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§ 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;

(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, email address, fax number, and the name of the FDA Division Director in whose division 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; 85 FR 16550, Mar. 24, 2020]

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 Division Director in whose division the detained article of food is located, at the mailing address, email address, or fax number identified 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

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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.

[69 FR 31701, June 4, 2004, as amended at 85 FR 16550, Mar. 24, 2020]

§ 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 record of the regulatory hearing under § 16.80(a) of this chapter;

(b) A request for a hearing under this section must be addressed to the FDA Division Director in whose division the article of food involved is located;

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart;

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart;

(e) Section 1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information;

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart;

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 calendar day, as appropriate;

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

(j) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart,

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