Cooley

FDA Expands Unannounced Inspections at Foreign Manufacturing Facilities

May 13, 2025

On May 6, the US Food and Drug Administration (FDA) **announced plans** to expand its use of unannounced inspections at foreign manufacturing facilities that "produce foods, essential medicines, and other medical products intended for American consumers and patients." While specific details regarding its implementation have not yet been released, this expansion could effectively subject all foreign facilities manufacturing FDA-regulated products to unannounced inspections. Historically, domestic facilities have received the majority of unannounced inspections, while foreign establishments have received up to 12 weeks' advance notice.

This announcement builds on the FDA's Foreign Unannounced Inspection Pilot program in India and China, which together account for more than one-third of the foreign establishments supplying the US market. The pilot program – launched in 2014, paused in 2015 and restarted in 2021 with an annual US congressional appropriation – is designed to increase unannounced surveillance inspections of foreign drug establishments specifically. This announcement also follows the May 5 publication of President Donald Trump's **executive order** titled, "Regulatory Relief to Promote Domestic Production of Critical Medicines," which, among other directives, directs the FDA to, by August 3, 2025, "develop and advance improvements to the risk-based inspection regime that ensures routine reviews of overseas manufacturing facilities involved in the supply of United States medicines, which shall be funded by increased fees on foreign manufacturing facilities to the extent consistent with applicable law." Further details about how these fees will be implemented were not included in the executive order or the FDA's announcement. One possibility is that they could be reflected in an increased facility registration fee. The executive order also directs the FDA to publicly disclose the annual number of foreign inspections, with specific details by country and manufacturer.

Given the historical shortage of investigators available to conduct foreign inspections, along with the recent reduction in force affecting the FDA, there are significant questions about how quickly and extensively this expansion can be implemented. Indeed, these limitations may delay implementation and lead to inconsistencies in enforcement. At the same time, the increased likelihood of unannounced inspections means companies must ensure their foreign manufacturing operations (and those of their business partners) remain in continuous compliance or else they could face operational disruption. Ultimately, more unannounced inspections could result in more significant findings by the FDA and enable it to use its regulatory enforcement tools, such as Import Alerts, to ensure noncompliant products do not enter the US supply chain. While such actions could result in drug shortages in the short term, in the long term, they could lead to improved product quality and safety.

The FDA's latest move is consistent with another goal announced by the Trump administration: to bring pharmaceutical manufacturing onshore, decreasing US reliance on foreign-manufactured pharmaceuticals. The White House's executive order notes that barriers to "establishing a domestic, resilient, and affordable pharmaceutical supply chain for American patients" are "heightened by unannounced inspections of domestic manufacturers by the [FDA], which are more frequent than such inspections at international facilities." Increasing unannounced inspections of foreign facilities could help level the playing field, ultimately supporting the White House's goal of stronger domestic pharmaceutical manufacturing.

your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our **legal notices**.

Key Contacts

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100
Auguste Humphries Washington, DC	ahumphries@cooley.com +1 202 776 2004