

apply when the terms are used in this subpart.

In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)).

Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA

representative may approve the additional 10 calendar day detention period at the time the detention order is issued or at any time within the 20 calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a limited conditional release under § 1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered to another entity under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act, it may not be delivered to any of its importers, owners, or consignees.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases

the article of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request for a limited conditional release of a detained article of food for any of the following purposes:

- (1) To destroy the article of food,
- (2) To move the detained article of food to a secure facility under the terms of a detention order,
- (3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for the limited conditional release of the detained article in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting a limited conditional release for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the "Federal Rules of Civil Procedure."

(e) If FDA approves a request for limited conditional release, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the limited conditional release of the article of food that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax or e-mail or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after