

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, we 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 credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.

(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 subject to a limited conditional release under § 1.381 of this part;

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

(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 of this part;

(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; and

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

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 of this part. 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 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^v of this part, 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^v of this part, 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 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, as defined in section 201(x) of the act, and FDA grants your request, the hearing will take place according to the following applicable timeframes:

(1) *Perishable food*: If the detained article is a perishable food, as defined in § 1.377 ~~of this part~~, the hearing will be held within 2 calendar days after the date the appeal is filed.

(2) *Nonperishable food*: If the detained article is not a perishable food, as defined in § 1.377 ~~of this part~~, the hearing will be held within 3 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 ~~of this part~~, 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 District Director in whose district the article 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 ~~two~~ 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart.

(e) Section 1.406 of ~~this part~~, 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 of ~~this part~~, rather than § 16.42(a) of this chapter, describes the FDA employees, e.g., regional food and drug directors or other officials senior to a district director, who preside at hearings under this subpart.

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

(h) Provisions of part 16 of this chapter that provide for the presiding officer to issue a report and recommended decision only do not apply. The presiding officer will issue the final agency decision.

§ 1.404 Who serves as the presiding officer at an informal hearing?

The presiding officer of an informal hearing on an appeal of a detention order, who also must decide the appeal, must be an FDA regional food and drug director or another FDA official senior to an FDA district director.

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a decision confirming or revoking the detention within 5 calendar days after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-day period, the detention order is deemed terminated.

(b) If you appeal the detention order but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming

or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 of this part or the detention period expires under § 1.379 if this part, whichever occurs first. ✓

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384 of this part. ✓

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of ^{5 U.S.C. 702} ~~section 702 of title 5, United States Code.~~ ✓ own style

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security ("classified information"), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such

Insert
on p. 108

§ 16.1 [Amended]

4. Section 16.1 Scope is amended in paragraph (b) (1) by numerically adding a new statutory provision "Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart K, of this chapter)."

detention will state whether it is based in whole or in part on that classified information.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

4. Amend § 16.1 by revising paragraph (b)(1) to read as follows:

~~§ 16.1 Scope~~

~~* * * * *~~

~~(b) * * *~~

~~(1) Statutory provisions:~~

~~Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g) of this chapter).~~

~~Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart K of this chapter).~~

~~* * * * *~~

*per Kent
Giles, OFD
9-28 '17*

§ 16.1 [Amended]

4. Section 16.1 Scope is amended in paragraph (b) (1) by numerically adding a new statutory provision "Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart K, of this chapter)."

X

Dated: _____

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S