

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, 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, 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, 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 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, 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 or the detention period expires under § 1.379, 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.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

#### **§ 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 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. Section 16.1 is amended in paragraph (b)(1) by adding a new statutory provision in numerical order as follows:

#### **§ 16.1 Scope.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

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).

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