



FDA Will Resume Domestic Inspections in Late July



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Months after halting most inspections amid the coronavirus disease (COVID-19) pandemic, the US Food and Drug Administration (FDA) is planning to resume on-site domestic inspections beginning the week of July 20, 2020. In a statement issued on July 10, 2020, FDA announced the resumption under COVID-19 conditions:

At this time, we are working toward the goal of restarting on-site inspections during the week of July 20. However, resuming prioritized domestic inspections will depend on the data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. In order to move to the next phase, we must see downward trends in new cases of COVID-19 and hospitalizations in a given area. Our ability to resume is also affected by other services that have been curtailed by the pandemic, such as public transportation. The availability of these services will be an important factor in how we determine resuming domestic inspections.

As a safety measure, FDA also will pre-announce all inspections to FDA-regulated businesses, except for retail tobacco inspections, for the foreseeable future. According to

the FDA, inspections of tobacco retailers will not be pre-announced because they intentionally are conducted as undercover operations without the retailer's knowledge.

The announcement comes nearly two months after the agency first announced that it would implement a phased approach to restarting surveillance inspections, and four months after the agency halted its domestic inspection program due to COVID-19 concerns.

FDA acknowledged that its planned resumption of inspections will depend on other services that have been curtailed by the coronavirus pandemic, such as public transportation. The availability of these services will be an important operational factor in how FDA resumes domestic inspections. Additionally, the agency will monitor the data about the virus' trajectory in a given state and locality, and the rules and guidelines that are put in place by state and local governments.

FDA will prioritize which inspections it conducts in the coming months using a new risk assessment system to determine the state- and county-level risk posed by the virus. FDA says the risk level will determine what types of regulatory activities the agency and its partners carry out at the county and municipal levels. The agency also issued assurances that all of its inspectors will be outfitted with personal protective equipment, and are provided with other necessary equipment to carry out their work while adhering to state and local guidance as well as applicable CDC guidance.

For more information regarding FDA inspections or Food Law generally, contact GrayRobinson's Food Law Group at (866) 362-5132 or foodlaw@gray-robinson.com



Richard M. Blau leads GrayRobinson's *Nationwide Alcohol Beverage and Food Law Department*, focusing on the laws that govern the manufacture, importation, processing distribution, marketing, sale and consumption of foods and beverages. Richard devotes a substantial portion of his practice to trade regulation, brand development and protection, M & A compliance guidance, litigation and mediation involving the members of the alcohol industry.