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MEMORANDUM

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Date: April 3, 2020

**Re: COVID-19 Update: FDA Deputy Commissioner Yiannas Issues PSA and FDA Updates
COVID-19 Food Safety Guidance**

This memorandum summarizes recent actions the U.S. Food and Drug Administration (FDA) has taken in response to the COVID-19 outbreak. First, FDA Deputy Commissioner for Food Policy and Response Frank Yiannas issued a food safety and supply public service announcement (PSA). ^{1/} The PSA states the U.S. food supply remains safe for both people and animals, and there is no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19. Deputy Commissioner Yiannas also reiterates that there currently are no nationwide shortages of food, despite local reports of shortages. Second, FDA has supplemented its food safety questions and answers guidance on COVID-19 to include Food and Beverage Issue Alliance (FBIA) suggested protocols among the resources available to industry for responding to COVID-19. ^{2/}

Deputy Commissioner Yiannas' PSA

In a recent PSA and accompanying press release, Deputy Commissioner Yiannas reiterates points the agency previously made with respect to the safety of the U.S. food supply. In addition to stating there is no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19, the agency also explains that because COVID-19 is a respiratory illness that is thought to spread mainly from person to person, foodborne exposure to SARS-CoV-2, the virus that causes COVID-19, is not known to be a route of transmission. For these reasons, FDA does not anticipate food products would need to be recalled or withdrawn from the market for reasons related to the COVID-19 outbreak, including if a person who works in a human or animal food facility is confirmed positive for the virus.

^{1/} FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19 (Apr. 2, 2020), available at <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-offers-assurance-about-food-safety-and-supply-people-and-animals-during-covid-19#PSA>.

^{2/} Food Safety and the Coronavirus Disease 2019 (COVID-19) (Apr. 2, 2020), available at <https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>.

Deputy Commissioner Yiannas also explains that currently there are no nationwide shortages of food. Based on the agency's discussions with industry, instances of shelves being empty of certain items reflect unprecedented demand, not a lack of capacity to produce, process, or deliver, and manufacturers and retailers are working around the clock to replenish store shelves. FDA is working with food manufacturers and grocery stores to monitor the food supply chain for any shortages, and also is in close contact with industry and its trade associations, which remain in touch with their members about supply chain issues.

The press release accompanying the PSA emphasizes FDA remains committed to protecting the health of FDA, state, and local food safety personnel, as well as the health of workers on farms and in human and animal food facilities. To help reduce the risk of infection for FDA investigators and state inspectors in ways that will not interrupt the process of how safe food reaches the market, FDA has postponed routine surveillance inspections of domestic human and animal food facilities and farms, but will continue to inspect "for cause" when a potential threat to public health is identified. ^{3/} In addition, FDA postponed most foreign inspections through April 2020 and will rely on other tools and authorities to ensure the safety of imported food, including inspections at ports of entry and the use of FDA's risk-based import screening tool, PREDICT, to focus examinations and sample collections. The agency also has issued guidance that FDA temporarily will not enforce onsite audit requirements for supplier verification under the FDA Food Safety Modernization Act (FSMA). ^{4/} Facilities are expected to temporarily select an alternative method to verify suppliers' compliance with food safety standards.

With respect to the safety of workers in food facilities, FDA notes that FSMA includes worker protections, including requirements that human food facilities have food safety plans to control risks associated with workers who are ill, regardless of the type of virus or bacteria. Requirements also exist for human food facilities to maintain clean and sanitized facilities and food contact surfaces, and food service workers also must continue to practice frequent hand washing and glove changes before and after preparing food. Similarly, animal food regulations include requirements for the cleanliness of the facility and personal cleanliness of employees.

FDA also reports that the agency is working with partners to address reported challenges associated with quarantines and travel restrictions that may impede food workers' ability to continue to work and transport food. This includes working with local, state, and federal officials and industry to help ensure food workers can get to and from their jobs in communities where curfews and shelter-in-place directives are enforced.

In a press call on April 2, Deputy Commissioner Yiannas also reportedly explained that FDA remains fully staffed and operational, and is ready to address potential issues in areas the agency typically oversees, including investigating food safety outbreaks, issuing warning letters, or monitoring food imports. He explained the agency is looking into options for remote, electronic inspections when permitted under FSMA. FDA also continues to monitor foodborne illness outbreaks, and Deputy Commissioner Yiannas reported the agency has not seen either an increase or decrease in outbreaks since consumers began preparing more meals at home in response to COVID-19. Deputy Commissioner Yiannas also reportedly emphasized that there is no evidence that this coronavirus is transmitted through food.

^{3/} See HL Memo, COVID-19 Update: FDA Temporarily Postpones Routine Domestic Inspections (Mar. 19, 2020), available at <https://www.hffoodlaw.com/2020/03/covid-19-update-fda-temporarily-postpones-routine-domestic-inspections/>.

^{4/} See HL Memo, COVID-19 Update: FDA and USDA Issue Guidance for Industry and Inspectors (Mar. 18, 2020), available at <https://www.hffoodlaw.com/2020/03/covid-19-update-fda-and-usda-issue-guidance-for-industry-and-inspectors/>.

FDA's Updated COVID-19 Questions & Answers

FDA has supplemented its COVID-19 and food safety questions and answers guidance to identify FBIA's protocols in its guidance regarding how establishments should respond when a worker in a food production facility or on a farm tests positive for COVID-19. In its response to the question, FDA identifies public resources, which now include FBIA's protocols for steps to take when: (1) an employee of a firm has a confirmed or presumptive case of COVID-19 and (2) a facility employee/facility or visitor/customer has been in close contact with an individual who is positive for COVID-19. ^{5/} FDA notes this protocol is specific to food manufacturing facilities, distribution facilities, distribution centers, and wholesale and retail outlets.

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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.

^{5/} Food Industry Recommended Protocols When Employee/Visitor/Customer Tests Positive for COVID-19 (Apr. 2, 2020), available at https://static1.squarespace.com/static/5e7d1107dac60a6b3e3f098d/t/5e8664c27e5db072ad336918/1585865924826/FBIA+COVID19%2BCase+Recommended+Protocols_2April20+Version+4.pdf.