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MEMORANDUM

From: Maile Gradison Hermida
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Date: April 3, 2020

Re: COVID-19 Update: FDA Announces Plans to Conduct Remote FSVP Inspections

In response to the COVID-19 outbreak, the U.S. Food and Drug Administration (FDA) has announced it will begin requesting that importers send the agency records required under the Foreign Supplier Verification Programs (FSVP) rule electronically or through other prompt means to allow the agency to conduct FSVP inspections remotely during the public health emergency. ^{1/} FSVP requires importers to perform certain risk-based activities to verify their foreign suppliers are producing food in accordance with U.S. food safety laws. FDA has been conducting its FSVP inspections by reviewing importers' records at the importer's place of business. However, FDA has the authority under the FSVP regulation to request that importers provide required records to the agency electronically or by other prompt means. Due to travel restrictions, social distancing, and other advisories associated with the COVID-19 pandemic, FDA has determined most routine onsite inspections are impractical to conduct at this time. Accordingly, FDA temporarily is shifting to conducting FSVP inspections remotely as practical until further notice.

FDA will begin conducting a limited number of remote inspections immediately, and will prioritize inspections of FSVP importers for food from foreign suppliers whose onsite food facility or farm inspections have been postponed due to COVID-19. FDA also plans to continue conducting previously assigned routine and follow-up inspections remotely during the public health emergency. An FDA investigator will contact importers subject to the remote inspection and will explain the process and make the agency's written request for records.

According to FDA, the agency may still choose to conduct an onsite FSVP inspection in rare situations. In those cases, an FDA investigator will make arrangements to conduct the inspection while practicing social distancing recommendations provided by the Centers for Disease Control and Prevention.

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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 contact us.

^{1/} Constituent Update: FDA To Temporarily Conduct Remote Importer Inspections Under FSVP Due to COVID-19 (Apr. 3, 2020), available at <https://bit.ly/2X81xte>.