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The FDA Issues Report Regarding its Oversight Activities

Related Professionals

Hamilton B. Barber
803.253.8236
HBarber@nexsenpruet.com

Practices

Health Law

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The U.S. Food and Drug Administration (FDA) has faced many operational challenges during the COVID-19 pandemic. Early on, the FDA temporarily postponed routine surveillance facility inspections, conducting mission-critical inspections on a case-by-case basis. Since then, the FDA has leveraged its available tools and implemented innovative approaches to prioritize and resume some routine inspections and has been taking on-going, concrete steps to help stabilize its inspection and assessment operations and meet its oversight responsibilities.

On May 5, 2021, the FDA released a report entitled Resiliency Roadmap for FDA Inspectional Oversight that outlines the FDA's approach to meeting its inspectional oversight responsibilities. The report details the state of the FDA's inspectional oversight and its plan to address inspectional work postponed due to the COVID-19 pandemic. According to the report, the FDA will focus on conducting mission-critical inspections; continue to prioritize pre-approval, pre-market, pre-license, and for-cause inspections; and will ensure that high-priority risk-based inspections are completed before addressing postponed surveillance work.

The report also describes the FDA's use of alternative tools and new approaches during the COVID-19 pandemic to provide some oversight of FDA-regulated products. The alternative tools and new approaches include the FDA's (1) utilization of its authority under section 704(a)(4) of the federal Food, Drug, and Cosmetic Act, which permits the FDA to request from an establishment records or information pertaining to drug and biologic products, in advance of or in lieu of an inspection; (2) conducting of remote inspections on human and animal food importers under its Foreign Supplier Verification Program regulation; (3) utilization of information shared with the FDA by trusted state, local, tribal, territorial, and foreign regulatory partners; (4) use of risk-based product sampling and analysis; and (5) use of its authority to refuse entry of unsafe imported products. To better support such innovation and approaches related to its oversight responsibilities, the FDA intends to undertake a multi-year modernization effort to further transform its data enterprise platforms and cross-program interoperability

infrastructure.

Recognizing the uncertainty caused by the COVID-19 pandemic, the FDA in its report details base-/best-/worst-case scenarios and their effects on progressing toward the resumption of standard operational levels. Each scenario estimates the surveillance work the FDA can reasonably accomplish given (1) a gradual transition to standard operations (Base-Case); (2) an immediate transition to standard operations (Best-Case); and (3) maintenance of an emergency-operations status (Worst-Case).

For further details regarding these scenarios or other information addressed in this article, please refer to the full report.