Update: FDA Temporarily Suspends FSMA On-Site Audit Requirements and Suspends Routine Domestic Facility Inspections

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FSMA Audits:

The U.S. Food and Drug Administration (FDA) recently announced that, due to the Coronavirus (COVID-19) public health emergency, it is issuing a temporary policy regarding supplier verification on-site audit requirements under the Food Safety Modernization Act (FSMA) in an attempt to minimize disruptions in the food-supply chain.

The FSMA's implementation regulations require food facilities and importers to conduct supplier verification activities as part of their Food Safety Plan or Foreign Supplier Verification Program. Often, on–site supplier audits are determined to be the most appropriate verification activity. Because new COVID-19 travel restrictions may make on–site audits impractical, the FDA announced today that it will not enforce FSMA supplier verification on–site audit requirements ***if other appropriate verification methods are used instead***. Other methods may include sampling and testing of food products or components and/or review of food safety records. The FDA plans to resume on–site audit activity within a reasonable time after it becomes practicable to do so. However, the FDA has committed to giving timely notice before withdrawing this temporary policy.

The full text of this temporary policy can be found here.

Domestic Inspections:

The FDA announced earlier this month that it was postponing most foreign facility inspections until April and that foreign inspections deemed mission-critical would be considered on a case-by-case basis. More recently, the FDA announced that it has temporarily

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postponed all domestic routine surveillance facility inspections.

The FDA is committed to ensuring the safety and quality of FDA-regulated products and will be evaluating additional ways of doing so without putting the health and safety of regulated firms or FDA staff at risk. Other safety and quality requirements, such as compliance with Current Good Manufacturing Practice and reporting obligations, remain effective. It is important to note that all domestic ***for-cause*** inspection assignments will be evaluated and will proceed if deemed mission-critical. The FDA will continue to respond to natural disasters, outbreaks and other public health emergencies relating to FDA-regulated products.

For more information or questions relating to this specific article, please contact Kimera Hall or Steven Ellcessor.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a Coronavirus Response Team. Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats to your business operations and workforce.

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