# FDA Brewery Inspections

BY
MARC E. SORINI
AND VANESSA K. BURROWS

Most breweries have numerous dealings with the Alcohol and Tobacco Tax and Trade Bureau (TTB) and understand the need to comply with TTB regulations; this includes preparation for TTB audits and inspections. But the TTB is not the only federal agency with the authority to conduct a brewery inspection.

The Food and Drug Administration (FDA) also inspects food facilities, including breweries, to ensure they comply with FDA regulatory requirements. The FDA may conduct inspections as the result of routine surveillance, product quality issues, consumer complaints, or recalls. The agency also may conduct inspections to follow up on a previous inspection or an FDA enforcement action. The FDA also contracts with state and local food protection programs to conduct inspections and provide certification and training.

## FDA Inspection Authority

FDA regulates food (a term defined broadly to include all alcohol beverages) and food ingredients offered for sale in interstate commerce. The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes the agency to enter and inspect, at reasonable times, within reasonable limits, and in a reasonable manner, any facility, vehicle, equipment, material, container, and labeling used to manufacture, process, pack, hold, or transport food. As a result, inspections of food facilities are typically unannounced.

In a food inspection, the FDA may evaluate manufacturing practices as well as the methods, facilities, and controls used in storing and distributing foods, according to the agency's *Investigations Operations Manual*. As part of the manufacturing process, FDA inspectors may observe how ingredients are handled and whether cleaning and inspectional operations performed on ingredients or materials are effective.

## Preparing for an Inspection

The best way to prepare for an FDA inspection is to have a good compliance program. In addition, brewers should develop procedures to follow in the event of an audit or an inspection by the FDA or other agency. These procedures should specify who will accompany the inspectors, who will take notes on their requests and observations, what safety measures the inspectors must follow, and what personal protective equipment must be used. The facility can advise the inspector as to its sanitation policies, such as handwashing, shoe sanitizing, the use of protective clothing or hair coverings, and restrictions on movements between different areas of the facility to avoid contamination. If such procedures are in place, breweries should inform FDA officials before the inspection. Additionally, inspection procedures should cover the segregation of attorney-client privilege and attorney work product documents, so the brewery does not inadvertently share confidential information and possibly waive protections.

It is crucial that brewery employees understand who they must notify if the FDA appears at the facility without warning, so that top management officials can mitigate potential problems. Legal counsel can be consulted as appropriate. A principal or other high-level person may welcome and/or accompany FDA inspectors, but the brewery should also designate a point of contact who has the time and knowledge to accompany the inspectors.

## What to Expect During an Inspection

Inspections may be conducted by a single FDA official, a team of FDA employees, jointly with state inspectors, or by state inspectors through a contract or partnership agreement. Depending on the size of the facility and the existence and/or severity of potential FDCA violations, inspections may last for days or weeks. For example, FDA may conduct a more detailed inspection

if the facility has a troubled history or lacks a current compliance program, if the inspector is unfamiliar with the brewing industry, or if objectionable conditions are discovered as the inspection progresses.

At the start of a domestic facility inspection, FDA officials will show the appropriate credentials and issue FDA Form 482, Notice of Inspection, to the top management official at the facility. The inspector may conduct an initial walkthrough in an attempt to become familiar with the facility's operations, products, processes, and records. The inspector may find potential areas of concern during this visual inspection.

The FDA may ask for many items, including:

1. Names, titles, educational backgrounds, experiential backgrounds of corporate officers, supervisors, and employees in managerial, production, control, and sanitation positions;
2. Test results;
3. Incident reports;
4. Information regarding the company's products, services, customers, and hours of operation;
5. Licenses held by the company;
6. Product labels[1];
7. Tables of contents for policies and standard operating procedures;
8. Copies of maintenance or equipment logs;
9. Records or company investigations related to product issues;
10. Queries from a company's database or electronic records;
11. Electronic data that the FDA may analyze;
12. Information regarding previous inspections conducted by the FDA or other federal, state, or local regulators;
13. Documentation regarding suppliers; and
14. Other records or information.

Management should compile a list of the copies of records obtained by the FDA. An inspector will provide receipts (FDA Form 484) to the highest management official available for any samples or physical evidence taken during an inspection. The agency may not collect any samples if the inspector does not see any violations or apparent violations of the FDCA. The FDA will not issue a Form 484 for labels (almost all of which are regulated by TTB), promotional material, or records collected during the inspection.

## Partial Exemption for Breweries

In 2011, the FDA Food Safety Modernization Act (FSMA) provided the agency with additional authority to inspect food facilities and access records. For example, FSMA provided the FDA with the authority to access, inspect, and copy all records relating to an article of food that the agency reasonably believes is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The FSMA also gave the FDA the authority to order

the detention of a beer found during an inspection if the FDA employee has reason to believe that the beverage is adulterated or misbranded.

The FSMA exempts a facility from the expanded records inspection requirement mentioned above if: (1) it is required to register as a food facility with the FDA because it manufactures, processes, packs, or holds one or more alcohol beverages; and (2) it is required to register with or obtain a permit from the TTB. Prior to the FSMA, FDA regulations issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required breweries to register as food facilities with the agency. Breweries also must obtain a brewer's notice from the TTB. Therefore, under this limited exemption, the activities of breweries that relate to manufacturing, processing, packing, or holding of alcohol beverages are exempt from the FDA's expanded inspection requirement.

Activities not related to manufacturing, processing, packing, or holding alcohol beverages are not explicitly exempt. Additionally, if the brewery receives and distributes non-alcohol food that is not prepackaged and that constitutes five percent or more of the facility's overall sales, the brewery no longer qualifies for the limited exemption.[2]



## Identification of Potential FDCA Violations

Inspectors may examine many areas of a brewery, including the facility and grounds, raw materials, equipment, manufacturing processes, sanitation, and distribution. For other food facilities, the FDA has identified the following FDCA violations during inspections. This list is not all-inclusive of possible FDCA violations or reasons that the agency may deem a product adulterated.

*A. Equipment and Sanitation*

- Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing;
- Use of duct tape and other non-cleanable surfaces on equipment;
- Failure to conduct cleaning and sanitizing operations for equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials;
- Use of sanitizing agents that are inadequate and unsafe under conditions of use; and
- Employees' failure to wash hands thoroughly in an adequate hand-washing facility.

*B. Materials in Food and Contamination*

- Failure to wear hair restraints as appropriate;
- Failure to provide safety-type lighting fixtures suspended over exposed food;
- Failure to take effective measures to protect against the inclusion of extraneous material in food;
- Ineffective exclusion of pests (insects, mice, birds, etc.) from processing areas;
- Ineffective measures to protect against contamination of food on the premises by pests;
- Failure to remove litter and waste and cut weeds or grass that may constitute an attractant, breeding place, or harborage area for pests;
- Failure to store finished food under conditions that would protect against physical and microbial contamination; and
- Failure to smoothly bond food contact surfaces to minimize the accumulation of organic matter and the opportunity for growth of microorganisms.

*C. Facility Design and Maintenance*

- Failure to construct the plant in a manner as to allow floors to be adequately cleaned;
- Inadequately installed or maintained plumbing that does not provide acceptable floor drainage; and
- Failure to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from becoming adulterated.

## Inspection Closeout Meeting

Following the inspection, the inspector will hold a closeout session with facility management to explain the issues identified and any next steps. During this meeting, the inspector typically discusses "observations of questionable

significance," which are deviations from FDA laws or rules that, in the inspector's judgment, are not important enough to include on FDA Form 483, Notice of Inspectional Observations. Instead, these observations, and specific actions the company takes to respond, will be reported in an Establishment Inspection Report (EIR). The EIR also contains the inspector's narrative observations, copies of FDA Forms 482, 483, and 484 issued during the inspection, and any exhibits.

## FDA Form 483

The facility's highest management official available will receive FDA Form 483 at the closeout session, indicating whether the investigator observed any "significant objectionable conditions" or other violations of the FDCA. The closeout meeting seeks to make management aware of the need to correct objectionable practices. An investigator will document such practices when observing conditions that indicate food has been prepared, packed, or held in conditions under which it may have become adulterated or injurious to health. The FDCA prohibits the adulteration of any food, as well as the introduction of adulterated food into the marketplace. If a food violates the conditions imposed by the FDCA, the FDA may take enforcement action, which may include seizing the product, seeking an injunction, or pursuing prosecution.

## Responding to FDA Form 483

Breweries should seek the assistance of counsel in preparing the company's response, as failure to respond appropriately to the FDA inspection could lead the agency to issue a warning letter or take other enforcement action. Typically, the FDA will provide a facility with 15 business days from the date it receives a warning letter to respond. A brewer may request a reasonable extension of time, which FDA is likely to grant. In order to ensure the FDA considers the facility's response, a company that receives an FDA Form 483 should respond within the 15-day timeframe. In the response, the company may discuss corrective actions taken or planned to address the FDA's observations. Corrective actions may include additional training, and new policies and procedures.

In many cases, the FDA will evaluate the company's response to Form 483, along with the EIR, and may decide to issue a warning letter or take further enforcement actions. However, the FDA is not required to wait for a company's response to the Form 483 and may take action at any time. In deciding whether to issue a warning letter, the agency may consider the company's ongoing or promised corrective actions. The FDA may take other factors into account, such as the risk to public health; any history of inspections or compliance problems; how difficult it will be for the brewery to correct any deviations; the brewery's willingness to undertake corrective actions; and the brewery's ability to follow through on corrective actions.

Warning letters are publicly available on the FDA website, and the violations cited may interest the press, especially trade publications. A warning letter may note that the company failed to take prompt corrective action to address the FDCA violations identified. Such failure may result in the FDA initiating another regulatory action without any further notice, such as a seizure. The FDA and the U.S. Department of Justice could seek a consent decree, which could specify the frequency with which the facility must be re-inspected by the FDA. The FDA may also advise other federal regulatory agencies, such as the TTB, of the warning letter.

## Conclusion

Currently, FDA inspections of breweries are not as common as TTB inspections. However, though the FDA allocates resources for high-risk facilities and inspects facilities linked to an illness or outbreak, the FDA also conducts routine inspections. Brewers must be ready. When developing procedures for inspections or audits, a brewery should remember to add FDA-specific

considerations to its preparations and compliance programs.

## References


1. Virtually all beer labels are regulated under the Federal Alcohol Administration (FAA) Act, provided they meet the definition of "malt beverages." Beer labels are unlikely to be a major source of concern for the FDA. The FDA has responsibility for labeling of beers (other than saké and similar products) that do not meet the definition of a malt beverage in the FAA Act.
2. FSMA does exempt such breweries from FDCA provisions regarding the FDA's allocation of resources for risk-based inspections of facilities.


**Marc E. Sorini is a partner in the law firm of McDermott Will & Emery LLP, based in the firm's Washington, D.C. office. He leads the firm's Alcohol Regulatory & Distribution Group, where he concentrates his practice on regulatory and litigation issues faced by supplier-tier industry members. Vanessa K. Burrows is an associate in McDermott Will & Emery LLP, based in the firm's Washington, D.C. office. She counsels clients on FDA laws, regulations, and guidance.** NB