develop a company inspection file
- Designate and train the individual that will accompany the inspector
 1. Typically the plant manager will accompany the inspector
 2. Also is appropriate for someone from regulatory to accompany the inspector
 3. These people should be trained and need to know their rights

Inspector Arrival

- Employees should be instructed to direct inspectors to a pre-determined company representative
- The inspector will present a “Notice of Inspection” (FD- 482)
- The statute authorizes an inspection to occur at reasonable times and within reasonable limits
 1. While inspections usually take place during normal business hours, they can take place at any time the plant is operating
 2. If your plant runs 24/7, the inspector could arrive at 3 a.m. on Saturday morning

Handling an Inspection: Arrival

- If the inspector arrives at an unusual time, it is appropriate to ask the inspector to wait while you contact the individual in the company that is charged with handling inspections
- Politely inform the inspector that the responsible individual is at home and ask if the inspection can be delayed until he/she arrives at the facility
- The inspector is not required to postpone the inspection
- If your facility runs 24/7, it would be advisable to have a trained person available for each shift

Pre-Inspection Interview

- Take inspector to a conference room or office where you can discuss the inspection prior to entering the manufacturing facility
- Take notice of the inspectors credentials
 - Typically inspectors will have 200-A, B, C, or D credentials
 - 200-D credentials are for inspectors from the Office of Criminal Investigation (OCI)
 - OCI inspectors will appear on routine inspections, but they also can appear on inspections when FDA is considering a criminal investigation

Pre-Inspection Interview

- Inspection also could be conducted by a state regulator for FDA or under the state's statutory authority—ask the inspector to clarify
- Ask the inspector why he/she is conducting the inspection
 - Routine inspection?
 - Inspection resulting from a complaint?
 - Investigation resulting from a contaminated product?
 - GMP/HACCP/LACF/Acidified Food Inspection?
 - Inspection after a product recall?
 - Training inspection?
 - Under Bioterrorism?

Pre-Inspection Interview

- The pre-inspection interview provides an opportunity to discuss the company policy on photographs and video equipment
- Make it clear you are not denying the inspection, but the company policy does not allow for video cameras
- The inspector also should be advised to direct all questions to you or the other designated individual when in the manufacturing environment
 - Advise the inspector that he/she should not ask the employees in the facility any questions
 - You do not want to distract the employees from their responsibilities

The Inspection

- Accompany the inspector during the inspection of the facility
- If the inspector identifies an issue of concern and it can be readily fixed or addressed, implement the remedial action
- Take copious notes of the inspection, including
 - Part of the facility inspected
 - Questions asked by the inspector
 - Comments made by the inspector
 - Corrective actions taken
 - Samples taken, etc.

The Inspection

- When accompanying the inspector, be cordial and responsive to questions, but don't volunteer too much information
- The inspector is on a fact finding mission and will take note of any information that is volunteered or disclosed as part of the inspection
- The inspector will ask to see records: Know your rights
 - Delicate balancing act
 - By denying certain records, you may be prolonging the inspection
 - Companies frequently will allow access to records in the spirit of cooperation

Post Inspection Procedures

- There should be a post-inspection meeting to discuss observations made during the inspection
- If the inspector took samples, he/she should be asked to confirm the analyses that will be performed and the company should repeat its request to obtain the results as soon as they are available
- Keep copious notes of comments made during the post-inspection meeting

Post Inspection Procedures

- At the conclusion of the inspection, FDA will present a FD-483 if the agency has observed conditions of potential concern
- The company should review the FD-483 carefully and in the event it contains an observation of a condition that the company corrected during the inspection, the inspector should be asked to note the corrective action on the form
- The mere existence of an observation in a FD-483 does not mean the company has produced adulterated or misbranded products

Post Inspection Reports

- After the inspection, the individual that accompanied the inspector should prepare a post inspection report
- Include the post inspection report in the company's Inspection file
- The post inspection report should include all relevant information from the inspection

Post-Inspection Report Content

1. Date and time of inspection
2. Inspector's name, credentials
3. Company personnel that accompanied the inspector
4. Suspected violations
5. Samples taken
6. Sample analysis
7. Post inspection report prepared by company
8. Establishment Inspection Report prepared by FDA
9. Post inspection correspondence with FDA
10. Corrective actions, including costs associated with such actions

Post Inspection Procedures

- If the company received a FD-483, it is advisable to prepare a written response
 - Under a policy announced in August 2009, companies have 15 days to respond to a 483 if they want FDA to consider it in assessment of whether additional enforcement action is warranted
 - The response should identify corrective actions that have been made and provide company position on whether some of the observations are legitimate

Post Inspection Procedures

- Response is advisable if the company wants to mitigate potential for a Warning Letter
- If 483 is issued as part of a disease-outbreak investigation, FDA will post the 483 on the agency website shortly after issuance

Post Inspection Procedures

- The FDA inspector will prepare an Establishment Inspection Report (EIR) that will contain his/her observations from the inspection
- FDA will provide the EIR to the company after the inspection (typically in two or three weeks)
- The EIR will contain the inspectors observations and frequently will contain proprietary information
- EIRs are subject to FOIA but the proprietary information in them is not
- A FOIA request should be submitted (but not on company letter head) and a copy of the EIR should be requested to make certain FDA has deleted confidential information

Questions?

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