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FDA Publishes Guidance on "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls"

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Food, Beverage, and Dietary Supplements

This morning (September 26, 2018), FDA announced the availability of a draft guidance for industry and FDA staff, "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls," that explains how and when FDA intends to publicize retail consignees that may have received recalled human or animal foods. The draft guidance is the second recall guidance FDA has issued this year[1] in response to the December 2017 report from the Office of Inspector General (OIG), which identified several shortcomings in FDA's food recall procedures. FDA has provided a 60 day comment period.

FDA's Authority for Publicizing Retailer Information

In promulgating the draft guidance, FDA relies on Section 206 of the Food Safety Modernization Act (FSMA), which directs FDA in conducting recalls to "consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall." As industry well knows, the long standing practice of the U.S. Department of Agriculture's (USDA) in Class I recalls is to make publicly available the name of retailers of recalled amenable foods.

FDA acknowledges that in publicizing retailer names it may release certain confidential commercial information (CCI), but states that such information may be necessary to effectuate a recall, consistent with 21 CFR 20.91.

FDA's Criteria For Determining Whether to Publicize Retailer Information

FDA's stated goal is to effectuate recalls by helping consumers identify recalled food – both packaged and unpackaged – as effectively and quickly as possible. FDA will most likely publicize retail consignees involved in Class I recalls, but may also publicize retail consignees

[1] *See* "FDA Announces Broad Plan to Improve and Expedite Dissemination of Recall Information to Consumers," Covington Alert (Jan. 22, 2018).

for some Class II food recalls, particularly where a company or FDA has issued a public warning or where the recalled food is associated with a foodborne illness outbreak. Given the potential lag time between initiating a recall and FDA's classification of a recall, FDA may publicize retail consignee information prior to classifying a recall if doing so is necessary to help consumers identify recalled food.

FDA will rely on two key criteria in assessing whether to publicize retailer names: (1) the food is not easily identified as being subject to a recall from its retail packaging (or lack thereof); and (2) 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). Even absent these two criteria, FDA proposes to publicize retailer names if a recalled food is associated with a foodborne illness outbreak.

How and What FDA Intends to Publicize

FDA intends to publish the retailer information on its website and may publicize the information "in other ways consistent with how FDA makes recall information public." The specific retailer information FDA publicizes may depend on the nature of the distribution of the recalled product. Where possible, FDA intends to publicize specific names and addresses of the retail stores, or, if the food is widely distributed, FDA may instead publicize the names of retail store chains and geographic locations (e.g., "all Grocery ABC stores nation-wide").

If a company is able to identify all of its retail consignees, FDA may allow the recalling firm the first opportunity to prepare and publicize its list of retailers that received the recalled food, so long as the information is complete and is released promptly. FDA intends to work with companies to prepare and publicize retailer information.

Recognizing the potential limitations of publicizing retail consignee lists and the practical reality that such lists may be both over and under inclusive – *e.g.*, identifying retailers that may not have received recalled food, identifying retailers that may have received recalled food, inadvertently including entities that are not "retail consignees" – FDA intends to identify such limitations when publicizing "retail consignee" lists.

FDA's Proposed Definition of "Retail Consignee"

Key to the scope of FDA's draft guidance is its proposed definition of "retail consignee":

> [R]etail establishments that, based on information available to FDA, have received or otherwise possess recalled food and that sell food products directly to consumers, traditionally meant to be consumed away from the establishment. This includes retail establishments that sell to consumers physically present in the store (*e.g.*, grocery stores, pet food stores, and convenience stores) and retail establishments that receive orders through any means (*e.g.*, phone, mail, internet order, and catalog, etc.) and deliver the food products directly, or through a third-party delivery service, to the consumer.

FDA explains that most restaurants and similar entities are not considered retail consignees under this policy because identifying them would not enable consumers to recognize recalled food in their possession, although FDA may apply its guidance to some restaurants and similar entities which have retail areas that sell directly to consumers.

Considerations for Industry

Companies could consider and provide to FDA comments on whether and to what extent retailer information is CCI and whether, in fact, publishing such information is consistent with FDA's authority. In addition, companies could assess whether FDA's proposed definition of "retailer consignee" is appropriate and is in line with industry's general understanding of this term or function. Finally, companies could consider whether to provide FDA feedback on how to ensure that public retailer information is not over- and under-inclusive, so that the information accurately conveys the scope of the recall and the retailers who have received recalled food and does not lead to undue consumer confusion or concern.

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The lawyers in Covington's food, beverage, and dietary supplement practice continuously monitor FDA's recall-related activities and frequently assist companies on all aspects of food recalls. If you have any questions concerning FDA's new draft guidance discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com