

than-truckload (LTL) carriers and small package carriers, who may have thousands of overnight or expedited shipments on one trailer. The comments express concern that importers and carriers of nonfood items and of compliant food items would be unfairly penalized because of a noncompliant entry. A comment states that Customs' regulations authorize different portions of merchandise imported in a single shipment and consigned to a single consignee to be cleared under separate consumption entries (19 CFR 141.52). The Customs regulation in 19 CFR 141.52 also authorizes separate entries for any portions of a shipment that will be covered by different types of entry, such as a bonded warehouse entry.

(Response) FDA agrees. In the preamble to the proposed rule, FDA recognized that food refused under section 801(m)(1) of the FD&C Act may be located in the same container or truck with nonfood items or food that is not refused under section 801(m). However, when mixed or consolidated imported freight contains refused articles of food that must be held, those articles that have been refused must be dealt with in a manner that is consistent with the limitations in section 801(m) of the FD&C Act. Therefore, FDA has added § 1.283(a)(3) to the interim final rule to state that if the article of food that is refused is part of a shipment that contains articles that have not been refused under section 801(m)(1) of the FD&C Act, the refused article(s) 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 and may be supervised by FDA or CBP.

c. *Costs (§ 1.283(a)(4))*. (Comments) Several comments ask who would be responsible for storage and transportation costs. One comment notes that the private parties to the importing transaction should be liable for storage and transportation costs when food was refused. One comment stated that the person submitting prior notice should be responsible for these costs. Another comment asks FDA to include a provision in the interim final rule that allows carriers to recover removal, storage, or disposition costs from the owner, purchaser, or consignee.

(Response) Inasmuch as articles for which adequate prior notice has not been received are considered general order merchandise, the expenses of transportation and storage will be the responsibility of those parties who are responsible under the general order statutes and regulations. FDA has thus decided it is not necessary to include a

provision in the interim final rule that specifies which private parties should be responsible for costs associated with refusal. However, we have added § 1.283(a)(4) to the interim final rule to clarify that the U.S. Government is not responsible for these costs.

(Comments) Some comments ask that the regulation establish a damage claim system for losses that occur when perishable foods are detained for administrative reasons. Some comments suggest that FDA should provide compensation for losses, including transportation and storage fees, if the agency mistakenly holds imported product because of an oversight in the government's processing of a prior notice.

(Response) FDA disagrees. The interim final rule provides in § 1.283(a)(4) that neither FDA nor CBP will be responsible for transportation, storage, or other expenses resulting from refusal. FDA notes that it has never assumed responsibility for expenses associated with refusal under the FD&C Act. Any claim against the government arising under these activities shall be governed by the Federal Tort Claims Act.

3. *Post-refusal submissions and resubmissions (§ 1.283(c))*. (Comment) Comments ask FDA to clarify how inadequate notice could be corrected and what steps must be taken to have the product released. One comment suggests that the regulation should state that a shipment with inadequate prior notice would be held only until the prior notice is corrected and that the correction should be required within 24 hours. One comment suggests that food should be held for 24 hours and then deemed released if FDA has not notified the person submitting the notice that the food will be examined.

(Response) FDA agrees that the rule should specify procedures for submitting or resubmitting a prior notice after refusal. These are set out in § 1.283(c)(i) and (c)(ii) in the interim final rule. FDA does not believe it is necessary to impose any limit on how long a person has to submit or correct a prior notice for refused foods since an article of food refused under section 801(m)(1) of the FD&C Act is considered general order merchandise. If no adequate prior notice is received within the timeframes set out in 19 CFR part 127, title in the refused food will vest in the United States and the refused food will be eligible for general order sale or other disposition. Also note that fruit, perishables, or merchandise liable to depreciation, may be characterized as "special merchandise" per 19 CFR 127.28. Alternate disposition, consistent

with the general order statutes, is then provided for.

The rules governing general order merchandise should be familiar to those in the business of importing food, as they are rules of long standing that are applied by CBP when no entry is made for food. FDA believes that it is up to the persons involved in importing the food into the United States to determine how quickly prior notice should be submitted or resubmitted for food refused under section 801(m)(1) of the FD&C Act.

FDA does not agree that the refusal should be deemed removed if the transmitter does not hear from FDA within 24 hours that FDA will be examining the product. Section 801(m)(2)(B)(i) of the FD&C Act states that refused food may not be released until prior notice has been submitted, reviewed by FDA, and determined by FDA to be adequate.

(Comments) Many comments state that the regulation should set limits on the time FDA has to determine the adequacy of a prior notice submitted after a food has been refused in order to ensure quick release of refused food. One comment explains that such language would be consistent with congressional intent as stated in the Conference Report:

if an article of food were offered for import without providing the required prior notice, the article of food would be held at the port of entry until the Secretary has determined that notice is complete, but it would not be held longer than the unelapsed period of prior notice unless there is other basis for doing so.

(Conf. Rept. at H2858.)

(Response) FDA agrees in part. The rule provides in § 1.283(c)(iii) that once the prior notice or corrections to a prior notice have been submitted and confirmed by FDA for review, FDA will make every effort to review and respond to the prior notice submission within the timeframes set out in § 1.279(a).

d. *Export after refusal (§ 1.283(a)(5))*. Although export under the general order provisions of the title 19 of the U.S. Code was discussed in the preamble to the proposed rule (68 FR 5432), the proposed rule did not address exportation of food refused under section 801(m) of the FD&C Act.

(Comment) One comment asks whether export would be required for food refused under section 801(m)(1) of the FD&C Act.

(Response) Export is not required for an article of food refused under section 801(m)(1) of the FD&C Act; it is, however, an option for an article of food refused under § 1.283(a) and as permitted under CBP's general order