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FDA Compliance & Enforcement ADVISORY ■

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FDA Postpones Foreign Inspections Through April 2020: Considerations for Industry

In an unprecedented move, on March 10, 2020, the U.S. Food and Drug Administration (FDA) announced it is postponing most foreign inspections through April as a result of the COVID-19 outbreak. Inspections outside the U.S. deemed "mission-critical" will still be considered on a case-by-case basis. This follows up on an earlier statement from the FDA, on February 24, 2020, announcing the agency had stopped inspections in China consistent with the U.S. Department of State's travel advisory not to travel to China due to the COVID-19 outbreak.

Since the passing of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012 and the Food Safety Modernization Act (FSMA), the FDA's risk-based inspection program has been a cornerstone in the FDA's efforts in ensuring the safety of drugs, medical devices, and food imported into the U.S. Despite conducting more inspections abroad than in the U.S. since 2015, in recent years, the agency has been under pressure to increase its foreign facility inspections. Based on this announcement, at least until May, the FDA will regulate manufacturing activities without its on-the-ground enforcement capabilities abroad.

In the March 10 statement, the FDA refers to a number of "additional tools" as part of its "multi-pronged and risk-based approach" to ensure the safety of products imported to the U.S., including: (1) denying entry of unsafe products into the U.S.; (2) physical examinations and/or product sampling at the U.S. border; (3) reviewing a firm's previous compliance history; (4) using information sharing from foreign governments as part of mutual recognition and confidentiality agreements; and (5) requesting records "in advance of or in lieu of" on-site drug inspections.

The authority to request records in advance of or in lieu of inspections has become a critical component of the FDA's inspection-related activities. Congress granted this authority to the FDA under Section 706 of the FDASIA. Under Section 706, the FDA may request "[a]ny records or other information that the [FDA] may inspect under this section." The FDA's Staff Manual Guide 9004.1, "Policy and Procedures for Requesting Records in Advance of or in Lieu of a Drug Inspection," informs staff that records received from an establishment under one of these records requests "may be used to inform inspection planning, prepare for a scheduled inspection, inform FDA's decision to adjust the interval between on-site inspections (e.g., surveillance), or use the records in lieu of certain inspections." The FDA has used this statutory authority to seek clarification of inspection-related correspondence and to resolve certain issues following the issuance of a warning letter, prior to reinspection. In the past two years or so, it has appeared to us that through these record reviews, the FDA has been able to streamline and focus its on-site inspection activities.

Since the beginning of the year, in light of travel restrictions necessitated by the spread of the COVID-19 virus, the FDA has already utilized this authority to conduct record reviews of manufacturing establishments in China. As the FDA indicated in the March 10 statement, it will expand the use of this authority to inspect records in other parts of the world at least until the end of April, in lieu of on-site inspections.

In addition to the tools to ensure product safety, as they pertain to the agency's efforts related to the COVID-19 outbreak, the March 10 statement notes that the FDA is "actively facilitat[ing] efforts to diagnose, treat and prevent the disease; survey the medical product supply chain for potential shortages or disruptions and help to mitigate such impacts, as necessary; and leverage the full breadth of our public health tools, including enforcement tools to stop fraudulent COVID-19 activity."

Key Issues to Consider

In light of the FDA's announcement, the following are key areas for FDA-regulated industries to consider as the FDA looks to maintain its oversight of the safety of imported products despite the evolving COVID-19 outbreak.

"Mission-critical" inspections

While the FDA's March 10 statement does not elaborate on what it might consider to be "mission-critical" inspections that it will conduct on a case-by-case basis, the announcement does point to: (1) facilitating efforts to diagnose, treat, and prevent disease; (2) helping mitigate against supply-chain shortages; and (3) stopping fraudulent COVID-19 activity. In this light, the FDA could assign "mission-critical" inspections to be performed to evaluate the manufacturing process for a potential vaccine for COVID-19, to help address a potential shortage of medically necessary medical devices or drugs, or to conduct a for-cause inspection of a facility engaged in, for example, producing a fraudulent COVID-19 drug. It remains to be seen whether the FDA will also continue conducting foreign inspections for "high-risk" facilities based on its existing risk-based inspection schedule.

Potential increase in domestic inspections

The delay of foreign inspections will create availability of resources, which could be diverted to domestic inspections, assuming that domestic travel is not limited.

Records requests "in advance of or in lieu of" drug establishment inspections

While some of these record requests may be for specific, existing documents, it is likely that some records requests will be more involved and will take the form of detailed questions (e.g., in place of the discussions and interviews that would normally take place during an on-site inspection) that require clear, concise, and well-developed written responses. Similar to a response to a Form FDA-483 or warning letter, responding to these written requests can be time-consuming and resource intensive and often benefit from the input of consultants and legal counsel to draft submissions that are responsive to the FDA's requests.

Waiving CGMPs under an EUA

The FDA has the authority to authorize the emergency use of an unapproved product or an unapproved use of an approved product under an emergency use authorization (EUA) issued pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA). Among other things, Section 564 authorizes the FDA to waive current good manufacturing practice (CGMP) requirements under an EUA. To address threats posed by the COVID-19 virus, the FDA could use its authority under Section 564 to permit the importation of products that it would not otherwise allow, absent a successful facility inspection or evidence obtained through record requests under Section 706.

Foreign inspections of medical device manufacturers

The FDA's authority under Section 706 to request records in advance of or in lieu of inspections does not apply to medical devices. If the FDA chooses to request records from foreign manufacturers of medical devices, manufacturers could voluntarily comply with such requests, but the refusal to produce such records would not be a statutory violation.

Focus on in vitro diagnostics

On February 29, the FDA issued an immediately-in-effect policy for detecting the COVID-19 virus using EUA tests. The FDA's policy permits laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvements Amendments (CLIA) to perform testing after completing test validation, but before the FDA authorizes an EUA, provided the laboratory notifies the FDA of the completed validation and an EUA submission is completed within 15 business days of notifying the FDA. Laboratories are also supposed to obtain independent verification for the first five positive and first five negative diagnoses obtained.

Though the FDA shares regulation of CLIA-regulated laboratories with the Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS, which has the primary responsibility for inspecting certified laboratories), an FDA white paper from January 13, 2017 makes clear that the FDA still asserts jurisdiction for individual tests developed and administered in CLIA-certified laboratories. With the potential increased availability in domestic inspection resources and recent comments about its regulatory authority over in vitro diagnostics (IVDs) in the February 29 policy statement, labs developing and administering tests (especially for COVID-19) are at a higher risk for FDA inspection.

We note, however, that it is more likely is that the FDA will attempt to assert its authority over IVDs through a more formal pathway, such as published guidance, regulation, or asking Congress to pass legislation. The FDA signaled its intent to begin exerting more regulatory oversight of IVDs in FDA Commissioner Hahn's speech to the American Clinical Laboratory Association on March 4, and the Department of Health and Human Services, the parent agency for the FDA, has provided technical consulting on the bipartisan VALID Act (introduced on March 6 in both the House and Senate), which would clarify the FDA's ability to regulate IVDs. Specifically, the VALID Act would require premarket submissions for certain high-risk tests and would provide lesser regulation for lower-risk tests and those tests already on the market.

Increased scrutiny over FSVP implementation for domestic food manufacturers

Without its ability to inspect foreign food facilities, domestic food manufacturers should be prepared for increased FDA scrutiny over implementation of the FSMA's Foreign Supplier Verification Program (FSVP) rule. As a preventive food safety measure, pursuant to the FSVP rule, importers are required to take steps to verify that food they import into the U.S. is produced in a manner that meets U.S. food safety standards. In recent months, domestic food manufacturers have seen increasing FDA oversight over FSVP implementation, with the FDA issuing its first warning letter in August 2019 over failure to implement FSVP requirements. And, as indicated in the FDA's Inspection Observation Data for Fiscal Year 2019, the failure to develop an FSVP program was the most-cited violation during FDA food facility inspections.

Conclusion

The FDA's March 10 announcement emphasizes, "As this remains a dynamic situation, we will continue to assess and calibrate our approach as needed to help advance federal response efforts in the fight against this outbreak." Regulated industry should continue to monitor the FDA's approach to foreign inspection and oversight of regulated products imported into the U.S. and be able to respond accordingly.

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