

subpart. Rather, the timeframes in proposed § 1.402(a) apply.

- 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. Instead, the timeframes in proposed § 1.402(c) apply.

- Proposed § 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.

- Proposed § 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., RFDDs or other officials senior to District Directors, who preside at hearings under this subpart.

- Under proposed § 1.403(f), the presiding officer may require that a hearing conducted under this section be completed within 1 day, as appropriate.

- Ordinarily under part 16 hearing procedures, the presiding officer issues a report and recommended decision and the Commissioner of Food and Drugs issues a final decision. However, under proposed § 1.403(g), the presiding officer will issue the final agency decision.

As described previously, the informal hearing requirements in part 16 state that its procedures are to be used when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see § 16.1(b)). Section 303 of the Bioterrorism Act provides for an informal hearing opportunity, but does not provide specific provisions for the informal hearing. In this proposed rule, we are applying part 16 procedures modified by the noted exceptions, which is consistent with § 16.5(b).

4. Who Serves as the Presiding Officer at an Informal Hearing? (Proposed § 1.404)

Proposed § 1.404 requires the FDA RFDD, or other official senior to a District Director, to act as the presiding officer of an informal hearing on an appeal of a detention order. As presiding officer, the RFDD would issue the decision on appeal. Because a detention must be approved at the District Director level, we believe it is appropriate that appeals of those decisions should be handled by persons in positions senior to the District Directors.

The presiding officer may be an RFDD from a region other than the one in which the detained article of food is located, or another official senior to a District Director.

5. When Does FDA Have to Issue a Decision on an Appeal? (Proposed § 1.405)

Proposed § 1.405 describes when FDA must issue a decision on an appeal. Proposed § 1.405(a) requires the presiding officer to issue a decision confirming or revoking the detention order within 5 calendar days after the appeal is filed. If FDA fails to provide an opportunity for a hearing, or fails to confirm or terminate the detention order within the 5-day period, the detention order is deemed terminated. While the Bioterrorism Act does not define the meaning of “an opportunity for an informal hearing,” we interpret this phrase to mean the FDA gives notice of the opportunity for a hearing (see also proposed § 1.403(a), which states that the detention order provides notice of opportunity for a hearing). Under this interpretation, a failure to provide an opportunity for a hearing means a failure to provide you with notice of your opportunity to request a hearing. This provision is consistent with requirements of section 303 of the Bioterrorism Act.

Proposed § 1.405(b) would allow you to appeal the detention order without a request for an informal hearing. Where you appeal without requesting a hearing, the presiding officer is still required to 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 issue a decision within the 5-day period, the detention order is deemed terminated.

Proposed § 1.405(c) states that if you appeal a detention order and request an informal hearing and your hearing request is denied, the presiding officer is still required to 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 issue a decision within the 5-day period, the detention order is deemed terminated.

Proposed § 1.405(d) states if the presiding officer confirms a detention order, the article of food would continue to be detained until FDA terminates the detention order under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first.

Proposed § 1.405(e) states that if the presiding officer terminates a detention order, or the detention period expires, FDA would be required to terminate the detention order as specified under proposed § 1.384 (i.e., FDA would be required to issue a detention

termination notice releasing the article of food).

Proposed § 1.405(f) states that confirmation of a detention order by the presiding officer is considered a final agency action for purposes of section 702 of title 5, United States Code (5 U.S.C. 702).

6. How Will FDA Handle Classified Information in an Informal Hearing? (Proposed § 1.406)

FDA expects that consistent with responding to bioterrorist threats, there may be instances where the credible evidence or information supporting a detention order consists of Classified National Security Information (“classified information”). Protection of information critical to our nation’s security is a priority (Executive Order 12958, April 17, 1995). While mindful of our duty to protect our national security interest, we are also mindful of our obligation to provide a fair, expeditious, and impartial hearing (see § 16.60 regarding hearing procedure). Proposed § 1.406 provides that FDA will not release classified information. However, if the presiding officer may do so, consistent with safeguarding both the information and the source, the presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information. 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.

Given the events of September 11, 2001, and the need to quickly respond to actual or threatened bioterrorist attacks, we are contemplating the development of general regulations that address handling classified information on an agency-wide basis for all the products regulated by FDA. We believe, though, that we should go forward with the current proposal in this context at this time.

IV. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(1) to include section 304(h) of the act relating to the administrative detention of food for human or animal consumption to the list of statutory provisions under which regulatory hearings are available.

V. Analysis of Economic Impact

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies