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CLIENT ALERT

FDA Presses Pause on Domestic and Foreign Inspections for all FDA-Regulated Products Due To COVID-19 Concerns

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In response to the recent COVID-19 pandemic, the U.S. Food and Drug Administration ("FDA") has temporarily paused all domestic and international on-site inspections not deemed "mission-critical."

On Wednesday, March 18th, FDA Commissioner Stephen Hahn announced that the Agency would temporarily halt domestic inspections not deemed "mission-critical," citing concerns for the health and well-being of its staff. These are inspections the FDA conducts every few years based on a risk analysis. Instead, during this interim period, the Agency will evaluate alternative ways to conduct inspectional work to ensure the safety of the firm and the FDA staff such as evaluating records in lieu of conducting onsite inspections. It is important to note that domestic for-cause inspections will proceed if considered "mission-critical."

Similarly, on March 10th, the Agency announced that it would temporarily scale back foreign inspections, through April, not deemed "mission-critical." The FDA cited a number of factors including State Department travel advisories, CDC travel recommendations, and other guidance. FDA stated that in the interim, it would employ additional tools to ensure the safety of imported products, including denying entry of unsafe products, physical inspection, product sampling at the border, and reviewing the manufacturer's compliance history, among others. As is the case with domestic inspections, inspections of foreign facilities deemed "mission critical" will continue on a case-by-case basis.

FDA encourages the industry to "own" safety and quality during this unprecedented time, and adhere to existing reporting and cGMP requirements pertaining to manufacturing, sanitation, and process controls.

In short, the spring on-site inspection that your business has been expecting probably won't happen. Domestic and foreign manufacturers, nonetheless, should continue adhering to all cGMP and reporting requirements, as FDA indicated it may rely on such reports to determine manufacturer compliance. In addition, we expect that the FDA will extend its suspension of non-critical foreign inspections beyond April.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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