

Food and Drug Administration, HHS

§ 1.500

the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

[69 FR 31701, June 4, 2004, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16550, Mar. 24, 2020]

§ 1.404 Who serves as the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16550, Mar. 24, 2020]

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

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under § 1.403(h), the presiding officer must issue a final decision within the 5-calendar day period 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-calendar 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-calendar 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-calendar 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.

Subpart L—Foreign Supplier Verification Programs for Food Importers

SOURCE: 80 FR 74340, Nov. 27, 2015, unless otherwise noted.

§ 1.500 What definitions apply to this subpart?

The following definitions apply to words and phrases as they are used in this subpart. Other definitions of these terms may apply when they are used in other subparts of this part.

Adequate means that which is needed to accomplish the intended purpose in