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MEMORANDUM

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Date: March 28, 2019

Re: **FDA Commissioner Gottlieb and Deputy Commissioner Yiannas Issue Statement on New Steps to Strengthen FDA's Food Safety Program for 2020 and Beyond**

FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Frank Yiannas recently issued a statement addressing new steps included in the President's 2020 Budget proposal to advance FDA's food safety program and expand food safety monitoring. 1/ The statement details how FDA would use requested funds, if provided by Congress, to build a "smarter, more technologically advanced food safety system" that "stands on the shoulders of the preventive framework" of the FDA Food Safety Modernization Act (FSMA). Below we highlight four key aspects of the funding request: (1) state inspection partnerships, (2) imported food inspections, (3) enhanced response to outbreaks of foodborne illness; and (4) premarket safety review of new food ingredients, including those utilizing genome-editing under the agency's Biotechnology Innovation Action Plan.

State Cooperative Agreement Program

FDA considers the states as critical partners in creating a prevention-based food safety system under FSMA. FDA's funding proposal seeks to shift even greater FSMA inspection responsibility to the states, proposing new resources to fund human and animal Preventive Controls and Produce Safety inspections through the State Cooperative Agreement Program. The proposed funding would allow states to be responsible for over 50% of human food inspections and over 80% of animal feed inspections required by FSMA. This new division of labor would represent a sea change for human food inspections and introduces important additional considerations for FDA and food companies alike, including the need for FDA to assure the consistency of inspections state-to-state, as well as for food companies to build relationships with their state regulators.

Imported Food Inspections

Ultimately, FDA hopes to achieve parity of oversight for domestic and imported food. However, the agency recognizes that the domestic food safety toolkit is not identical to the imported food safety

1/ Statement from FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Frank Yiannas on new steps to strengthen FDA's food safety program for 2020 and beyond (Mar. 19, 2019), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633864.htm

toolkit and the latter requires substantial investment of time and resources. The proposed increase in state-conducted domestic inspections is key to achieving parity because it would free up the agency staff to focus more heavily on the agency's imported food safety strategy. 2/ To bolster imported food safety programs, FDA has requested additional resources to assess the agency's Import Alert Program and to increase industry compliance with the Foreign Supplier Verification Programs (FSVP) regulation.

Outbreak Response

For Fiscal Year 2017, FDA's Center for Food Safety and Applied Nutrition (CFSAN) responded to 794 recall events due to issues such as microbial contamination and undeclared allergens, and oversaw the recall of 3,609 products—more than any other FDA Center. To more effectively combat microbial contamination issues in foods, FDA intends to rely more heavily on Whole Genome Sequencing (WGS). WGS allows for analysis of the entire genomic DNA sequence of a pathogen. More widespread use of WGS in recent years has increased the number of detected outbreaks and subsequent investigations, with 2017-2018 having twice as many potential outbreaks identified as in the prior two years.

As WGS provides the ability to identify and investigate outbreaks faster, FDA plans to look to other technologies, such as blockchain, to assist industry in implementing more targeted and efficient recalls. Blockchain uses a decentralized, secure, ledger that is shared by all parties in the supply chain to provide transparency on a product's origins. The statement says that one of the biggest challenges of a recall is the complexity of supply chain tracking and management when records are kept mostly on paper.

Premarket Safety Review of New Food Ingredients

In addition to augmenting its inspection programs, the agency also has requested additional resources to improve the timeliness of premarket safety reviews for new food ingredients such as food and color additives, and to encourage innovations under the biotechnology voluntary consultation process outlined in the agency's Plant and Animal Biotechnology Innovation Action Plan released in October 2018. 3/ The statement acknowledges that biotechnologies are enabling the development of many innovative food products, such as genome-edited animals and plants. A fully funded Action Plan would foster such innovation, according to these agency officials.

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We will continue to monitor developments related to FDA's food safety and inspection efforts. Please contact us if you have any questions.

2/ FDA Strategy for the Safety of Imported Food (February 2019), available at: https://www.fda.gov/downloads/Food/GuidanceRegulation/ImportsExports/Importing/UCM631864.pdf.

3/ FDA's Plant and Animal Biotechnology Innovation Action Plan (October 2018), available at: https://www.fda.gov/Safety/Biotechnology/ucm624416.htm; FDA's Voluntary Plant Biotechnology Consultation Program Eases Pathway to Marketplace (Mar. 22, 2019), available at: https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm634021.htm