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CLIENT ALERT

FDA Announces the Resumption of Domestic Inspections As Part of Evolving COVID-19 Pandemic Response

JULY 16, 2020

On July 10, 2020, the Food and Drug Administration (FDA or the Agency) announced preparations to resume prioritized domestic inspections as early as the week of July 20, 2020. FDA preparations include a new risk-assessment system that outlines that the performance of on-site inspections will depend on available data about the virus' trajectory in a given state or locality, and will be consistent with the rules and guidelines established by the relevant state and local governments. Importantly, FDA has determined that, for the foreseeable future, it will pre-announce prioritized domestic inspections to FDA-regulated businesses.[1] Moreover, FDA notes that the it must see a downward trend in new COVID-19 cases and hospitalizations in a given area in order for it to resume prioritized domestic inspections there.

See Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system, *available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-prepares-resumption-domestic-inspections-new-risk-assessment-system?utm_campaign=071020_PR_Coronavirus%20%28COVID-19%29%20Update%3A%20Daily%20Roundup%20July%2010%2C%202020&utm_medium=email&utm_source=Eloqua.

While FDA paused on-site surveillance inspections in March 2020, the Agency's investigators have continued to conduct critical inspections and other activities, including remote assessments, import alerts, and other compliance actions to ensure FDA-regulated industries meet applicable FDA requirements. FDA notes that it prioritized those inspections, and likely will continue to do so, based on risk and other factors outlined below.

In resuming on-site inspections, FDA has monitored reopening criteria on the federal, state, and county levels in order to identify when and where to resume domestic inspections. The Agency's new COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time state and national data to qualitatively assess the number of COVID-19 cases in a local area to determine when and where it is safest to conduct prioritized domestic inspections. The COVID-19 Advisory Level is based upon the outcome of certain metrics: the Phase of the State (as defined by the White House guidelines[2]) and statistics measured at the county level to gauge the current trend and intensity of infection. Moreover, the COVID-19 Advisory Level data will be made available to contracted state partners who conduct inspections of FDA-regulated entities on the Agency's behalf. In order to move to the next phase and resume inspections, FDA must see downward trends in new cases of COVID-19 and hospitalizations in the given

area. Moreover, FDA is restricted by other services that may have been curtailed by the pandemic (e.g., public transportation). The availability of such services is an additional important factor in resuming domestic inspections.

Upon consideration of the various factors, FDA will identify which of its regulatory activities that can occur within the given geographic area. For instance, at the county level, FDA announced it will undertake (i) mission critical inspections, (ii) all inspections with caveats to help protect staff who have self-identified as being in a vulnerable population, and (iii) resumption of all regulatory activities.

To ensure the health, safety, and well-being of Agency investigators, regulated entity employees, and the public, FDA represents that these prioritized domestic inspections will be pre-announced for the foreseeable future and that Agency investigators will have personal protective equipment and will be appropriately equipped to carry out their work while adhering to state and local guidelines, and guidance from Centers for Disease Control and Prevention. FDA believes this will provide the safest possible environment to accomplish the Agency's regulatory activities and ensure the appropriate staff are on-site for inspection. That said, the Agency has not yet gone farther to detail what other temporary changes it anticipates in the fact- and data-gathering and validation aspects of its inspection process nor have they provided any indication of how much advance notice FDA-regulated businesses will receive. Stay tuned.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

All entities should consult legal counsel for compliance issues and questions related to rapidly evolving COVID-19 legislation and policy.

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For further information or questions on FDA's statement and subsequent inspections, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, or your Winston relationship attorney.

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[1] However, due to the nature of retail tobacco inspections, these inspections will not be pre-announced when they resume, as they are meant to be undercover operations where the retailer is unaware an inspection is taking place.

[2] Opening Up America Again, *available at* https://www.whitehouse.gov/openingamerica/#vulnerable-individuals.

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