

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 proposed § 1.381;

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

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 proposed § 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; and

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

#### *D. What Is the Appeal Process for a Detention Order?*

##### **1. Who is Entitled to Appeal? (Proposed § 1.401)**

Under proposed § 1.401, any person who would be entitled to be a claimant for such article of food, if seized under section 304(a) of the act, would be able to appeal a detention order. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C(6)(a) to the “Federal Rules of Civil Procedure.”

##### **2. What Are the Requirements for Submitting an Appeal? (Proposed § 1.402)**

Proposed § 1.402 describes the requirements for submitting an appeal. As required by section 303 of the Bioterrorism Act, as part of your appeal, you may request an opportunity for an informal hearing. Proposed § 1.402(a) will require you to submit your appeal in writing to the FDA District Director in whose district the detained article of food is located using the contact information provided in the detention order. We propose to allow you to submit your appeal in person, by mail, e-mail, or fax.

The timeframe for filing an appeal is determined by whether the detained

article of food is perishable or nonperishable. If the detained article of food is perishable, as defined in proposed § 1.377, you would be required to file your appeal and request for a hearing within 2 calendar days of receipt of the detention order.

If the article of food subject to the detention order is nonperishable, you would be required to file a notice of intent to request a hearing within 4 calendar days of receipt of the detention order. The notice of intent would enable the agency to determine whether resources should be allocated to preparing for a regulatory hearing. If you do not file a notice of intent by day four, you do not receive a hearing. However, without filing a notice of intent by day four, you may still file an appeal without a hearing request. Whether or not you are requesting a hearing, your appeal involving a detained nonperishable food must be filed within 10 calendar days of receipt of the detention order.

We are using calendar days for the bifurcated deadlines for filing appeals to provide the most expeditious procedure for perishable food, and to provide a consistent approach for counting days. We are asking for comment on whether there are other ways we should be counting days for filing appeals, while adhering to the statutory deadline of 5 days for FDA to issue a decision on appeal (for both perishable and nonperishable food).

Proposed § 1.402(b) provides that your request for an appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food. Under “Federal Rules of Civil Procedure,” Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of an action must file a verified statement identifying the interest or right. The meaning of “verified statement” under Supplemental Rule C(6)(a) is governed by the local federal district court rules in which the detention takes place, and usually means that the statement must be accompanied by an oath or affirmation attesting to the statement’s veracity.

Proposed § 1.402(c) provides that the appeal process would terminate 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 detained article of food.

Proposed § 1.402(d) describes the requirements for requesting an informal hearing as part of the appeals process. Your request for a hearing must be in writing and be included with your appeal. You may appeal a detention

without requesting an informal hearing; however, if you want an informal hearing, you must include your request when you file your appeal. This proposed section describes the timeframes for holding the hearing if FDA grants your request for an informal hearing (see § 16.26 regarding denial of hearing). If the detained article of food is perishable, the hearing would be held within 2 calendar days after the date the appeal is filed. If the detained article of food is nonperishable, the hearing would be held within 3 calendar days after the date the appeal is filed. The quick timeframes for holding the hearing are necessary to ensure that FDA can adhere to the statutory requirement to issue a decision on appeal within 5 calendar days after the appeal is filed. FDA notes that under this proposal, the timeframes for perishable and nonperishable appeals will not be significantly different in instances where an appeal is filed immediately upon receipt of a detention order. For example, if you file an appeal and request for a hearing on the same calendar day (day one) the detention is ordered for a perishable food, the hearing would be held by calendar day three, and the decision on appeal could be issued as early as calendar day three but no later than calendar day six. If a nonperishable food was detained in the same example, the hearing would be held by calendar day four, and the decision on appeal could be issued as early as calendar day four but no later than calendar day six.

We are requesting comment on the timeframes for holding the informal hearing.

##### **3. What Requirements Apply to an Informal Hearing? (Proposed § 1.403)**

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA would conduct the hearing in accordance with part 16, with the following exceptions:

- The detention order under proposed § 1.393, rather than the notice under § 16.22(a) of this chapter, would provide notice of opportunity for a hearing under this section and would be part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

- A request for a hearing under this section must be addressed to the FDA District Director in whose district the detained article of food is located in accordance with proposed § 1.402(a).

- 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