Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Christine Forgues

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Re: FDA Issues Draft Guidance on Publishing Retail Consignees Lists to Effectuate Certain Human and Animal Food Recalls

On September 26, 2018, the Food and Drug Administration (FDA or the agency) issued a statement by FDA Commissioner Scott Gottlieb, M.D. on FDA's commitment to disclose retailer information for certain food recalls to improve consumer safety. 1/ Additionally, on September 27, 2018, FDA published a Federal Register Notice announcing availability of a draft guidance on the Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls (Draft Guidance). 2/ Publication of the Draft Guidance is the second of a series of policy steps the agency is taking as part of a broader plan to improve oversight of food safety and the recall process.

Importantly, FDA states that it will focus primarily on publicizing retail consignee lists for food recalls where there is a reasonable probability that the use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals (i.e., Class I recalls). Criteria the agency will focus on when considering whether to publish information include:

- Whether the food is easily identifiable as being subject to a recall from its retail packaging; and
- Whether the food is likely to still be in a consumer's possession.

Both criteria must be met in order for the agency to publish the retail consignee list. Comments are due on the Draft Guidance by November 26, 2018.

1/ FDA Statement from FDA Commissioner Scott Gottlieb, M.D. on New FDA Commitment to Disclose Retailer Information for Certain Food Recalls to Improve Consumer Safety (Sept. 26, 2018) https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm621692.htm.

2/ 83 Fed. Reg. 48825 (Sept. 27, 2018) https://www.gpo.gov/fdsys/pkg/FR-2018-09-27/pdf/2018-21042.pdf; FDA Draft Guidance, Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff (Sept. 2018) https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM621668.pdf.

Background

As background, when a food recall is initiated, FDA typically works with companies to publicize labeling information, product descriptions, lot numbers, photographs, and sometimes geographic or retail-related distribution information. The goal of providing this information is to help consumers identify whether they have purchased the recalled product. Generally, consumers then either throw away the product or return it to the place of purchase.

In the past, the agency has not traditionally released lists of specific retailers where recalled foods may have been purchased because supply chain information was considered confidential commercial information (CCI) protected by law and regulation. Moreover, in most cases, the information publicized by FDA and the recalling company was sufficient to allow consumers to identify and avoid recalled product. However, under FDA's longstanding regulations, the agency has the authority to disclose information such as CCI that would not otherwise be publicly disclosed if necessary to effectuate a recall. 3/ Lastly, FDA's practice has always been to assess each recall on a case-by-case basis to determine the information that may be helpful to the public and consumers. The Draft Guidance describes specific food recall situations and the criteria FDA will consider when deciding to make retail consignee information publicly available. Although FDA intends to focus on publicizing information for Class I recalls, the agency may also publicize retail consignee lists for some Class II food recalls, particularly where FDA has issued a public warning or where there is an association with an outbreak of a foodborne illness. 4/ The agency also recognizes there will be limitations to accessing and compiling the consignee lists (e.g., where they cannot fully verify the accuracy or completeness of the information it receives from recalling firms or distributors, lists may not include all retail locations that have received the food, or lists may include retail locations that did not receive the food). In publishing the lists, the agency will identify these limitations, and will direct consumers to other identifying information in addition to the list to identify recalled product.

In recent months, the agency has already begun taking actions that align with the Draft Guidance approach. The Draft Guidance provides greater transparency on the intention to regularly use this approach in these and other scenarios.

As a note, although publication of retail consignee lists is a new practice for FDA, implementation of this policy is consistent with the current practice of United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). Especially for larger recalls, FSIS creates a store-by-store list of all locations that have received the recalled product and makes the list publicly available on the FSIS website.

Criteria for Publicizing Retail Consignee Lists for Certain Food Recalls

FDA intends to publicize retail consignee lists for food recalls when both of the following criteria are met:

- the food is not easily identified as being subject to a recall from its retail packaging (or lack thereof); and

3/ 21 CFR § 20.91.
4/ The agency notes that it may also apply the Draft Guidance criteria to recalls that have not yet been classified.

- the food is likely to be available for consumption (i.e., given its shelf-life or perishability, it may still be in a consumer's possession). 5/

Examples of foods that meet both criteria include foods sold directly to consumers with no universal product code (UPC) and/or bar code (e.g., deli cheese, nuts, rawhide chews, or pet treats sold in bulk); fresh fruits and vegetables sold individually; or when the food product lacks a lot number, or other identifier. Of note, FDA may elect not to publicize the consignee information in cases where doing so would undermine a public health warning (e.g., if FDA has warned the public to avoid a specific food commodity in general, and the recalled food was only sold through a limited number of retail outlets).

In terms of specific information that will be included, the agency intends to provide a specific retail store name and its address. However, depending on the nature of the distribution, FDA may list retail store chains and general geographic locations rather than the locations of specific retail stores (e.g., "all Grocery ABC stores nation-wide"). As noted above, FDA will make clear any limitations associated with the lists, including the inability to fully verify the completeness or accuracy of the information it receives from firms or distributors, the list may be over and under inclusive, may not include all retail locations that received the food, or may include retailers that did not receive the food.

FDA will post lists of retail consignees associated with a specific recall on its website, and may publicize this information in other ways consistent with how FDA currently makes recall information public. In some limited circumstances, a recalling firm may be able to identify all of the retail consignees itself because it provided the recalled food directly to the retail consignees. In these limited cases, FDA may give the recalling firm the first opportunity to prepare and issue publicly its list of retail consignees that received the recalled food, if the firm's release of this information would be timely and complete.

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We will continue to monitor developments concerning public availability of retailer and other information released during recalls. Should you have any questions, or wish to discuss these issues further, please do not hesitate to contact us.

5/ FDA will also consider publicizing retail consignee lists in other recall situations that do not meet both of these criteria, including for recalls which may include packaged food, especially when a recalled food is associated with a foodborne illness outbreak