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MEMORANDUM

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Re: FDA Finalizes Guidance on Public Warning and Notification of Recalls

The U.S. Food and Drug Administration (FDA) has issued final Guidance regarding *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C*. 1/ The document makes limited changes to the Draft Guidance that was issued in January 2018. 2/ The Guidance outlines circumstances when a company should issue a public warning about a voluntary recall, describes the general timeframe for companies to issue such a warning, discusses what information should be included in a public warning, and describes situations where the FDA may take action to issue its own public warning should a company's warning be deemed insufficient. The document's recommendations apply to all voluntary recalls, including both firm-initiated and FDA-requested recalls, and covers foods and dietary supplements (as well as all other FDA-regulated products). This memorandum provides background for FDA's development of the Guidance, as well as a high-level summary of the Guidance's recommendations.

A statement by FDA Commissioner Scott Gottlieb announcing the Guidance demonstrates the agency's increased interest in public notifications. 3/ For example, Commissioner Gottlieb explained that, in accordance with the Draft Guidance, FDA issued alerts or consumer warnings related to products such as recalled vegetables and romaine lettuce. Commissioner Gottlieb also noted that FDA's publicizing of recalls has become more prominent, with the agency speaking more frequently and sometimes directly to consumers through social media. The statement also discusses the steps FDA has taken to implement additional recommendations from the Draft Guidance, including exercising its mandatory recall authority for the first time in April 2018 and releasing detailed retail distribution information by state during a recall of pre-cut melon associated with a *Salmonella* outbreak this past summer.

1/ Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C: Guidance for Industry and FDA Staff (Feb. 2019), available at https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf.

2/ *See* Hogan Lovells memorandum dated January 29, 2017, *FDA Issues Draft Guidance on Public Warning and Notification of Recalls and Announces Move to Expedite Release of Recall Information*.

3/ Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to strengthen the agency's process for issuing public warnings and notifications of recalls (Feb. 7, 2019), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630906.htm.

The Guidance provides a good reminder about FDA's expectations for recall communications. The agency's fundamental expectation is that public notifications will be made when it is necessary to alert the public that a product being recalled presents a serious health hazard. FDA recommends a public warning for recalls that have been or are likely to be classified as Class I recalls, unless there are specific circumstances indicating a warning would not be beneficial to the public health (e.g., there is not enough information to convey risk and appropriate actions) or when the product is limited to a small number of consignees that are easily identified and can be reached quickly through targeted contact. The agency also recommends or may issue public warnings for some urgent Class II recalls that present a serious hazard to health (e.g., foods with low levels of undeclared allergens), though they do not rise to Class I hazards.

The Guidance also advises that the agency generally will provide a timeframe for when a firm should issue a public warning. Though these timeframes will vary, the 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. FDA's expectation is that firms post their public warnings prominently on their own web pages and that the posts should remain publicly accessible until the product is no longer expected to be used or consumed.

FDA stated it also may elect to issue a public warning on its own initiative. This can happen when, for example, the public needs immediate warning and the firm has not issued a public warning, or when a firm's public warning is deficient. If a firm's warning is deficient, FDA may supplement or correct the firm's warning with its own. Additionally, if a firm's warning is not reasonably likely to be adequately received by the target audience, FDA may ask the firm to reissue the public warning, or it may issue its own public warning. FDA also may issue information that addresses outstanding questions concerning the nature of the incident or the agency's actions. When FDA issues its own warning, it ordinarily will work with the firm to ensure factual accuracy, but the Guidance states that FDA is not required to contact the firm before issuing a public warning or allow its review of the proposed statement.

Notably, the Guidance states that when recalled products have only been distributed to direct accounts, and the recalling firm has records that show the location of the products, a prompt and effective communication to those accounts may be adequate rather than making a public notice. In such situations, recalling firms should be able to confirm that business accounts received the communication and understand the instructions conveyed to them. For internet purchases, the consumer level is considered the direct account, so for online only sales it is possible that no public notice would be required. However, FDA also states that for some internet purchases, prompt and effective communication may not be feasible and a public warning may be warranted. Where communication is feasible, FDA expects the internet seller to attempt to confirm receipt of the communication.

The Guidance also states 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 Guidance also encourages firms, when possible, to provide specifics about the retailers 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 Guidance notes that FDA's regulations authorize the release of CCI when necessary to effectuate a recall. 4/

Finally, the Guidance reiterates FDA's policy of posting a listing of recalls according to their classification in the FDA Enforcement Report. In particular, if the recall posted in the FDA Enforcement Report has not yet been classified, FDA will document the recall as not yet classified.

4/ 21 C.F.R. § 20.91.

Indeed, FDA has begun posting information relating to some voluntary recalls prior to review and classification.

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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.