

provisions unless FDA or CBP were to seize or administratively detain the food under other authority. We have added § 1.283(a)(5) to the interim final rule to make this clear. If an article of food that has been refused admission under section 801(m)(1) of the FD&C Act is exported, the prior notice should be cancelled within 5 calendar days of exportation. FDA and CBP note that any time an article of food leaves the country after arriving at the port of arrival, it is considered an export for CBP purposes, and the applicable line or entry is deleted and, if prior notice was transmitted with the entry via ACS, the prior notice will be cancelled as well. This is true regardless of whether the intent is to re-import the article, even if the re-import occurs after a brief period of time.

To import that article of food, the prior notice must be re-submitted, and a new entry must be made, and the new prior notice will have the effect of "restarting the clock" in terms of when the prior notice has been submitted to FDA. If prior notice had been transmitted via the FDA Prior Notice System Interface, the prior notice is not automatically canceled when the article of food is exported. The only way to cancel a prior notice that was transmitted via the FDA Prior Notice System Interface is to use that system to explicitly cancel the prior notice.

*e. Abandoned merchandise (§ 1.283(a)(6)).* (Comment) One comment states that the regulation should address what happens if refused food is not claimed by the owner, purchaser, or consignee.

(Response) The interim final rule, in § 1.283(a)(6), provides that if no prior notice or correction is received in a timely fashion or export has not occurred, the food shall be dealt with as set forth in CBP regulations relating to be general order merchandise, except that it may only be sold for export or destroyed as agreed to by CBP and FDA.

#### 5. International Mail (§ 1.283(e))

Although the proposed rule applied to food imported or offered for import by mail, *see, e.g.*, 68 FR 5436, there were no proposed provisions specific to refusal of food arriving by international mail.

(Comments) No comments submitted comments specific to refusal of food arriving by international mail were submitted.

(Response) FDA believes that separate refusal procedures are necessary for food arriving by mail given differences between mail and cargo. FDA believes that these procedures are authorized under section 701(b) of the FD&C Act

because they are necessary to ensure that the refusal provisions of section 801(m)(1) of the FD&C Act can be efficiently and effectively applied to food that arrives by mail. The interim final rule thus provides in § 1.283(e) that in the case of food arriving by international mail with inadequate prior notice, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the parcel is refused and there is a return address, the article may be returned to sender stamped "No Prior Notice—FDA Refused." If there is no return address or FDA determines that the articles of food in the shipment appear to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP will return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

#### 2. Food Carried by or Otherwise Accompanying an Individual (§ 1.283(b))

Although the proposed rule applied to food imported or offered for import in baggage that was not brought in by a traveler for personal use, there were no proposed provisions specific to refusal of food in baggage in the proposed rule.

(Comments) No comments submitted comments specific to refusal of food carried by or otherwise accompanying an individual.

(Response) FDA believes that separate refusal procedures are necessary for food carried by or otherwise accompanying an individual given differences between these kinds of imports and cargo. FDA believes that these separate procedures are authorized under section 701(b) of the FD&C Act because they are necessary to ensure that the refusal provisions of section 801(m)(1) of the FD&C Act can be efficiently and effectively applied to food carried by or otherwise arriving with an individual.

(Interim final rule) Section 1.279(f) provides that the individual who carries or is accompanied by food must have a copy of the confirmation of prior notice when arriving in the United States. Section 1.283(b) provides that if there is inadequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the article of food is subject to refusal. If before leaving the port, the individual cannot arrange to have the refused food held at the port or exported, the article of food may be destroyed.

#### 4. FDA Review After Refusal, § 1.283(d)

(Comments) Several commenters suggest there should be an efficient

appeal mechanism in the event that the submitter, importer, owner, or consignee believes that food products have been inappropriately refused and held.

(Response) Although such a process is not required by § 801(m) of the FD&C Act, FDA agrees that having a review process designed to address prior notice issues is warranted. Section 1.283(d) of the interim final rule sets out parameters under which a request may be submitted to obtain FDA review of whether the article is subject to the requirements of this subpart under § 1.276(b)(5) (*i.e.*, meets the interim final rule's definition of food) or § 1.277 (*i.e.*, is within the scope of the interim final rule) or whether the contents of a prior notice submission were accurate. The interim final regulation provides that a request must be submitted within 5 days of refusal and that FDA will respond within 5 days. FDA notes that if the product is perishable, the sooner the request is submitted, the sooner FDA will respond. FDA chose these timeframes because they are consistent with the timeframes for perishables contemplated under the new administrative detention provisions at § 304(h) of the FD&C Act, 21 U.S.C. 334(h). After review, if FDA determines that the article is not subject to prior notice or that the prior notice submission is accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the FD&C Act.

#### 5. Prohibition on Delivery Outside of the Port, § 1.283(f)

(Comments) One commenter suggests following existing procedures and allowing refused foods to be held at the importer's place of business, quarantined and considered to be undeliverable, but held for sampling and release. Another commenter asks for clarification on whether product could be shipped to the importer, purchaser, or consignee's facility, if prior notice is inadequate.

(Response) The statute explicitly states that an article of food that is refused under the provisions of section 801(m)(1) must be held and shall not be delivered to the importer, owner, or consignee. See § 801(m)(2)(B)(i). Thus, the provisions of the Bioterrorism Act specifically override certain existing procedures that apply when food is subject to refusal under § 801(a) of the FD&C Act. In accordance with the new procedures specified in the Bioterrorism Act, § 1.283(de) of the interim final rule provides that, notwithstanding § 801(b) of the FD&C Act, 21 U.S.C. 381(b), an