



FDA Compliance & Enforcement ADVISORY ■

MARCH 20, 2020

FDA Temporarily Postpones Routine Domestic Inspections

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A week after the FDA took the unprecedented step of postponing foreign inspections until April 2020, on March 18, 2020, the [FDA announced](#) that it has temporarily postponed all domestic routine surveillance facility inspections. As we [previously reported](#), the FDA's risk-based inspection programs have been a cornerstone of the FDA's oversight and regulation of product manufacturing. The FDA made the decision to postpone these facility inspections (1) to protect the health and well-being of FDA staff and contracted inspectors; and (2) in response to industry's concerns about visitors at FDA-inspected facilities.

In contrast to the announcement for foreign inspections, which indicated that certain mission-critical inspections will be considered, the March 18 statement states that *for-cause* domestic inspections "will be evaluated and will proceed if mission-critical." As written, this suggests a higher standard, or narrower scope, for mission-critical domestic inspections. We think it is more likely that the new language, drafted after the World Health Organization (WHO) declared COVID-19 a global pandemic on March 11, and the Administration declared a national emergency on March 13, represents a change in the FDA's risk analysis.

The March 18 statement refers to "the White House Coronavirus Task Force and cross-government guidance." This would appear to include the March 17 [memo](#) from the Office of Management and Budget, which stated that "[n]on-mission-critical functions that cannot be performed remotely or that require in-person interactions may be postponed or significantly curtailed." The March 18 statement also refers to the FDA's directive earlier this week to all eligible FDA employees to begin teleworking, while clarifying that this does not apply to personnel performing "non-portable activities" (e.g., certain lab activities or the monitoring of imported products).

Similar to its March 10 statement, the FDA again highlighted its ability to request records in lieu of an on-site inspection "on an interim basis when travel is not permissible" as part of its "multi-pronged approach" to ensure the safety and quality of FDA-regulated products. Stemming from Section 706 of the Food and Drug Administration Safety and Innovation Act (FDASIA), the FDA has relied upon this authority to focus the agency's inspection activities, and we are aware that the FDA has already been using this authority to conduct record reviews of manufacturing establishments in China. As we discussed in our [previous report on the postponement of foreign inspections](#), Section 706 of FDASIA only applies to drug establishments, but medical device establishments, for example, could voluntarily comply with such requests from the FDA.

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In a shift in tone from previous announcements, the FDA's March 18 statement states that "inspections are not what cause quality to happen," placing primary responsibility on regulated industry to produce safe and quality products. While highlighting industry's partnership with the FDA, the March 18 statement highlights the importance of compliance with current good manufacturing practice (CGMP) requirements for both the medical product and food industries, as well as the food industry's preventive control requirements, to reduce or eliminate food safety hazards.

Even though the FDA states that, during the last fiscal year, "the overall domestic violation rate was only about 5%," it is important to put that into perspective. Based on the [FDA Data Dashboard](#), in Fiscal Year 2019, the FDA completed a total of 1,172 inspections of drug establishments, 1,850 inspections of medical device establishments, and 8,079 inspections related to food and cosmetics establishments.

Key Questions

What for-cause inspections will be deemed "mission critical"?

For-cause inspections, according to the March 18 statement, will proceed only if "mission critical." While the FDA's March 18 statement does not define what it might consider to be mission-critical inspections, in the same context, the FDA's March 10 statement points to: (1) facilitating efforts to diagnose, treat, and prevent disease; (2) helping mitigate against supply-chain shortages; and (3) stopping fraudulent COVID-19 activity. Based on this, the FDA could consider a for-cause inspection of a facility engaged in producing a fraudulent COVID-19 drug as mission critical. Fraudulent COVID-19 products continue to enter the market as evidenced by the [FDA and Federal Trade Commission's March 9 announcement](#) that the agencies had issued joint warning letters to seven companies for selling fraudulent COVID-19 products.

Drugs

The FDA's [Compliance Program Guidance Manual \(CPGM\) – Program No. 7356.002 \(Drug Manufacturing Inspections\)](#) states that "for-cause" inspections include the following: (1) follow-up compliance inspections performed to verify corrective actions after a regulatory action has been taken; and (2) inspections performed in response to specific events or information (e.g., FARs, complaints, recalls, and other indicators of defective products) that bring into question the compliance and/or quality of a manufacturing practice, facility, process, or drug.

Devices

The FDA's [Compliance Program Guidance Manual – Program No. 7382.845 \(Inspection of Medical Device Manufacturers\)](#) states that "for-cause" inspections are performed in response to "specific information that raises questions, concerns, or problems associated with [an] FDA regulated firm or commodity." The CPGM provides a number of potential sources of this information, such as observations made during prior inspections, complaints, adverse reaction reports, and suspicions of fraud. In addition, as part of the FDA's risk-based approach for medical device establishments, manufacturers of Class I devices generally are the lowest priority for inspections, with Class II manufactures having a higher priority than Class I, and Class III manufacturers having a higher priority than Class I and Class II.

Food

The FDA's [Compliance Program Guidance Manual – Program 7303.040 \(Preventive Controls and Sanitary Food Operations\)](#) details the FDA's risk-based inspection approach for human food facilities and states that inspections prioritize the following types of facilities: (1) those responsible for a Class I recall since the previous inspection; (2) a facility's previous inspection was classified "Official Action Indicated" (OAI); (3) a facility is known to manufacture high-risk foods; and (4) a facility is implicated in an event that may impact public health.

What does this mean for companies seeking reclassification of an OAI status?

Historically, the FDA has required a follow-up inspection to reclassify an inspection. Because a reclassification decision often depends on the FDA's ability to observe manufacturing activities, we think that in most cases, it is unlikely that the FDA will use its authority under Section 706 to reclassify an inspection based solely on a record review. However, the FDA could use this authority, coupled with review discretion, to approve certain applications associated with OAI facilities to address drug shortages or make medically necessary products available.

Conclusion

As the FDA continues to "assess and calibrate [its] approach as needed" during the COVID-19 outbreak, regulated industry must be prepared for the FDA's expanded use of its existing authorities, creative alternatives to ensure the safety of FDA-regulated products being produced in tens of thousands of manufacturing facilities across the globe, and continued modifications to the FDA's policies on both domestic and foreign inspections.

Alston & Bird has formed a multidisciplinary [task force](#) to advise clients on the business and legal implications of the coronavirus (COVID-19). You can [view all our work](#) on the coronavirus across industries and [subscribe](#) to our future webinars and advisories.

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