

and the transmitter that the article of is food no longer refused.

1. *Relationship to admissibility* (§ 1.283(g)). A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

6. What Are the Other Consequences of Failing To Submit Adequate Prior Notice or Otherwise Failing To Comply With This Subpart? (§ 1.284)

In accordance with section 301(ee) of the FD&C Act, the proposed rule (§ 1.278(g)) provided 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 FD&C Act, or otherwise to violate any requirement under section 801(m). In addition, the proposed rule provided that the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts and bring a criminal action in Federal court to prosecute persons who commit prohibited acts. In addition, 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.

(Comments) Some comments ask that FDA provide a transition period for implementing the regulation, during which a submitter would not be prosecuted for providing inadequate or incomplete prior notice.

(Response) The requirements of the statute do not allow for this kind of a transition period. FDA will, however, provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances. While this transition

period is important, FDA also intends to provide guidance to its staff on enforcing the prior notice requirements after a transition period. These guidance documents will be made available to the public, and FDA will publish a notice of availability in the **Federal Register**.

This enforcement discretion with regard to refusals of foods under 801(m) and 801(l) will not impact FDA's ability to take other actions that may be necessary, such as conducting inspections for food safety and security concerns, determining whether an article of food is subject to refusal under section 801(a) of the FD&C Act at the port of entry, or taking any other action under the FD&C Act. FDA may consider the failure to provide prior notice as a factor in determining whether to examine the product at destination. In addition, it will not impact upon CBP's ability to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

(Interim final rule) Section 1.284 of the interim final rule establishes a separate provision to cover the other consequences of failing to submit adequate prior notice or otherwise comply with 21 CFR part 1, subpart I. The interim final rule provides that the failure of a person who imports or offers for import an article of food to submit prior notice is a prohibited act under section 301(ee) of the FD&C Act (21 U.S.C. 331(ee)). The interim final rule also sets out the civil, criminal, and debarment actions that the United States may bring against persons who commit a prohibited act.

K. "What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required To Register Under 21 CFR Part 1, Subpart H?" (§ 1.285)

As set out in the preamble to the interim final rule on registration of food facilities under section 415 of the FD&C Act, FDA has decided to include in the prior notice interim final rule the provisions that address what happens when imports from unregistered foreign food facilities arrive at the port. FDA decided this course was most appropriate because, in the first instance, we will be using the prior notice review process to ensure that foreign food facilities are registered. Moreover, FDA believes that the procedures for dealing with food from unregistered foreign facilities should be, as they were in the proposed registration rule, identical in most respects to the prior notice procedures, and thus it makes sense to consolidate them in one regulation.

(Comments) Comments on the registration proposed rule are described in the preamble to the interim final registration rule, published elsewhere in this issue of the **Federal Register**.

(Response) Responses to comments on the registration proposed rule are described in the preamble to the interim final registration rule, published elsewhere in this issue of the **Federal Register**.

7. Interim Final Rule (§ 1.285)

FDA revised the proposed rule to provide for more specificity, to clarify the status of food under hold, and to provide a mechanism for FDA review after a hold is imposed.

a. *Failure to register* (§ 1.285(a) and (b)). If an article of food from a foreign manufacturer that is not registered as required under section 415 of the FD&C Act (21 U.S.C. 350d) and 21 CFR part 1, subpart H, is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the FD&C Act and 21 CFR 1.283(a) for failure to provide adequate prior notice. The failure to provide the correct registration number of any foreign manufacturer if registration is required under section 415 of the FD&C Act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete.

If an article of food from a foreign facility that is not registered as required under section 415 of the FD&C Act and 21 CFR part 1, subpart H, is imported or offered for import, it is subject to a hold within the port of entry for the article unless directed by CBP or FDA under section 801(l) of the FD&C Act unless exported.

b. *Status and movement of held food*. An article of food under hold is considered general order merchandise under section 490(a) of the Tariff Act of 1930, as amended. The 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 the hold. It must be taken directly to the designated facility, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

c. *Segregation* (§ 1.285(d)). If a food placed on hold is part of a shipment that contains other articles, the food may be segregated from the rest of the shipment within the port of arrival or where the article is held, if different.

d. *Costs* (§ 1.285(e)). Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from a hold.

e. *FDA review after hold* (§ 1.285(j)). After an article of food has been placed