

to take custody of or pay for the holding of such food. We seek comment on this issue.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(1) provides that the article of food must be held at the port of entry or in 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 the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

FDA recognizes that food may be shipped in the same container or truck with non-food items. Since articles that are not food are not subject to this proposed rule, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles that have been refused must be dealt with before the rest of the shipment proceeds.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(2) makes clear that food under a hold may not be delivered to the importer, owner, or consignee and that section 801(b) of the act does not apply. Therefore, delivery will not be allowed under a basic importation or entry bond. Even though delivery to them is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under 801(m) of the act can make arrangements for food to be held; these arrangements can be made without taking possession of the food.

The proposed rule (proposed § 1.278(f)) differentiates between a refusal of admission under section 801(m)(1) of the act (prior notice) and refusal of admission under section 801(a) and other provisions of the act or other U.S. laws. The proposed rule makes clear that a determination that an article of food is no longer subject to refusal of admission under section 801(m)(1) of the act does not mean that it will be admitted to the United States. The other provisions of the act and other U.S. laws that currently apply to food imported or offered for import to the United States still apply and also govern admissibility.

Although FDA believes that information in a prior notice will help facilitate admissibility decisions under section 801(a), FDA is not proposing to specify in the rule that it will make an 801(a) admissibility decision at the time it receives a prior notice. A prior notice is a pre-entry submission to comply

with requirements under section 801(m). FDA will make the 801(a) decision when the complete entry information is submitted to U.S. Customs and transmitted to FDA. Normally (in about 98 percent of the cases), this is accomplished by electronically filing certified entry information with U.S. Customs ACS, which electronically transmits it to FDA's OASIS System. FDA's 801(a) admissibility decisions are transmitted from OASIS to the filer.

In accordance with section 301(ee) of the act, the proposed rule (§ 1.278(g)) provides that it is a prohibited act to import or offer for import an article of food without complying with the requirements of section 801(m) of the act or otherwise violate any requirement under section 801(m). The proposed rule explains that, under section 302 of the act, the United States can bring a civil action in federal court to enjoin persons who commit a prohibited act and, under section 303 of the act, can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. The proposed rule also explains that, under section 305a of the act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

FDA notes that there are several differences between refusal of admission under sections 801(a) and (b) of the act and refusal of admission under new section 801(m). First, in section 801(m) of the act, Congress did not provide for any kind of application, petition, or appeal of FDA's determination that an article shall be refused admission for failing to comply with prior notice requirements. Congress provided that an article that has been refused admission under section 801(m) of the act can be admitted only if the necessary information is subsequently submitted, examined by FDA, and found to be adequate. Second, food refused admission under section 801(m) cannot be delivered under bond pursuant to section 801(b) and, as we describe elsewhere, must be held at the U.S. port of entry. Finally, the Bioterrorism Act does not provide specific procedures for the disposition of food refused admission under section 801(m) when no subsequent adequate notice is submitted. Section 801(a) and (b) provide that food refused admission under section 801(a) must be destroyed or reexported. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not

been made apply in these circumstances.

Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 days after the food arrives in the United States. See 19 CFR Part 1422. If entry is not made within this timeframe, the carrier or other authorized party is required to notify U.S. Customs and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR Part 127. Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be reexported. FDA and U.S. Customs plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to refusal under section 801(m) of the act.

C. Requirements to Submit Prior Notice of Imported Food

1. Who is Authorized to Submit Prior Notice for an Article of Food That is Imported or Offered for Import Into the United States? (Proposed § 1.285)

FDA is proposing that a purchaser or importer of an article of food who resides or maintains a place of business in the United States is authorized to submit prior notice. FDA is also proposing that an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer is authorized to submit prior notice. FDA believes that the customs broker/filer should be authorized to be a submitter if it is the U.S. agent of the U.S. importer or U.S. purchaser.

FDA is proposing that, if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the in-bond carrier. The types of entries that cover these importations are known to FDA and U.S. Customs as Transportation for Exportation (T&E) and Immediate Export (IE).

FDA believes that the proposed rule should specify which parties are responsible for submitting prior notice and that this specificity will minimize confusion about who should or will submit prior notice among the several parties who can be involved in importing food. Less confusion will lead