Client Alert

July 2013

FDA Issues Draft Guidance on Drug Facility Inspections

On July 15, 2013, the Food and Drug Administration (FDA) issued a draft guidance that describes the circumstances that, in the agency's view, will constitute delaying, limiting or refusing the inspection of a drug manufacturing, processing, packing or holding facility.

Background

To evaluate whether a drug is in compliance with the Federal Food, Drug and Cosmetic Act (FD&C Act) and FDA regulations, FDA conducts establishment inspections. The Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the FD&C Act, provides that a drug will be deemed to be adulterated if it "has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection." FD&C Act § 501(j). Moreover, under the FD&C Act, it is a prohibited act to refuse to permit the inspection of a facility or to refuse access to or copying of any records necessary to conduct an inspection. *See id.* § 301(e)-(f). Persons who engage in prohibited acts are subject to criminal penalties. *See id.* § 303(a).

The draft guidance issued by FDA describes four circumstances that the agency believes will constitute a violation of FD&C Act § 501(j):

- Delaying a drug facility inspection;
- Denying an inspection;
- Limiting an inspection; and
- Refusing to permit entry into or inspection of a drug facility.

Delaying an Inspection

Per the draft guidance, FDA may deem a drug to be adulterated if the drug facility's owner, operator or agent causes the delay of an inspection. The draft guidance identifies three types of delay:

1. *Delay scheduling pre-announced inspections*: FDA often contacts a drug facility's management to schedule an inspection. The agency may determine that the facility is delaying the inspection if it (a) refuses to agree to a proposed inspection date without providing a reasonable explanation, (b) requests a later inspection date or (c) does not respond.

2. *Delay during inspections*: Actions taken by a facility's owner, operator or agent either before or after the beginning of an inspection that impede an FDA investigator from performing the inspection may be considered delaying the inspection.

3. *Delay producing records*: A critical aspect of FDA's inspection is the review and collection of certain records bearing on whether a drug is adulterated, misbranded or otherwise in violation of

the FD&C Act and FDA regulations. A delay in producing such records to FDA, without reasonable explanation, may be considered delaying the inspection.

Denial of Inspection

FDA may deem a drug to be adulterated when the behavior of an owner, operator or agent of a drug facility prevents an authorized FDA representative from conducting or completing an inspection.

Limiting of Inspection

FDA may deem a drug to be adulterated when an owner, operator or agent of a drug facility prevents an authorized FDA representative from conducting an inspection to the extent allowable under the law. The draft guidance identifies three types of limitations:

1. *Limiting access to facilities and/or manufacturing processes*: Prohibiting an FDA representative from obtaining reasonable access to an area of the site that FDA is entitled to inspect may be considered limiting the inspection.

2. *Limiting photography*: Preventing photography by an FDA investigator may be considered a limitation if such photographs are determined by the investigator to be necessary to conducting the inspection.

3. *Limiting access to or copying of records*: Preventing an FDA inspector from accessing or copying records that FDA is entitled to inspect, including failing to provide records that FDA requests, may be considered limiting the inspection.

Refusal to Permit Entry or Inspection

Finally, FDA may deem a drug to be adulterated if the owner, operator or agent of a drug facility does not take affirmative steps to permit an inspection. The draft guidance states that "refusal" includes passive behavior and nonaction that results in the inability to enter or inspect a facility.

How Hunton & Williams LLP Can Help

FDA is accepting comments on this draft guidance through September 13, 2013. Our lawyers have extensive experience advising clients on FDA enforcement matters, including those affecting drug manufacturing. If you would like to know how this draft guidance affects you, or if you need assistance preparing comments on this draft guidance or responding to an FDA inspection, please contact us.

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