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MEMORANDUM

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Re: FDA Issues Final Guidance on Mandatory Recall Authority under FSMA

The Food and Drug Administration (FDA) recently issued final Guidance regarding its mandatory recall authority, which was granted to FDA by the FDA Food Safety Modernization Act (FSMA). 1/ Together with the release of this Guidance, FDA Commissioner Scott Gottlieb, M.D., released a statement addressing FDA's goal of expanding use of the mandatory recall authority in cases where FDA has to intervene quickly to help protect consumers from unsafe foods. 2/

The Guidance outlines how the FDA will give the responsible party an opportunity to conduct a voluntary recall before ordering a mandatory recall, as the law requires. It also offers more detail about the evidence or circumstances the FDA may consider when deciding to move forward with a mandatory food recall and provides clarity around situations when the FDA would deem a food a serious health risk. Commissioner Gottlieb's statement explains that providing this additional clarity can enable the FDA to make more robust use of the mandatory recall authority.

Background

In May 2015, FDA issued a Draft Guidance document titled "Questions and Answers Regarding Mandatory Food Recalls." The Draft Guidance set out the basic framework governing the agency's use of mandatory recall authority, which was granted by Section 206 of FSMA and codified in Section 423 of the Federal Food, Drug and Cosmetic Act (FFDCA). The Draft Guidance largely parroted the legal framework governing use of the mandatory recall authority. The FFDCA gave FDA the authority to order a responsible party to recall food when FDA determines that there is a

1/ FDA Guidance, Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff (Nov. 2018), *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM445437.pdf.

2/ FDA Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's Effort to Make More Robust Use of Mandatory Recall Authority to Quickly Remove Unsafe Foods from the Market (Nov. 5, 2018) https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625061.htm.

reasonable probability that the article of food is adulterated or misbranded due to the presence of undeclared allergens, and that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

The statute sets out a specific process that FDA must follow in order to mandate a recall. Once FDA has determined that the criteria for a mandatory recall have been met, the agency must first provide the responsible party with an opportunity to voluntarily cease distribution and recall the article of food. The statute further provides that, if the responsible party refuses to, or does not voluntarily, cease distribution or recall the food as requested by FDA, the agency can use its mandatory recall authority and order the responsible party to cease distribution.

Overview of Guidance

The Guidance is largely unchanged from the Draft Guidance. It includes information in a question-and-answer format on why mandatory recall authority is important, foods subject to FDA's mandatory recall authority, who qualifies as a "responsible party," criteria for mandatory recalls, the process FDA will follow, when foods are considered adulterated or misbranded, and how FDA will publicize information about mandatory recalls.

There are two areas where the Guidance differs from the Draft Guidance. First, FDA clarified that it will evaluate all applicable evidence when determining whether there is a reasonable probability the article of food (other than infant formula) is adulterated or misbranded, and that the use of or exposure to such article will cause SAHCODHA. These circumstances or evidence may include:

- Significant food safety observations made during establishment inspections;
- Results from sample analyses, which may include those for raw materials or finished food products, and certain sample swabs from the food facility manufacturing environment;
- Epidemiological data (e.g., food borne outbreak data directly related to the food product that suggest disease or injuries have already occurred from the consumption of/exposure to the product);
- Vulnerability of the population that normally consumes or is exposed to the food product (the assessment of the hazard will take into account the segment of the population, e.g., infants, toddlers, the elderly, pregnant women, medically compromised individuals, certain pets, young livestock);
- Nature of the food product (e.g., ready-to-eat food, raw, cooked);
- Reportable Food Registry data;
- Consumer and trade complaints; and
- Whether the responsible party has failed to initiate a voluntary recall.

Second, FDA provided the following examples of situations generally representing a SAHCODHA risk:

- Peanut butter, alfalfa sprouts, and deli products found to be contaminated with *Salmonella spp.*;
- Under-processed canned chili that contained *Clostridium botulinum* toxin;
- Smoked salmon and pumpkin seeds found to be contaminated with *Lm*;
- Products containing undeclared allergens (e.g., milk, peanuts, or eggs);
- Baby food that posed a choking hazard;

- Horse feed contaminated with elevated levels of monensin;
- Pet foods contaminated with elevated levels of melamine and cyanuric acid, or contaminated with *Salmonella spp.* or *Lm*; and
- Sheep feed containing elevated levels of copper.

Statement from Commissioner Gottlieb

In his statement accompanying the Guidance, Commissioner Gottlieb explained that he is working to make sure FDA takes recall actions more swiftly and provides timely, actionable information to consumers. Since gaining the mandatory recall authority under FSMA, the FDA has only had to issue one mandatory recall order of a food product in order to protect public health. In April 2018, the FDA issued a mandatory recall order for all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC, after several products were found to contain *Salmonella*.

Commissioner Gottlieb explains that FDA is committed to working with industry to facilitate orderly and prompt voluntary recalls, which is why FDA's Recall Coordinators are available to assist firms during the recall process. His statement also says that the mandatory recall Guidance is "another of a series of meaningful step[s] we're taking this year to make our recall processes more efficient and transparent. A few weeks ago, we issued new draft guidance 3/ that describes situations when disclosing retail information for recalled products. We also took an important step in January when we released a draft guidance 4/ on public warnings for consumers that outlined situations where the FDA and companies would publicize public warnings to help carry out a recall." Dr. Gottlieb also says that FDA has already acted on these draft guidance documents, citing two examples where FDA issued has public warnings. 5/

Dr. Gottlieb concluded with the message that more actions to improve FDA's recall policies will be forthcoming, as the agency is committed to ensuring that all recalls are initiated, overseen, and completed promptly and effectively.

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We will continue to monitor developments concerning FDA's recall authority. Should you have any questions, or wish to discuss these issues further, please do not hesitate to contact us.

3/ *See* Draft Guidance, Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls (Sept. 2018) https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM621668.pdf.

4/ *See* Draft Guidance, Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C (Jan. 2018) https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf

5/ *See* FDA Investigated Multistate Outbreak of Vibrio parahaemolyticus Linked to Fresh Crab Meat Imported from Venezuela (Sept. 2018) https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm613500.htm; see also FDA Alerts the Public Regarding Recalled Vegetable Products (Oct. 2018) https://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm623828.htm.