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ALERTS

Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Definition Of Denying, Delaying, Limiting Or Refusing To Permit Inspection

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The FDA recently issued a draft Guidance to define the types of actions (or inaction) that constitute "delaying, denying, or limiting inspection, or refusing to permit entry or inspection" for the purposes of § 501(j) of the Food, Drug & Cosmetic Act (FD&C Act). A little over a year ago, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted. Section 707 of FDASIA adds 501(j) to the FD&C Act to deem adulterated a drug that "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." Section 707(b) of FDASIA required the FDA to issue guidance that defines the circumstances that would violate section 501(j). This draft guidance is the FDA's attempt to do so.

The most noteworthy and likely controversial part of the draft Guidance is the FDA's position that "limiting" an investigation includes not allowing an FDA inspector to take photographs that the investigator deems necessary to conduct the investigation effectively. FDA has long asserted its power to take photographs, and lawyers have questioned that power for an equally long time. FDA has traditionally argued that two court cases give it this power, but most lawyers agree that the cases do not support the FDA's position. Nonetheless, many lawyers advise their clients to allow an FDA inspector to take photographs to maintain goodwill and because the FDA can almost certainly obtain a subpoena authorizing it to do so anyway.

Other non-exclusive examples of conduct cited by the draft Guidance that could result in a determination that a drug is adulterated under § 501(j) include:

- Delay scheduling pre-announced inspections
    - A facility will not agree to a proposed inspection start date and does not give a reasonable explanation for its failure to do so
    - After scheduling an inspection, a facility requests a later start date without giving a reasonable explanation
    - A facility fails to respond following FDA's attempt to contact the facility's designated contact(s)
- Delay during an inspection

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    - A facility does not allow the FDA investigator access to an area of the facility until a specific future date or time even though the area is operational and is an area of the inspection site that FDA has authority to inspect
    - A facility leaves the FDA investigator in a conference room without access to necessary documentation or responsible individuals for an unreasonable period of time that interferes with the investigator's ability to complete the inspection
- Delay producing records
    - During an inspection, the FDA investigator requests records FDA has authority to inspect within a specific, reasonable timeframe, but the facility fails to produce the requested records within the timeframe requested by FDA, without adequate justification
    - FDA requests records pursuant to section 704(a)(4) of the FD&C Act, but the facility fails to produce the requested records in a timely manner, without adequate justification
- Denial of inspection
    - A facility rejects FDA's attempt to schedule an inspection
    - A facility does not allow the FDA investigator to begin an inspection of a facility, even if it has been pre-scheduled
    - A facility does not allow the FDA investigator to inspect the facility because certain staff members are not present
    - A facility does not allow the FDA investigator to inspect the facility by falsely alleging the facility does not manufacture drugs
- Limiting an inspection
    - Limiting access to facilities or manufacturing processes
    - Limiting access to or copying of records
    - Limiting or preventing collection of samples
- Refusal to permit entry or inspection
    - The facility bars the FDA investigator from entering the facility or certain areas of the facility, for example, by not unlocking the areas or taking other necessary actions that would permit access by the investigator(s)
    - Following FDA's attempt to contact the facility's designated contact(s), the facility fails 224 to respond
    - The facility does not answer calls from the FDA investigator who is present at the facility, despite clear evidence of the presence of employees engaged in job-related functions

As a review of these examples reveals, another troublesome aspect of

the draft Guidance is that many of these are vague or subjective ("reasonable," "timely," "without adequate justification").

As always, it important to remember that a Guidance document, even when final, does not establish legally enforceable responsibilities, but simply represents the FDA's current thinking on a subject.

A copy of the draft Guidance can be found here.

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