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INSIGHT: FDA Suspends Routine Domestic Drug, Device Inspections Due to Coronavirus

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The Food and Drug Administration is suspending routine foreign facility inspections, but for-cause inspections will proceed if deemed "mission critical." Morgan Lewis attorneys say the FDA suggests it may attempt to conduct domestic inspections through other means.

The FDA on March 18 suspended onsite routine domestic inspections in an effort to slow the spread of the new coronavirus and help flatten the pandemic curve. Domestic for-cause inspection assignments will be evaluated and will proceed if deemed "mission-critical."

The FDA also indicated it was evaluating alternative methods to conduct inspections (e.g., record reviews) during this interim period that would not jeopardize public safety and protect both company employees and FDA staff.

It did not discuss how (or whether) it would address preapproval inspections required for certain medical device, drug, and biologic submissions (e.g., marketing applications and supplements), though these inspections will likely be delayed. It is, however, possible the FDA could exercise discretion on a case-by-case basis to approve products based exclusively on a desk review.

On March 10, the FDA announced its intent to postpone routine foreign inspections until April. The FDA also stated inspections outside the U.S. deemed mission-critical (e.g., for-cause inspections) will still be considered on a case-by-case basis.

In the both communications, the FDA explained that it will continue to rely on its other tools to oversee the safety and quality of FDA-regulated products. These include:

- screening products imported into the U.S. through the FDA's risk-based import screening tool (PREDICT);
- evaluating product performance through required manufacturer product reporting of events; and
- relying on manufacturers to comply with the current Good Manufacturing Practice (cGMP) regulations.

Implications

There is no doubt that the suspension of the FDA's inspection program (both domestically and abroad) will create a backlog of work for FDA investigators.

- For facilities that require pre-approval inspections before beginning product distribution or receiving application clearance/approval, a delay can lead to later product market entry than may have otherwise been anticipated.
- For facilities that have been the subject of enforcement and have been able and are prepared to demonstrate to the FDA a remediated quality system, delayed inspections may prevent the closure of agency enforcement cases. This becomes especially critical when these facilities are hoping to re-obtain Certificates to Foreign Government (CFG) needed to demonstrate compliance to foreign governments by successfully passing a FDA re-inspection.
- For facilities that help utilize positive FDA inspection results to defend against product liability claims, a delay in inspections can prevent effective use of such arguments in litigation.

  In light of the Covid-19 pandemic, the FDA does, however, appear to be willing to grant enforcement discretion in ways not previously seen. For example:

- The FDA told medical product and dietary supplement manufacturers and distributors via a March 19 guidance that if, due to employee shortages or increasing rates of adverse event reports, firms are unable to meet statutory and regulatory safety reporting timeframes for certain products and reports, the information may be stored for submission at a later date.
- The FDA has issued multiple guidance documents to ease premarket submission burdens for certain device types, including laboratory diagnostic tests, ventilator and anesthesia machines, and remote monitoring devices. For example, the FDA issued on March 22 a new guidance, under which the FDA explained that it would not object to changes made to ventilators and anesthesia gas machines during the Covid-19 public health emergency that could otherwise trigger a premarket notification so long as the modifications do not create an "undue risk."

  Therefore, for manufacturers seeking a pre-approval inspection, it is possible that the FDA may turn to alternative means during and after the Covid-19 pandemic to approve manufacturing sites.

As noted above, this may include approval based on a "desktop" record review. Manufacturers that pursue this pathway should keep lines of communication open with the FDA reviewer as misunderstandings and misinterpretations can lead to unnecessary delays.

For complex procedures and/or processes, the manufacturer should consider creating storyboards or aids that can be sent along with the records to help with the FDA review.

For companies needing a re-inspection in order to close out an enforcement action, the FDA will likely require a traditional in-person visit (unless such facility is providing critical-need items in response to Covid-19). This period, however, can provide additional time for these companies to ensure that their procedures and processes fully comply with FDA requirements and expectations.

Without inspections, it may be more difficult.

Quality System Requirements Must Be Met

For all other companies, not having to worry about a FDA inspection can appear to be a relief. However, as noted above, the FDA believes and expects that companies will continue to follow all regulatory requirements including the cGMPs.

Therefore, when routine inspections fully come back online, the FDA investigators will expect to see adherence to company quality system requirements during this period.

If a company is unable to legitimately meet a quality system requirement during this period (e.g., due to employee shortage), the company should assess the potential product impact, document its legitimate incapability and mitigations utilized to prevent undue harm to patient safety or product quality, and, depending on any necessary changes or potential regulatory challenges, discuss the issue with the FDA to understand any steps that may be needed to ensure regulatory compliance.

Notably, the FDA has experienced shortages within its inspection capabilities before (for example, during government shutdowns). While this suspension is not man-made, companies should be prepared for the FDA to come back online in a timely manner once the pandemic subsides, necessitating that companies continue to abide by robust quality and compliance systems.

In the meantime, the FDA is seeking to fulfill its mission to protect patient health and safety through other means.

This pandemic has placed a great emphasis on drug, biotechnology, and device companies in meeting critical-health needs. Companies can demonstrate their commitment to their public health missions and develop further trust with the FDA and the public by helping to sustain compliant operations during this period.

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