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MEMORANDUM

From: Joseph A. Levitt
Samantha Dietle

Date: January 11, 2018

Re: **Update on Impact of Government Shutdown on Scope of FDA Food Facility Inspections and FSIS Label Submissions**

As previously reported, 1/ the Food and Drug Administration (FDA) and the U.S Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) are operating under significantly reduced functions since funding for the agency lapsed on December 22, 2018. Recently, there have been a number of media reports with updated information from FDA Commissioner Gottlieb regarding the scope of FDA food facility inspections during the government shutdown, which is summarized in this memorandum. We will continue to monitor major developments related to the scope of FDA's food safety activities during the government shutdown; food companies may also wish to follow Commissioner Gottlieb's Twitter account for the most recent developments on this issue. 2/ In a related update, we understand that FSIS is now in the process of reviewing label submissions in a limited capacity.

As summarized in our previous memorandum, until a new appropriations bill granting funding to FDA is passed by Congress, FDA is unable to support the majority of its compliance and enforcement activities related to food, including routine establishment inspections. 3/ Commissioner Gottlieb has since updated FDA's plans to state that the agency would begin conducting routine food safety inspections of facilities with products meeting the agency's criteria for "high-risk" in accordance with the inspection frequency provision of the FDA Food Safety Modernization Act (FSMA).

FSMA sets forth factors for FDA to consider in identifying "high-risk" food facilities. 4/ Generally, FDA's approach to categorizing high-risk facilities is based on the known food safety risks of the food commodity category, as well as the facility's compliance history with regard to food recalls,

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1/ *See* Impact of Government Shutdown on Scope of FDA, FSIS, and CPSC Activities, *available at* https://www.hlfoodlaw.com/2019/01/impact-government-shutdown-scope-fda-fsis-cspc-activities/.
2/ *See* https://twitter.com/SGottliebFDA.
3/ FY 2019 HHS Contingency Staffing Plan for Operations in the Absence of Enacted Annual Agriculture and Interior Appropriations, *available at* https://www.hhs.gov/about/budget/fy-2019-hhs-contingency-staffing-plan/index.html.
4/ FFDCA § 421(a)(1).

outbreaks of foodborne illnesses, and violations of food safety standards. In a series of tweets, Commissioner Gottlieb identified the following commodities as high-risk:

- Modified atmosphere packaged products;
- Acidified and low acid canned foods;
- Seafood;
- Custard-filled bakery products;
- Dairy products including soft, semi-soft, soft ripened cheese and cheese products;
- Unpasteurized juices;
- Ready-to-eat sprouts;
- Fresh fruits and vegetables and processed fruits and vegetables;
- Spices;
- Shell eggs;
- Sandwiches;
- Prepared salads;
- Infant formula; and
- Medical Foods.

Note that a particular facility's compliance history is also factored into this decision, including facilities with product categories not on this list. Commissioner Gottlieb explained that inspecting food facilities meeting the "high-risk" criteria during this shutdown is broader than the scope of agency activities during the 2013 government shutdown, by the agency taking "a different posture based on sound public health and legal rationale." 5/

Commissioner Gottlieb noted that 31% of FDA's inventory of domestic food facility inspections is considered high-risk, and that FDA normally conducts approximately 160 food facility domestic routine inspections per week. Commissioner Gottlieb reiterated that FDA is conducting all planned foreign food inspections during the shutdown.

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We will continue to monitor major developments related to the government shutdown. Please contact us if you have questions on this or any other matter.

5/ *See* https://twitter.com/SGottliebFDA/status/1083055700593516545.