

the border, but that they would be responsible. A comment also states that FDA should engage the manufacturer or processor when the situation involves a bioterrorism threat or event.

(Response) FDA and CBP have determined that the most appropriate notification point is the carrier. When an article of food arrives at the border without adequate prior notice (*i.e.*, none, inaccurate, or untimely), the carrier is the clearest immediate point of contact that FDA and CBP staff at the border have. Thus, FDA or CBP intend to notify the carrier that the article of food is refused due to inadequate prior notice when the food is presented for CBP processing. It will be up to the carrier to communicate the prior notice refusal to other persons or firms. Neither FDA nor CBP currently has sufficient capability at the border to communicate these refusals to other persons and still process arrivals and examinations in a reasonable amount of time. We recognize that this will affect carriers. We will be exploring ways to provide notice to the transmitter and others, as well. FDA notes that if carriers want to ensure, for any food they are transporting, that prior notice has been submitted to FDA and confirmed for review, they can ask that a copy of the PN confirmation be provided to them. Indeed, under § 1.279(g), for prior notices transmitted through the FDA PN System Interface, the carrier must present the PN confirmation number to CBP or FDA upon arrival.

We do not agree that FDA should provide routine advance notice that it intends to refuse, examine, or hold food or has asked CBP to do so. Although FDA and CBP are structuring implementation to ensure that changes in ports and arrival times will not mean that food which should be refused, held, or examined at the port of arrival slips past us, we believe that routine advance notice could make it easier for the unscrupulous to evade FDA requirements and import unsafe food. Finally, whether we contact importers or manufacturers when there is a bioterrorism threat or other food-related emergency will depend on the particular circumstances.

(Comments) Some comments state that inconsistency in time and changes in the port of arrival should not result in refusal of the article. One comment asks whether a shipment that arrives one-half hour late will be treated the same as one that arrives 12 hours late.

(Response) As explained elsewhere, changes in the anticipated arrival information or planned shipment information will not be a basis for a refusal under section 801(m)(1) of the

FD&C Act if FDA wants to examine the shipment; however, these changes may mean waiting while FDA is notified by CBP and arranges to examine the shipment. This is more likely to be the case with changes in ports and in arrivals that are much later than the anticipated time.

When it comes to changes in arrival time, what matters is whether the prior notice time was submitted sufficiently in advance of arrival, in accordance with the timeframes set out in § 1.279(a) of the interim final rule. These timeframes are what FDA has determined are necessary, as a general matter, to ensure that FDA has enough time to receive, review, and respond to each prior notice appropriately. However, § 1.283(a)(1)(iii) of the interim final rule does provide that if an article of food arrives early, before the prior notice time has elapsed, its arrival will not be considered untimely if FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. FDA believes there is no need to make the food wait if the agency has been able to accomplish its prior notice review sooner than anticipated.

(Comments) One comment asks for clarification on whether the article would be refused if the classification of goods under the HTS code has been changed by Customs officials after the shipment arrives.

(Response) If the FDA Product Code is accurate, then the article will not be refused if the HTS code provided is later changed by CBP during its review of the entry for CBP purposes.

(Comments) One comment asks whether there would be a penalty for canceling and resubmitting a prior notice when the changes that need to be made to the prior notice cannot be made by an amendment or an update.

(Response) FDA has removed the provisions relating to amendments and updates. If required information (with the exception of estimated quantity, anticipated arrival information, and planned shipment information) changes, *e.g.*, the manufacturer is different than the one originally submitted or the complete FDA product code is not accurate, you should cancel the prior notice and must resubmit prior notice (if you still plan to import or offer for import the article of food into the United States). The timeframes set out in § 1.279(a) of the interim final rule will start to run again from the time the new prior notice is confirmed for review by FDA.

a. *Status and movement of refused foods (§ 1.283(a)(2)).* FDA proposed in § 1.278(b) that if an article of food is

imported or offered for import is refused under section 801(m)(1) of the FD&C Act, the food shall be held at the port unless directed to a secure facility under proposed § 1.278(c). Proposed § 1.278(d) provided that the person submitting prior notice was responsible for arranging for movement of refused food. Proposed § 1.278(e)(2) stated that refused food could not be delivered under bond to the importer, owner, or consignee. In the preamble to the proposed rule (68 FR 5432), we explained that the provisions in title 19 of the U.S. Code relating to imports for which entry cannot be made would apply.

i. *General order status (§ 1.283(a)(2)(i)).* (Comments) One comment asks for confirmation that the provisions in title 19 of the U.S. Code that apply to unentered merchandise would apply to articles of food that have been refused under section 801(m)(1) of the FD&C Act.

(Response) FDA and CBP generally agree with this comment. However, we have concluded that the interim final rule should specify that these provisions will apply immediately upon refusal under section 801(m)(1) of the FD&C Act because entry of an article of food refused under section 801(m)(1) cannot be made for want of proper documents or other cause, as described in section 490(a)(1)(C) of the Tariff Act of 1930, as amended (19 U.S.C. 1490(a)(1)(C)). Accordingly, § 1.283(a)(2)(i) of the interim final rule specifies that an article of food that has been refused under section 801(m)(1) of the FD&C Act shall be considered general order. Thus, an article of food refused under section 801(m)(1) meets the criteria of general order and must be handled in accordance with sections 490 and 491 of the Tariff Act (19 U.S.C. 1490 and 1491) and CBP's implementing regulations at 19 CFR part 127 except as otherwise specified in 21 CFR part 1, subpart I.

ii. *Locations for holding refused food (§ 1.283(a)(2)(ii)).*

(Comment) One comment suggests using the existing system where shipments may be held in place at the port for 14 days after which they must be moved to general order.

(Response) After merchandise has arrived in the United States, the Customs regulations prescribe a 15-calendar day period during which entry must be made. If entry is not made during this time, the merchandise then must be sent to general order inasmuch as entry has not been completed (see 19 CFR 4.37, 122.50, or 123.10). However, as described previously, this 15-calendar day period is not applicable to articles refused under section 801(m)(1)