

*Contains Nonbinding Recommendations*

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# **Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff**

## ***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-1752.

For questions regarding this draft document contact the ORA Office of Strategic Planning and Operational Policy (OSPOP) at [ORAPolicyStaffs@fda.hhs.gov](mailto:ORAPolicyStaffs@fda.hhs.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine**

**SEPTEMBER 2018**

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# **Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA, we, or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## **I. INTRODUCTION**

This guidance provides information on how and when FDA intends to publicize the identities of retail consignees that may have received recalled human or animal foods.<sup>2</sup> FDA will primarily focus on those 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, which are also referred to as Class I recalls,<sup>3</sup> and where providing such information is needed to help consumers identify recalled food. Identifying retail consignees can be a time-consuming process that often involves obtaining information from multiple entities throughout a supply chain, including the recalling firm and intermediate distributors. Therefore, FDA's goal is to collect, compile, and make public retail consignee lists for those food recalls where publicizing this additional information will be of the most use to help consumers identify recalled food and to determine whether that food is in their possession as effectively and quickly as possible.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance has been prepared by the Office of Regulatory Affairs in cooperation with the Center for Food Safety and Applied Nutrition at the Food and Drug Administration and the Center for Veterinary Medicine.

<sup>2</sup> Under section 201(f) of the Federal Food, Drug, and Cosmetic Act, the term "food" includes articles used for food or drink for man or other animals.

<sup>3</sup> See 21 CFR 7.3(m).

## **II. BACKGROUND**

This guidance outlines the circumstances under which FDA intends to collect, compile, and make public lists of retail consignees that may have received recalled foods that pose a risk to humans or animals.

This guidance also responds to section 206 of the 2011 FDA Food Safety Modernization Act (FSMA), which directs the Agency, in conducting recalls under the section (which provides FDA authority to mandate the recall of a food under certain circumstances), 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 and shall consider providing such a list to the public,” as determined appropriate by the FDA [21 U.S.C. § 350l(g)(2)]. The Department of Agriculture (USDA) policy is to make publicly available the names and locations of retail consignees of recalled meat or poultry products that USDA compiles in connection with a recall where there is a reasonable probability that the use of the product could cause serious adverse health consequences or death (Class I recalls). 9 CFR 390.10.<sup>4</sup>

Currently, FDA makes certain recall information public by providing information gathered from press releases and other public notices about recalls of FDA-regulated products.<sup>5</sup> FDA generally provides labeling information, product descriptions, lot numbers, and photographs, as well as some geographic or retail-related distribution information, if such information is available to FDA. In addition, all recalls of FDA-regulated products are included in the FDA’s Enforcement Report.<sup>6</sup>

With respect to public warning and notification of recalls, FDA evaluates the particular circumstances of each individual recall in determining whether a public warning is needed in accordance with 21 CFR 7.42(b)(2) as part of the recall strategy. FDA may issue a public warning or notification before formally classifying a recall under 21 CFR 7.4. We note that due to the level of hazard associated with Class I recalls, FDA has generally issued, and/or sought issuance of, public warnings in Class I recalls unless specific circumstances indicate that one would not be beneficial to the public. While public warnings may be issued by either the recalling firm or by FDA, the Agency generally gives the recalling firm the first opportunity to prepare and issue a public warning concerning its recall. FDA’s staff regularly work with the recalling firm to prepare public warnings to ensure that they contain adequate information.

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<sup>4</sup> USDA uses the term “retail consignee” to mean retail establishments that receive meat and poultry and sell directly to consumers which is intended for consumer preparation at home. USDA excludes restaurants and intermediate consignees from this term. See Final Rule: “Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls,” 73 FR 40939, 40941 and 40945 (July 17, 2008).

<sup>5</sup> Available online here <https://www.fda.gov/Safety/Recalls/default.htm>.

<sup>6</sup> Available online here <https://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

### **III. DISCUSSION**

#### **A. Meaning of Retail Consignee**

For this guidance, FDA is using the term “retail consignee” to refer to retail 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. Most restaurants and similar entities<sup>7</sup> are not considered retail consignees under this policy because identifying them would not enable consumers to recognize recalled food in their possession. Intermediate distributors and suppliers that do not sell food directly to consumers are also not retail consignees under this policy because identifying them would also not enable consumers to recognize recalled food in their possession.

#### **B. Authority to Publicize Retail Consignee Lists**

In some recalls, identifying “retail consignees” may reveal confidential business relationships between suppliers and customers which may be confidential commercial information (CCI), the disclosure of which is restricted by law and FDA regulation. FDA has the authority to disclose CCI about recalled products that is relevant to the recall, whether a recall is voluntarily initiated or ordered by FDA, but would not otherwise be publicly disclosed by FDA. Under 21 CFR 20.91, information otherwise exempt from public disclosure, such as CCI, is nevertheless available for public disclosure to the extent necessary to effectuate a recall. Therefore, when relying on this authority to make public, information that could be CCI, FDA will first make a determination that there is a “recall” as defined under 21 CFR 7.3(g), but may not have determined its classification under 21 CFR 7.3(m). FDA’s authority under 21 CFR 20.91 is not limited to Class I recalls. FDA believes that publicizing retail consignee lists for the recalls described in this guidance will help consumers to identify recalled food (including recalled food associated with foodborne illness) and to determine whether that food is in their possession as effectively and quickly as possible, and therefore is necessary to effectuate such recalls.

#### **C. Scope of this Guidance’s Application**

FDA’s practice has been to assess each individual recall in determining what information is helpful to the public and consumers. This guidance describes specific food recall situations and

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<sup>7</sup> Some restaurants and similar entities have retail areas that sell directly to consumers. FDA may apply this guidance to such restaurants and entities.

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the criteria FDA will consider when deciding to make retail consignee information publicly available.

While FDA intends to focus on recalls where there is a reasonable probability that the use of or exposure to the violative product will cause serious adverse health consequences or death to humans or animals (i.e., Class I recalls), we may also publicize retail consignee lists for some Class II food recalls,<sup>8</sup> particularly where FDA has issued a public warning or where there is an association with an outbreak of a foodborne illness. In addition, in order to ensure the timely dissemination of information, FDA may apply this guidance to recalls that have not yet been classified as a Class I or Class II recall.

#### **D. Potential limitations of the retail consignee lists**

There is typically no single source that FDA can access to readily obtain a list of retail consignees of a recalled food product. Instead, identifying the retail consignees often involves obtaining information from multiple entities throughout a supply chain, including the recalling firm and intermediate distributors. In addition, for a variety of reasons, FDA may not be able to fully verify the accuracy or completeness of the information it receives from recalling firms or distributors. In such cases, the information available to FDA about retail consignees may be both over and under inclusive, in that it may not include all retail locations that have received the food or may include retail locations that did not receive the food. In addition, it may not be clear from the information provided by the recalling firm to FDA whether its consignees are “retail consignees” as defined in this guidance. FDA intends to explain these limitations when publicizing retail consignee information and remind consumers of the importance of using other available product specific information to help identify recalled food.

#### **E. Publicizing retail consignee lists for certain food recalls**

##### **1. When will FDA publicize retail consignee lists?**

FDA’s goal is to publicize retail consignee lists for those food recalls, especially those that are likely to be classified as Class I recalls, where providing this additional information will be of the most use to consumers to help them identify recalled food and to determine whether that food is in their possession as effectively and quickly as possible. This may include food that is either packaged or unpackaged.

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

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

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<sup>8</sup> A Class II recall is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. 21 CFR 7.3(m)(2).

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(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).

Examples of such foods may 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); and fresh fruits and vegetables sold individually; or when the food product lacks a lot number, or other identifier, which consumers can use to readily identify the product as one subject to the recall.

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 -- when doing so will be of most use to consumers in identifying a recalled food and is consistent with 21 CFR 20.91. For example, FDA might post retail consignee information for a packaged food that was distributed in a particular geographic region or through a particular online retailer if the agency determined that providing such information would help prompt consumers who may have received or purchased such recalled food to consider whether they possess the recalled product.

FDA believes that providing retail consignee information for these recalls is especially important to enable consumers to identify recalled foods. It will also improve the efficiency of recalls by helping consumers to identify and focus on the foods that are recalled. Therefore, the disclosure of any CCI that may occur when FDA makes this information public is necessary to effectuate a recall, consistent with 21 CFR 20.91. However, FDA may elect not to publicize this information in cases where doing so would undermine a public health warning (for example, if FDA has warned the public to avoid a specific food commodity in general, and there has only been a limited recall of this food).

## **2. What information will FDA provide?**

FDA generally intends to provide information that typically includes a specific retail store name and its address. However, depending on the nature of the distribution, FDA may list retail store chains and geographic locations rather than the locations of specific retail stores (for example, “all Grocery ABC stores nation-wide”). In providing this information, FDA will make clear that FDA may not be able to fully verify the accuracy or completeness of the information it receives from recalling firms or distributors. FDA will make clear that the disclosure of retail consignees may be both over and under inclusive, in that it may not include all retail locations that have received the food or may include retail locations that did not receive the food.

## **3. How will FDA publicize this information?**

FDA will post lists of retail consignees associated with a specific recall on FDA's website and may publicize this information in other ways consistent with how FDA makes recall information public. In some limited circumstances, a recalling firm may be able to identify all of the retail

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consignees because the recalling firm provided the recalled food directly to the retail consignees. In these 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. FDA staff will work with such recalling firms to prepare and issue a release of these lists.