Contains Nonbinding Recommendations

Guidance for Industry
What You Need to Know About Administrative Detention of Foods Small Entity Compliance Guide

Final Guidance

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

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I. Introduction

This guidance document provides updated information pertaining to the Food and Drug Administration's (FDA) authority to order the administrative detention of human or animal food under section 304(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 334(h)]. Congress originally established this authority in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and amended it in January 2011 as part of the FDA Food Safety Modernization Act (FSMA).

FDA prepared this guidance to restate the legal requirements in section 304(h) of the FD&C Act. Previously, this guidance restated the legal requirements for FDA's administrative detention regulation at 21 CFR Part 1, Subpart K, implementing section 304(h) of the FD&C Act. This guidance also served as FDA's Small Entity Compliance Guide (SECG) for 21 CFR Part 1, Subpart K in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). However, as explained above, section 304(h) was amended by FSMA in 2011. Accordingly, in October 2011, FDA updated this document to provide guidance intended to help any entity comply with the requirements of section 304(h) of the FD&C Act, including the amendments to section 304(h) of the FD&C Act made by section 207 of FSMA. This update clarifies that this document continues to serve as FDA's SECG for 21 CFR Part 1, Subpart K.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 guidances means that something is suggested or recommended, but not required.

II. Background

The Bioterrorism Act was signed into law on June 12, 2002. Among other things, the Bioterrorism Act amended the FD&C Act by adding subsection (h) to section 304. This provision provided FDA the authority to order the detention of any article of food if, during an inspection, examination, or investigation, an FDA officer or qualified employee finds there is credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act also amended the FD&C Act by adding subsection (bb) to section 301, making it a prohibited act to move an article of food in violation of a detention order or to remove or alter any mark or label required by a detention order that identifies an article of food as detained.

In the Federal Register of June 4, 2004 (69 FR 31660), the FDA issued the final regulations establishing the procedures for administrative detention, including, among other provisions, the criteria for ordering administrative detention. The administrative detention regulations took effect on July 6, 2004, and have been codified at Title 21, Code of Federal Regulations (CFR) Part 1, Subpart K (21 CFR Part 1, Subpart K).

Section 207 of FSMA, signed into law on January 4, 2011, amended the criteria for ordering administrative detention of human or animal food in section 304(h)(1)(A) of the FD&C Act [21 U.S.C. 334(h)(1)(A)]. Under the new criteria, FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. In accordance with section 207 of FSMA, the FDA issued an interim final rule (IFR) amending the criteria for administrative detention in the regulations found in 21 CFR Part 1, Subpart K. The IFR was published in the Federal Register on May 5, 2011 (76 FR 25538), and became effective on July 3, 2011. On February 5, 2013, FDA issued a final rule adopting without change the requirements in the IFR (76 FR 25538).

III. Questions and Answers

1. Why is administrative detention needed?
Administrative detention provides a means through which FDA can hold adulterated or misbranded food and prevent it from reaching the marketplace, thus further enhancing FDA's ability to ensure the safety of food for U.S. consumers.

2. What food is subject to administrative detention?
The term food refers to (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article (section 201(f) of the FD&C Act [21 U.S.C. § 321(f)]). The term food also refers to dietary supplements, which are to be treated as food under the FD&C Act (section 201(ff) [21 U.S.C. § 321(ff)]). The term dietary supplement refers to a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. A dietary ingredient in these products may include: vitamins, minerals, herbs, or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates and may

come in many forms as long as they are labeled as a dietary supplement and not represented as a conventional food or sole item of a meal or diet.

The FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded. Food that is regulated exclusively by the United States Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is not subject to administrative detention. All other food is subject to this regulation, whether or not it enters interstate commerce.

3. How long may FDA administratively detain an article of food?
FDA may detain an article of food for a reasonable period, not to exceed 20 calendar days, after the detention order is issued. However, an article of food may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The entire detention period may not exceed 30 calendar days (21 CFR 1.379).

4. What criteria does FDA use to order an administrative detention?
An officer or qualified employee of FDA may order the administrative detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act if the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded (21 CFR 1.378). When ordering an administrative detention FDA will have factual information that a food is adulterated or misbranded. As expressed in the final rule which adopts, without change, the IFR as final, FDA will consider ordering administrative detention on a case-by-case basis because these decisions rely on the factual information and circumstances specific to each situation. Further, FDA intends to use this tool in a manner that furthers the Agency's public health and prevention-based goals.

5. Who approves an administrative detention order?
An administrative detention order is approved by the Director of the FDA District where the food to be administratively detained is located, or an official senior to such Director (21 CFR 1.391). For more information about FDA's procedures consult the Regulatory Procedures Manual (RPM) chapter 4.

6. What information must FDA include in the administrative detention order?
The following information is included in the administrative detention order (See 21 CFR 1.393 for a complete list):

- Detention order number
- Hour and date of the order
- Identification of the detained article of food
- Detention period
- Statement that the article of food identified in the order is detained for the period shown
- Brief, general statement of the reasons for the detention
- Address and location where the article of food is to be detained and the appropriate storage and transportation conditions.

- A statement that the article of food is not to be consumed, moved, altered or tampered with in any manner during the detention period, unless the detention order is first modified under 21 CFR 1.381(c)
- Name and title of the authorized FDA representative who approved the detention order

7. May an administratively detained article of food be delivered to another entity or transferred to another location?

It is a prohibited act under section 301(bb) of the FD&C Act [21 U.S.C. 331(bb)] to transfer an article of food subject to an administrative detention order and/or to alter or remove any mark or label that identifies an article of food as administratively detained. However, there can be exceptions which permit the movement of detained articles of food under the supervision and control of FDA, as identified in 21 CFR 1.381(c).

8. Can an administrative detention order be modified?

FDA may approve a request for modification of an administrative detention order to allow for the destruction of the article of food or movement of the detained article of food to a secure facility, to maintain or preserve the integrity or quality of the article of food, or for any other purpose that the authorized FDA representative believes is appropriate in the case (21 CFR 1.381(c)). Requests for modification of a detention order must be submitted in writing to the FDA representative who approved the original detention order and must include the information specified in 21 CFR 1.381(d).

9. What labeling or marking requirements apply to an administratively detained article of food?

An administrative detention order *may* require that the detained article of food be labeled or marked as detained. The FDA tag or label (FDA Form 2290) will include among other information, a statement that the article of food *must not* be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative (21 CFR 1.382).

10. What constitutes "perishable food?"

FDA defines perishable food as food that *is not* heat-treated, *not* frozen, and *not* otherwise preserved in a manner to prevent the quality of the food from being adversely affected, if held longer than seven (7) calendar days under normal shipping and storage conditions (21 CFR 1.377).

11. What expedited procedures apply when FDA initiates a seizure action against an administratively detained perishable food?

If FDA initiates a seizure under section 304(a) of the FD&C Act [21 U.S.C. 334(a)] against a perishable food that is subject to an administrative detention order, FDA will send the seizure recommendation to the Department of Justice within four (4) calendar days after the administrative detention order is issued, *unless* extenuating circumstances exist (21 CFR 1.383).

12. Where and under what conditions must the administratively detained article of food be held?

The administratively detained article of food must be held in the specified location and under the conditions specified by FDA in the detention order (21 CFR 1.380). The administrative detention order may require removal of the detained article of food to a secure facility; however, movement of the detained food is only permitted after FDA has modified the detention order under 21 CFR 1.381(c) (21 CFR 1.380(c)).

13. Who receives a copy of the administrative detention order?

FDA will issue the administrative detention order to the owner, operator, or agent in charge of the location where the article of food is being detained. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article of food is detained, then FDA will also provide a copy of the administrative detention order to the owner of the article of food, if the owner's identity can be determined readily (21 CFR 1.392 (a)).

If FDA issues an administrative detention order for an article of food located within a vehicle or other carrier used to transport the food, FDA also must provide a copy of the administrative detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily (21 CFR 1.392 (b)).

14. What's the difference between an import detention and administrative detention?

FDA's authority to administratively detain food under section 304(h) of the FD&C Act [21 U.S.C. 334(h)] is *separate* and *distinct* from detention that may occur during FDA's import admissibility review. Under section 801(a) of the FD&C Act [21 U.S.C. 334(h)], when food is imported or offered for import into the United States, FDA conducts an admissibility review to determined whether to admit the product into United States or detain the product. When it appears that an article of food may be subject to refusal of admission, FDA issues a notice explaining that it is detaining the product and providing the owner or consignee an opportunity to provide testimony (21 CFR 1.94). Although referred to as "detention," generally neither FDA nor U.S. Customs and Border Protection (CBP) has physical custody or control of the food; the importer generally has actual possession and posts a bond with CBP. For more information about import detention, please refer to the Regulatory Procedures Manual (RPM) chapter 9.

On the other hand for administrative detentions under section 304(h) of the FD&C Act, FDA will issue an order to the owner of the suspect food notifying him that FDA is administratively detaining the food and that he has an opportunity to appeal the detention with or without a hearing (see 21 CFR Part 1 Subpart K).

15. Who is entitled to appeal a detention order?

Any person who would be entitled to be a claimant of the administratively detained article of food if it were seized under section 304(a) of the FD&C Act [21 U.S.C. 334(a)] may appeal the detention order (21 CFR 1.401).

16. What are the requirements for submitting an appeal?

For perishable food, an appeal must be filed to the FDA District Director whose district detained the article of food within two (2) calendar days of receipt of the administrative detention order. For non-perishable food, a notice of intent to file an appeal and to request a hearing must be filed within four (4) calendar days of receipt of the administrative detention order. The actual appeal, even if it does not include a request for a hearing, must be filed within ten (10) calendar days of the receipt of the administrative detention order (21 CFR 1.402 (a)). If the owner of the administratively detained food decides to appeal the detention order, the owner may also request a hearing as part of the appeal by filing a timely notice of intent to request a hearing and then noting this request for a hearing as part of the owner's appeal. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Presiding Officer determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided, explaining the reasons for denial of the hearing. If the owner requests a hearing as part of the owner's appeal, the owner should submit the materials, data, and information that the owner believes shows that there is a genuine and substantial issue of fact regarding the propriety of the detention and any other information that the person would like the Presiding Officer to consider when deciding the appeal and request for hearing. Likewise, if the owner does not request a hearing as part of the owner's appeal the owner should still submit materials, data, and information that the owner wants the Presiding Officer to consider when deciding the appeal.

17. Will a hearing be held if an appeal is made?

If the appellant requests a hearing, and FDA grants the request, then for both perishable and non-perishable foods, the hearing will be held within two (2) calendar days after the date the appeal has been filed (21 CFR 1.402 (d)).

18. When does FDA have to issue a decision on an appeal?

FDA must confirm, modify or terminate the administrative detention order within five (5) calendar days after an appeal is filed and after providing an opportunity for an informal hearing, if requested (21 CFR 1.405).

19. When does an administrative detention order terminate?

If FDA terminates an administrative detention order or the detention period expires, an authorized FDA representative will issue an administrative detention termination notice to any person who received the detention order (or that person's representative), releasing the article of food, as quickly as possible. If FDA fails to issue an administrative detention termination notice and the detention period expires, the administrative detention is deemed to be terminated (21 CFR 1.384). FDA intends to notify the owners of administratively detained goods of the termination of administrative detentions, as soon as practicable. If a detention termination cannot be issued on the same day as the decision to terminate the detention because, for instance, the parties who would receive the termination notice are unavailable, FDA will issue the termination notice, as soon as possible.

If the owner of the administratively detained goods would like to terminate the detention before the detention period expires, the owner can request a modification of the detention order as

discussed in number 8 of this document and FDA can modify the order to allow for the voluntary destruction of the goods and effectively terminate the detention. FDA routinely monitors such destruction activities.

20. **Who pays the costs associated with the detention order, such as storage, moving, disposal or reconditioning?**

As stated in the preamble to the 2004 final rule (69 Federal Register 31659 at 31690), the party or parties responsible for paying the storage costs of food that FDA orders administratively detained is a matter between the private parties involved with the food. FDA is not liable for those costs. An owner, operator, or agent in charge of the place where the food is located can always request modification of a detention order to destroy the food if they do not want to store it.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of October 19, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after October 19, 2011. FDA has verified that these web addresses are still available for the content as of April 29, 2012.

1. For more information on the Food Safety Modernization Act, go to:
   http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm

2. The Interim Final Rule to revise 21 CFR 1.378 that published in the Federal Register on May 5, 2011 (76 FR 25538) is located at:
   http://www.fda.gov/Food/FoodSafety/FSMA/ucm257986.htm

3. The Regulatory Procedures Manual is located at:
   http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm