

Food and Drug Administration, HHS

§ 1.393

for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the DOJ of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

HOW DOES FDA ORDER A DETENTION?

§ 1.391 Who approves a detention order?

An authorized FDA representative, *i.e.*, the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the 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.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has reason to believe that such article of food is adulterated or misbranded.

(b) The detention order must include the following information:

- (1) The detention order number;
- (2) The date and hour of the detention order;
- (3) Identification of the detained article of food;
- (4) The period of the detention;
- (5) A statement that the article of food identified in the order is detained for the period shown;
- (6) A brief, general statement of the reasons for the detention;

§ 1.401

21 CFR Ch. I (4–1–13 Edition)

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) 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 § 1.381(c);

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located;

(13) A statement indicating the manner in which approval of the detention order was obtained, *i.e.*, verbally or in writing; and

(14) The name and the title of the authorized FDA representative who approved the detention order.

[69 FR 31701, June 4, 2004, as amended at 76 FR 25541, May 5, 2011]

WHAT IS THE APPEAL PROCESS FOR A DETENTION ORDER?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the “Federal Rules of Civil Procedure.”

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identi-

fied in the detention order according to the following applicable timeframes:

(1) *Perishable food*: If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) *Nonperishable food*: If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the “Federal Rules of Civil Procedure.”

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative