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MEMORANDUM

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Date: March 19, 2020

Re: **COVID-19 Update: FDA Temporarily Postpones Routine Domestic Inspections**

Late yesterday, the U.S. Food and Drug Administration (FDA) announced that due to the COVID-19 pandemic the agency has temporarily postponed all domestic routine surveillance facility inspections. This announcement is not limited to the food industry, but the impacts for the food industry are the focus of this memorandum. FDA is taking this action for the health and well-being of inspection personnel and because of industry concerns about visitors. FDA will continue to conduct domestic for-cause inspections if they are determined to be mission-critical. This announcement was preceded by a Stakeholder conference call FDA held directed specifically to the food industry. This memorandum provides FDA's official statement, along with feedback from the Stakeholder call, and summarizes the key takeaways regarding FDA's new policy.

FDA's Official Statement

The following is the crux of the official statement from FDA Commissioner Stephan Hahn M.D. regarding the temporary postponement of routine domestic inspections:

> Today, we're announcing that for the health and well-being of our staff and those who conduct inspections for the agency under contract at the state level, and because of industry concerns about visitors, we have temporarily postponed all domestic routine surveillance facility inspections. These are facility inspections the FDA traditionally conducts every few years based on a risk analysis. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical. We will continue to respond to natural disasters, outbreaks and other public health emergencies involving FDA-regulated products. 1/

1/ *Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections* (March 18, 2020), available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic.

This follows FDA's statement earlier this month that the agency is postponing most foreign facility inspections through April and that inspections outside the U.S. deemed mission-critical will be considered on a case-by-case basis as the outbreak continues to unfold. 2/

Key Takeaways

FDA held a Stakeholder conference call on March 18, 2020 and provided additional insights on this new policy. 3/ The key takeaways from the Stakeholder call and Commissioner's statement are as follows:

- FDA will continue to conduct "for cause" inspections if they are deemed "mission-critical." Examples of these types of inspections may include, but are not limited to, food products associated with a foodborne outbreak and food products subject to a Class 1 recall. FDA will consider the safety of its inspectors when determining whether to conduct these inspections.

- Domestic inspections typically will be pre-announced. We understand FDA will provide the facility notice 5 days in advance of conducting the inspection.

- The Commissioner's statement explains that FDA is evaluating additional ways to conduct its inspectional work that would not jeopardize public safety and would protect both facilities and FDA staff. His statement says: "This could include, among other things, evaluating records in lieu of conducting an onsite inspection on an interim basis when travel is not permissible, when appropriate." For food companies, we understand such action would be taken in collaboration with industry.

- FDA's statement applies to federal inspections, including inspections conducted by state inspectors under contracts or cooperative agreements with FDA. This announcement does not, however, govern whether states could still conduct inspections under their own authorities.

- We expect FDA will take this approach for the foreseeable future, as appropriate, and that the agency likely will reevaluate this approach on a periodic basis.

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We will continue to monitor FDA's response to COVID-19. Should you have any questions or if we can be of assistance with your COVID-19 response strategy, please do not hesitate to contact us.

2/ *Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections* (March 10, 2020), available at https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections.

3/ *FDA Briefing for Foods Stakeholders on Coronavirus Disease 2019 (COVID-19)* (March 18, 2020), available at https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/fda-briefing-foods-stakeholders-coronavirus-disease-2019-covid-19-03182020-03182020?utm_campaign=FSMA_COVIDcall_03172020&utm_medium=email&utm_source=Eloqua. An audio file is available at https://www.fda.gov/media/136259/download.