

the port entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice.* If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 of this subpart for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)), unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food.* (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended, 19 U.S.C. 1490.

(ii) Refused food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of refusal. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated location.

(3) *Segregation of refused foods.* If an article of food that is refused is part of a shipment that contains articles of food that have not been placed underhold, the refused article of food may be segregated from the rest of the shipment. This segregation must take place within the port, of arrival or where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs.* Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal.* An article of food that has been refused under § 1.283(a) may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under § 1.283(a) is exported, the prior notice should be cancelled within 5 business days of exportation.

(6) *No post-refusal submission or request for review.* If an article of food

is refused under section 801(m)(1) and no prior notice is submitted or resubmitted, no request for FDA review is submitted in a timely fashion, or export has not occurred in accordance with paragraph (a)(7) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(b) *Food carried by or otherwise accompanying an individual.* If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual arrange to have the food held at the port or exported, the article of food shall be destroyed.

(c) *Post-Refusal Prior Notice Submissions.*

(1) If an article of food is refused under § 1.283(a)(1)(i) (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c) of this subpart.

(2) If an article of food is refused under § 1.283(a)(1)(ii) (inaccurate prior notice) and the food is not exported, you should cancel the prior notice in accordance with § 1.282 and must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) *FDA Review After Refusal.*

(1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(4) or § 1.277, or whether the information submitted in a prior notice is accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax, or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Prior Notice. A request must include all factual and

legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5 calendar days of the refusal. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277 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 act.

(e) *International Mail.* If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m) of the act and there is a return address, the parcel may be returned to sender stamped "No Prior Notice—FDA Refused." If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears 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 may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer.*

(1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1).

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1). After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions.* A determination that an