

or information that is “worthy of belief or confidence; trustworthy.” See Webster’s Unabridged Dictionary (1998 ed.) (definition of “credible”). Although various statutes and regulations use this or a similar standard, and courts have invoked or applied the standard of credible evidence or information in a large number of decisions, no precise definition of the standard exists. Instead, determinations of what constitutes credible evidence or information have been made on a case-by-case basis. Likewise, FDA has administered evidentiary standards under other provisions of the act (see e.g., section 304(g)) on a case-by-case basis without further defining those standards in regulation. We believe that a similar approach here is appropriate. In applying the credible evidence or information standard to administrative detention, FDA may consider a number of factors including, but not limited to, reliability, reasonableness, and the totality of the facts and circumstances.

The officers or qualified employees of FDA who may order a detention include, but are not limited to, FDA field investigators, other government employees commissioned or deputized by FDA, and FDA employees who have security clearance to receive national security information. An “authorized FDA representative” as defined in proposed § 1.377, would have to approve a detention order before the FDA officer or qualified employee may order a detention.

3. How Long May FDA Detain an Article of Food? (Proposed § 1.379)

Proposed § 1.379 sets forth the period of administrative detention, (i.e., the length of time an article of food may be detained), consistent with the requirements of section 303 of the Bioterrorism Act. The period of administrative detention must be a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless it is determined that a greater period is required either to seize the article of food or to institute injunction proceedings. The Bioterrorism Act provides that FDA may detain food for up to 10 additional calendar days if necessary to enable FDA to institute a seizure or an injunction action. Proposed § 1.379 incorporates this authority. An example of when FDA envisions using this authority is when the results of confirmatory testing or other evidentiary development is not complete. The authorized FDA representative, defined in proposed § 1.377, may approve the additional 10 days of detention at the time the detention order is issued, or at

any time within the initial 20-calendar-day period, by amending the detention order.

Proposed § 1.379 states that the entire detention period may not exceed 30 calendar days in total. This proposed section also allows the authorized FDA representative, in accordance with proposed § 1.384, to approve the termination of a detention order before the expiration of the detention period. FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

4. Where and Under What Conditions Must the Detained Article of Food be Held? (Proposed § 1.380)

Proposed § 1.380(a) requires you to hold the detained article of food in the location and under the conditions specified by FDA in the detention order. Use of appropriate storage conditions, such as temperature, humidity, and other conditions may be necessary to protect the safety and wholesomeness of the detained article of food. This proposed requirement is consistent with the legislative history of the Bioterrorism Act (see H. Conf. Rept. No. 107–481, at 131 (2002)).

In proposing § 1.380(a), we also considered the experience that States have had with embargoes. As described in comments from States familiar with embargoing food on behalf of FDA or on their own initiative, States have ordered food embargoed and have provided requisite conditions that must be maintained while the food is embargoed, e.g., segregation from other products in the same warehouse.

In proposed § 1.380(b), the detained article of food must be moved to a secure facility if FDA determines that such movement is appropriate. FDA’s determination of whether it is appropriate to require movement of a detained article will depend, in part, on whether we believe there is danger of the detained article entering the stream of commerce. FDA will make such determinations on a case-by-case basis considering several factors, including the adequacy of security where the detained article is located, and the ability to prevent the movement of the food. For example, if it appears likely that the detained food would be diverted, we would require the food to be moved to a secure facility. However, if the storage conditions are such that there appears to be no danger of the detained article of food moving into the stream of commerce, we would decide to keep the article of food detained at its current location.

There may be instances where we relocate the detained article of food to a secure facility. For example, FDA may not be confident that parties involved will adhere to a detention order. Rather than risk losing control over the detained article of food, FDA would relocate the detained article of food. There may be other situations where FDA decides to relocate the detained article to a secure facility.

Proposed § 1.380(b), also states that a detained article of food remains under detention before, during, and after movement to a secure facility, if FDA has requested such movement. As such, we will also state in the detention order any applicable conditions of transportation of an article of detained food. This may include determinations that the article to be removed to a secure facility must be moved under certain conditions. Similar to determinations of whether to require that food be removed to a secure facility, determinations of the appropriate conditions of transportation will be made on a case-by-case basis.

Proposed § 1.380(c) requires you to have received a limited conditional release under proposed § 1.381(c) before you move the detained article of food to a secure facility.

Proposed § 1.380(d) requires you to ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement to the secure facility. This requirement applies until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

Proposed § 1.380(e) provides that the movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act. This proposed provision is consistent with the statutory language in section 303 of the Bioterrorism Act.

5. May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location? (Proposed § 1.381)

Proposed § 1.381 describes whether an article of food subject to a detention order can be delivered to another entity or transferred to another location. Proposed § 1.381(a) states that a detained article of food may not be delivered to another entity under the execution of a bond. Similarly, this proposed section also states that an article of food detained under section 303 of the Bioterrorism Act may not be delivered to any of its importers, owners, or consignees under section