



Food, Drug & Device/FDA ADVISORY ■

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How to Respond When FDA Knocks: What Happens When You Say No?

Two months ago, the Food and Drug Administration (FDA) issued a Draft Guidance entitled “Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection” (“Draft Guidance”).¹ Congress required FDA to issue this guidance within a year of the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA), which strengthened FDA’s authority regarding inspection refusals, so that now delaying, denying, limiting or refusing to permit inspection causes a drug to be adulterated. 21 U.S.C. § 351(j) (a drug is adulterated if “it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment” where the owner has refused to permit entry or inspection).

It is true that the “refusal to permit entry or inspection as authorized by section 704” has long been a prohibited act. 21 U.S.C. 331(f). However, because a refusal now causes all drug products in that establishment to be adulterated, Congress required FDA to elaborate on circumstances that would fall within the scope of 21 U.S.C. § 351(j). The Draft Guidance also raises the question whether FDA’s views will be applied to regulated products other than drugs.

The Draft Guidance provides the following examples of actions that, in FDA’s view, constitute delaying, denying, limiting or refusing an inspection:

- not allowing an FDA investigator to inspect the facility because certain staff members are not present;
- ordering the discontinuation of manufacturing during the duration of the FDA inspection;
- limiting FDA’s opportunity to perform direct observation to “an unreasonably short amount of time”;
- “unreasonably restrict[ing] entry to a particular facility without adequate justification”;
- limiting the investigator’s ability to take photographs; and
- providing the investigator documents that have been “unreasonably redacted.”

Given the broad scope of FDA’s inspection authority under Section 704 of the FDCA, these examples should come as no surprise to industry. However, FDA’s silence in the Draft Guidance on several points prompts questions. For example, with regard to restricted entry, the Draft Guidance does not allow “unreasonably restricting entry to a particular facility without adequate justification,” but the Draft Guidance does not define the term “unreasonable.” Nor does the Draft Guidance define “adequate justification,” or provide examples of circumstances in which restricted entry would be appropriate.

¹ <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf>

In certain cases, restricted entry may be entirely appropriate for safety reasons or to ensure that a complicated process is performed without distractions. FDA provides no guidance to help resolve these issues. Without clarification of these terms, there is a risk that FDA could consider reasonable restrictions to be inspection refusal.

Similarly, the Draft Guidance requires establishments to respond to inspection requests in a “timely” manner, but never describes what would be considered “timely.” In the event that paper records are stored offsite, either in storage or at another facility, it may not be possible to produce records quickly. Without further guidance, there is a risk that, despite a company’s best efforts to produce the records as soon as possible, an FDA investigator will assert that the company has delayed the inspection.

The Draft Guidance is also silent regarding refusals to permit interviews with staff. It is not clear, therefore, whether an establishment’s decision not to allow interviews with staff constitutes an inspection refusal.

Another open question is whether, and to what extent, FDA will use this expanded authority to be more aggressive in enforcement. Delaying, denying, limiting or refusing to permit an inspection has long been a prohibited act under the FDCA, which subjected any person responsible for such refusal to criminal penalties of not more than one year in prison and not more than a \$1,000 fine. 21 U.S.C. §§ 303(a), 331(e), (f). Because an inspection refusal now causes a drug to be adulterated, an inspection refusal could serve as the basis for an in rem seizure proceeding, import alert or other enforcement action based on the introduction of adulterated product into interstate commerce, which is also prohibited under the FDCA. See 21 U.S.C. §§ 334, 381(a).

The agency has already started to embrace its new authority. During the summer of 2013, FDA imposed import alerts and issued two warning letters citing violations for delaying, denying, limiting or refusing to permit an inspection.

On May 1, 2013, FDA imposed an import alert for products manufactured by Hangzhou Hetd Industry Co., Ltd. and Hangzhou Hetd Pharm & Chem Co., Ltd. due to “refusal to permit inspection of a foreign facility or provide reasonable access to FDA’s personnel[, which] provides an appearance that the firm’s products are manufactured, processed, or packed under insanitary conditions.”²

In a recent Warning Letter, FDA identified denial and limitation of an inspection as the first violation. FDA cited several instances in which the establishment “delayed, denied, limited an inspection or refused to permit the FDA inspection” during FDA’s inspection of facilities. The examples included: torn raw data found by the investigator in a waste area that was not provided to the investigator upon request; dumping unlabeled vials into a sink when asked what the vials contained, instead of answering the investigator’s questions about the contents; making incorrect statements to the investigator; and failing to provide records for two days, despite multiple requests for the documents.

This particular Warning Letter suggests that FDA may view it “untimely” if a facility takes longer than one day to provide records.

In another recent Warning Letter, FDA also cited the establishment’s inspection delays as violations. Examples of delays included: providing misleading information, which occurred when an employee denied that certain events had occurred; refusing to provide requested information; making incorrect statements about where data was stored; an employee’s attempts to hide manufacturing-related records in his pocket; and removal of certain equipment during the inspection to conceal data manipulations.

The Warning Letter expressly stated that because of the delay, the products were deemed adulterated.

² http://www.accessdata.fda.gov/cms_ia/importalert_521.html

The Draft Guidance highlights the need for proper inspection management training prior to an inspection. Companies need to understand the scope of FDA's inspection authority and the legal significance of an inspection refusal. In addition, companies need to establish well-defined procedures for FDA's entry and notice of inspection, and need to understand what to do if those procedures are not followed. For example, law enforcement personnel who are conducting an investigation will not provide a Form FDA-482, Notice of Inspection. It is important for outside counsel to be involved in order to ensure that the client manages these investigations appropriately.

Outside counsel should assist the company in preparing employees for interaction with FDA investigators. For example, employees must be advised of the need to be truthful in all cases, and the legal risks of not doing so. Similarly, within respect to documents, employees must be advised not to alter or hide documents, and the legal consequences of not providing requested information.

While FDA's inspection authority under Section 704 is quite extensive, on occasion, FDA investigators may request documents that fall outside the scope of FDA's inspection authority, or at least raise the question whether the requested documents must be provided. Outside counsel is in the best position to determine whether an inspection request falls within the scope of FDA's inspection authority.

The lawyer can also provide guidance regarding redactions before or during an inspection. Outside counsel is in the best position to provide advice about what information is within the scope of FDA's inspectional authority and what is not.

The lawyer can provide advice regarding FDA requests to take photographs and present affidavits to company officials. Note that this conversation should occur well before an inspection, so the client will have time to revise its inspection management procedure, but in the event that this has not occurred, the client should contact outside counsel.

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