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MEMORANDUM

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Date: January 29, 2017

Re: FDA Issues Draft Guidance on Public Warning and Notification of Recalls and Announces Move to Expedite Release of Recall Information

The U.S. Food and Drug Administration (FDA) has issued Draft Guidance on public warning and notification of recalls under 21 C.F.R. Part 7, and has announced steps to release recall information more quickly. The Draft Guidance provides recommendations to industry and FDA staff regarding the use, content, and circumstances for issuing public warnings and public notifications, and also discusses the parties responsible for issuing public warnings. 1/ The document's recommendations apply to all voluntary recalls, including both firm-initiated and FDA-requested recalls, and covers food, dietary supplements, and cosmetics (and other FDA-regulated products). Importantly, the Draft Guidance discusses the release of retail consignee information as a part of public warnings of recalls and signals that there may be more to come from FDA in this area. In addition, FDA issued a blog post, reflecting the Draft Guidance, announcing that the agency has adopted a new policy to release recall information in FDA's weekly Enforcement Report, even when the recall has not yet been classified. 2/

Background

In December 2017, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a report that identified flaws in FDA's oversight and execution of food recalls. The report followed an "early alert" OIG issued in June 2016 notifying FDA of its preliminary findings that the agency lacks policies and procedures to ensure firms or responsible parties initiate food recalls promptly. Following the more recent OIG report, FDA Commissioner Scott Gottlieb, M.D., issued a public statement emphasizing that ensuring FDA has effective recall practices in place is one of his highest priorities. 3/

1/ Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C: Guidance for Industry and FDA Staff (Jan. 2018), available at https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf.

2/ Douglas Stern, J.D., "FDA to Expedite Release of Recall Information" (Jan. 18, 2018), available at https://blogs.fda.gov/fdavoice/index.php/2018/01/fda-to-expedite-release-of-recall-information/.

3/ Statement from FDA Commissioner Scott Gottlieb, M.D. on efforts to support more efficient and effective food recalls (Dec. 26, 2017), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm590423.htm.

In the statement, Commissioner Gottlieb said FDA would issue guidance on recall communications during the first half of 2018. He also foreshadowed that FDA had begun reviewing its stance on the inclusion of supply-chain information in recall communications. Commissioner Gottlieb said "FDA is examining in what situations it can help consumers get information about the stores and food service locations that may have sold or distributed a potentially unsafe, recalled food," explaining that disclosing this information would help consumers determine if they have been exposed to a recalled product.

Draft Guidance on Public Warning and Notification of Recalls

The Draft Guidance provides a good reminder about what FDA's expectations are for recall communications. In addition, FDA's publication of the Draft Guidance so soon after the OIG report underscores that Commissioner Gottlieb and the agency are taking OIG's report seriously and demonstrates their willingness to take swift action to respond with improvements to FDA's recall policies.

The Draft Guidance also extends upon Commissioner Gottlieb's previous response to the OIG report and includes a statement that in some cases it may be necessary to include the recalling firm's supply–chain relationship to alert the public of the product being recalled. The Draft Guidance also encourages firms, when possible, to provide specifics about the firms to which it sold recalled product. Although certain information such as supply-chain relationships and product distribution data may be considered confidential commercial information (CCI) protected from disclosure under the Freedom of Information Act (FOIA), the Draft Guidance notes that FDA's regulations authorize the release of CCI when necessary to effectuate a recall. 4/

In announcing the Draft Guidance, Commissioner Gottlieb said the document is the first of several steps FDA will take this year as part of a broader plan to improve its oversight of food safety and its implementation of the recall process. FDA currently is developing a new policy on what information FDA will make available to help the public to identify a hazardous recalled food. In the interim, Commissioner Gottlieb said "FDA can and will" publicize information such as which stores may have sold a recalled food "if it is necessary to effectuate a recall." 5/

The Draft Guidance also reviews the circumstances under which firms should issue public warnings about recalls and when FDA may issue its own warning or supplement a firm's warning. The Draft Guidance states that when FDA issues its own warning, it ordinarily will work with the firm to ensure factual accuracy, but that FDA is not required to contact the firm before issuing a public warning or allows its review of the proposed statement. In addition, the Draft Guidance advises that the agency will generally provide a timeframe for when a firm should issue a public warning. Though these timeframes will vary, the Draft Guidance states that firms generally should issue a public warning within 24 hours of FDA notifying the firm that it believes a public warning is appropriate.

New Policy for Enforcement Reports

Simultaneous to its release of the Draft Guidance, FDA issued a blog post announcing that the agency has developed a new policy to release recall information in FDA's weekly Enforcement Report sooner after a product has been recalled. The Draft Guidance includes consistent statements to that effect. Previously, FDA had only included recalls in the Enforcement Report after

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4/ 21 C.F.R. § 20.91.

5/ Statement from FDA Commissioner Scott Gottlieb, M.D., on new policy steps for strengthening public warning and notification of recalls (Jan. 18, 2018), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592777.htm.

FDA had classified the recall as a Class I, Class II, or Class III recall. However, according to FDA, the classification process can sometimes take weeks or months, and consumers would benefit from having more information about recalls as soon as possible.

Accordingly, going forward, FDA will include recalls in the Enforcement Report while classification work remains ongoing, and FDA will document the classification in the Enforcement Report as "not yet classified." FDA already has included multiple non-classified recalls in its Enforcement Reports and has updated its search engine to enable searching for "not yet classified" recalls. Food companies conducting a recall should be aware, therefore, that there may be multiple news cycles where the recall gets reported in the FDA Enforcement Report and picked up by the media.

Comments on the Draft Guidance are due March 20, 2018, and must be submitted to Docket No. FDA-2016-D-3548.

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We will continue to monitor developments related to FDA's recall policies. Please contact us if you would like further information on this issue.