

What to Expect in an FDA Inspection

by Jeffrey S. Baird, Esq.



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As a general rule, pharmacies should not be concerned about a Food and Drug Administration inspection. This is because the FDA has no jurisdiction over pharmacies that engage in traditional pharmacy practice. The FDA does, however, have jurisdiction over manufacturers. If the agency believes that a pharmacy's compounding practice has "crossed the line," then it will assert that the pharmacy is acting like a manufacturer and, thus, falls within the FDA's jurisdiction. This is when the pharmacy can be hit with a surprise FDA inspection. This article gives an overview of FDA inspections.

The FDA, under 21 U.S.C. §374(a)(1) (Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act) can have inspectors to enter, at reasonable times, facilities in which drugs are manufactured, processed, packed, or held for introduction into interstate commerce. Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act allows the FDA to request, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, any records or other information that may be inspected under Section 704(a).

INSPECTION CATEGORIES

There are three basic categories of inspections.

A *comprehensive inspection* is requested by FDA headquarters or the district office and can cover everything in the pharmacy subject to FDA jurisdiction. These inspections can take less than a day, or they may last for weeks.

An *abbreviated inspection* is an inspection that covers only critical factors that are identified in the Inspectional Guidelines, the FDA Investigations Operations Manual (IOM), or under an inspectional program from FDA headquarters.

An *as directed inspection* is triggered by an identifiable event, such as a recall, consumer complaint follow-up, competitor complaint, or other specific incident.

Regardless of the type of inspection, the key issue will be whether the FDA believes the pharmacy is a manufacturer. If the inspector believes this is the case, he or she will issue an FDA-483 Inspectional Observations.

Key personnel should be familiar with their roles in dealing with the inspector. Although pharmacy inspections ordinarily involve only one FDA inspector, the agency can send two or more. Once the inspection begins, it is crucial that key personnel in all operations be promptly made aware of the FDA's presence. If a corporate inspection leader is not available to respond to the FDA, other personnel need to understand the pharmacy's policies when answering the inspector's inquiries.

BE PREPARED FOR AN INSPECTION

FDA inspections are usually unannounced. Thus, the pharmacy must always be prepared for an inspection. Contacts with FDA inspectors require the utmost professionalism. Inspectors have a job to perform. The FDA's Investigations Operations Manual says that investigations "must always be conducted with tact, honesty, diplomacy, and persuasiveness" per §5.2.5.4.

It is important that the pharmacy not create an adversarial environment, as it is counterproductive. On the other hand, the pharmacy must recognize that the inspector is not there to befriend it. No matter what the inspector says, that person is not there for the pharmacy's benefit. The inspector should be courteously received during the course of his or her visits. Usually, this attitude will achieve the best results for the pharmacy and establish a better long-term relationship with the FDA. Conversely, a series of confrontations with the inspector can cause an otherwise manageable situation to deteriorate rapidly.

The degree of the pharmacy's cooperation will be reflected in the inspector's Establishment Inspectional Report (EIR). The EIR is an internal FDA document that comprehensively describes the inspection. The EIR describes all aspects of the investigation, such as the history of the pharmacy, pharmacy management, inspectional findings, the facility layout, and discussions with management about problems, to name several. The pharmacy's attitude will be reflected in the EIR, which will then go into the FDA's permanent file on the pharmacy. It is often helpful to obtain a copy of the EIR through a Freedom of Information Act request once the inspection has been concluded.

ASSIGN AN INSPECTION LEADER

An inspection leader must be assigned to deal with the FDA. This designated individual may also be appointed to handle telephone communications. This leader should be aware of all aspects of the pharmacy's policies, operations, and record-keeping systems. Alternatively, an inspection group can be set up. This group would then assign a leader who would be responsible for the group's actions. The group would be made up of persons familiar with the pharmacy's policies for dealing with the FDA and with the pharmacy's operations.

The leader and/or the group should accompany the inspector throughout the inspection. The FDA may follow up the inspection with a telephone call. All telephone calls from the FDA should be handled by the pharmacy's inspection leader.

The inspector should be made aware at the outset that there is a pharmacy policy for dealing with the FDA. This will help when questions arise on how to answer the inquiries made by the inspector. An FDA inspector will more readily accept a denial based on established policy than a refusal based on an "instant policy" created on the spot. In responding to issues such as the taking of photographs, access to corporate records, and signing affidavits, along with other problem areas, the pharmacy should politely explain that the inspector's request cannot be granted because of an existing pharmacy policy. ■

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