

MEMORANDUM

FROM Maile Gradison Hermida
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RE: COVID-19 Update: FDA Provides Update on Inspection Plans

The U.S. Food and Drug Administration (FDA) recently provided an update regarding its plans for conducting routine surveillance inspections of domestic and foreign facilities during the COVID-19 pandemic. ^{1/} FDA announced in March that it would temporarily postpone foreign and domestic inspections, with the exception of certain “mission critical” inspections, as identified on a case-by-case basis. ^{2/} In its most recent update, FDA Commissioner Stephen Hahn M.D. stated that the agency’s current approach will continue as local, national, and international conditions warrant.

The new statement also explains that FDA is collaborating with the Centers for Disease Control and Prevention (CDC) to develop a process that would govern how and where to return to on-site facility surveillance inspections in accordance with the criteria outlined in the “White House Guidelines for Opening Up America Again.” ^{3/} FDA expects this to be a “phased approach” driven by scientific data. Commissioner Hahn’s statement emphasizes that the agency’s priority and commitment are to first protect the health and well-being of FDA’s workforce, state contract inspectors, and workers in the industries FDA regulates. FDA also explains that it is in close contact with its industry partners, as well as its domestic and foreign regulatory counterparts, to inform its assessment of the feasibility of a return to routine inspections as conditions improve.

Additionally, the statement also emphasizes that FDA is confident in its ability to maintain oversight during this pandemic by leveraging all available authorities, alternative tools, and scientific methods to ensure the integrity and availability of safe and quality products. The agency explains that product

^{1/} *Coronavirus (COVID-19) Update: FDA updates on surveillance inspections during COVID-19* (May 11, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-updates-surveillance-inspections-during-covid-19>. This announcement applies to all FDA-regulated entities.

^{2/} *HL Memo, COVID-19 Update: FDA Temporarily Postpones Routine Domestic Inspections* (March 19, 2020), <https://www.hoganlovells.com/en/publications/covid-19-update-fda-temporarily-postpones-routine-domestic-inspections>.

^{3/} *White House Guidelines, Opening Up America Again* (April 2020), <https://www.whitehouse.gov/openingamerica/>.

safety and quality are ultimately the regulated establishment's responsibility, and the agency believes that most FDA-regulated firms understand and appreciate their responsibility to ensure the safety of the products they manufacture or produce.

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We will continue to monitor FDA's response to COVID-19. If you have any questions, please don't hesitate to contact us.