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Making Good Decisions When FDA Investigators Come Knocking

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Inspection authority is one of the most valuable tools the FDA has to create its gold-standard culture of safety and efficacy. No drug or device maker is happy to see FDA when they come calling to scrutinize operations, but every consumer of their products demands the rigor that inspections ensure.

And while any legitimate drug or device maker is, in the big picture, happy that FDA enforces a system that ensures that their products—and all others—are safe and effective, the other side of that coin is that no one enjoys it when the knock is at *your* door, and the FDA investigator demands to occupy *your* conference room and see *your* documents. There may be moments of unease, or even panic, as plant managers ask themselves if there is any way to put this off for just a few days, so they can improve that one nettlesome area or complete that one unfinished quality project.

The answer to that question is almost always a resounding "no." When the inspector arrives, the time for preparation is over; the test has already started. And, in fact, attempts to delay, deny, limit, or refuse an inspection may do more harm than simply incurring FDA's ire. Doing so may render the drugs or devices adulterated under the FDA's controlling statute, the federal Food, Drug, and Cosmetic Act (FDCA).

How best to prepare for the eventuality of an inspection, so as to avid these pitfalls? FDA's June 2024 final guidance for industry, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection," provides some helpful touchstones that plant managers and their staffs should take away.

What's In The Guidance?

The new final guidance explains how FDA's inspection authority is founded in the FDCA, where it is laid out in clear, expansive terms. 21 U.S.C. § 374(a) gives FDA broad inspection authority over "any" facility where regulated products are made. While pre-approval and pre-license inspections are often scheduled in advance, surveillance inspections rarely are. In essence, facilities registered under the FDCA volunteer to be inspected without prior notice.

At 21 U.S.C. 351(j), the FDCA also states clearly that drugs and devices are adulterated as a matter of law if an inspection is delayed, denied, limited, or refused. The FDCA, of course, also prohibits the introduction of adulterated drugs and devices into interstate commerce, so playing fast and loose with an inspection can be a quick ticket to further legal action.

FDA is especially sensitive to inspection hindrances due to the demand for transparency that the FDCA imposes on regulated facilities. The FDCA is a public health statute that rises and falls on the voluntary compliance of regulated industry. When its provisions geared toward prohibiting or punishing bad behavior intersect with questions of public health and safety, enforcement can be difficult. Thus, FDA's expectations are high that facilities will freely promote cooperation so that these conflicts are avoided.

Delayed Inspections

Putting down obstacles for investigators can take many forms, and the final guidance offers some helpful descriptions of the ways that bad-acting or ill-advised facilities have obfuscated inspections in the past. For example, to FDA's thinking, delays of pre-approval or pre-licensing inspections include not agreeing to an announced start date without reasonable explanation as to why, changing an inspection date without a reasonable explanation, or failing to respond to FDA altogether on scheduling questions.

Other delays may creep into a pre-approval or surveillance inspection once it has started, such as refusing to make relevant personnel available, shutting down relevant processes without a reasonable explanation, or refusing or delaying the production of records.

Denied Inspections

The expectations of transparency are also countermanded when regulated facilities deny access for inspections. Denial includes actions like barring an investigator's entry, refusing to allow inspection of some parts of the facility once the investigator enters, falsely claiming that the facility does not make regulated products, or sending relevant staff home so that they become unavailable to investigators. In some cases, FDA has gone to magistrate judges to obtain administrative warrants in order to inspect facilities.

Limited Inspections

As the statute describes the illegality of limiting inspections, FDA went to the trouble of describing what that looks like in practice. Limiting an inspection can include restricting access to parts of a plant or to relevant employees, restricting the taking of photographs, or otherwise interfering with the review of records.

Refusals

The 2024 guidance concludes with a description of refusals and emphasizes that "not only active, but also passive behavior and inaction by the owner, operator, or agent of a facility" can amount to prohibited behavior. Examples of such prohibited, coy behavior include keeping areas of the facility under lock and key or failing to respond to FDA's inquiries or phone calls. There is overlap between refusals and the other three statutory sins. One person's denial might easily be described as a refusal, and so on.

Managing A Relationship With FDA.

If a facility chooses to engage in the kind of obstructive behavior that the final guidance describes, it will likely find itself swiftly sailing out of the usually calm procedural waters of the transparent compliance the FDCA describes and into the churning sea of FDA enforcement, which carries the risk of FDA's litigation partners at the Department of Justice (DOJ) joining in. That could entail high litigation costs in the short term, but probably more dire are the long-term costs of wrestling with FDA and, eventually, DOJ.

Whatever the outcome, this kind of behavior will at the least almost certainly pique the interest of regulators and will likely motivate them to dig deeper into the true motivations behind the disruptive activity. Relationships with customers could be at least as difficult, as they are unlikely to react well to a fraught, prolonged exercise of regulatory defiance, no matter the motivation.

Managing any relationships in the complex, scientific, and innovative industries that FDA regulates can be difficult. This final guidance is certainly designed, at least in part, to instruct drug and device makers that the path of least resistance for inspections is likely to be facing the sometimes-uncomfortable scrutiny from FDA. The alternatives—delay, denial, limitations, or refusals—run the high risk of exposing facilities to more expensive and unpalatable realities.

About The Author:

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