

under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) 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.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil

action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

Requirements to Submit Prior Notice of Imported Food

§ 1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 When must the prior notice be submitted to FDA?

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in §§ 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 How must you submit the prior notice?

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System at [a Website that will be provided in the final rule], except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in

person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

§ 1.288 What information must be submitted in the prior notice?

For each article of food that is imported or offered for import into the United States, you must submit the information listed in this section. (The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.)

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the