

the causing of a prohibited act and being responsible for the commission of a prohibited act are both subject to sanction under the act (21 U.S.C. 331). Thus, under the interim final rule, the owner, operator, or agent-in-charge of any facility that manufactures/ processes, packs, or holds food for consumption in the United States, who is required to register the facility with FDA but fails to do so, commits a prohibited act under section 301 of the FD&C Act. Similarly, the owner, operator, or agent in charge that fails to update mandatory information or cancel a registration within 60 days (if changes at the facility require an update) commits a prohibited act.

FDA has also clarified that the disposition of a food from an unregistered foreign facility when offered for import into the United States will be governed by subpart I of this part (Prior Notice of Imported Food). FDA is publishing elsewhere in this issue of the **Federal Register** a interim final rule implementing section 307 of the Bioterrorism Act, which requires, among other things, an importer to submit to FDA prior notice of a shipment of food that is offered for import. As discussed in response to comment 162, FDA addresses the consequences for importation of food for failure to register in the interim final rule implementing prior notice published elsewhere in this issue of the **Federal Register**.

With regard to the comment on debarments, § 1.241 merely relates the grounds for debarment specified in section 306(b)(3)(A) of the FD&C Act. The agency's implementation of the details of the debarment provisions of the Bioterrorism Act are outside the scope of this interim final rule.

3. Food Held at the Port

(Comment 151) Many commenters express concerns about the custody and responsibility for products placed under hold. Several commenters ask who is responsible for costs associated with food held at the port. One commenter asks FDA to clarify that any party in the commercial import process, including the shipper, could be responsible for arranging the bonded hold, and that such arrangements are not FDA's responsibility. A commenter requests that FDA be responsible for any costs incurred from mistakes made in enforcement of the rule that results in the holding of imported food. One commenter recommends that a clear chain of custody and fiduciary responsibility must be established for products placed on hold. One commenter requests that FDA and

Customs issue guidance on holding food before December 12, 2003.

(Response) In proposed § 1.241, we described the consequences of failure to register when food is imported or offered for import from a foreign facility that is required to register under section 305 of the Bioterrorism Act. At the same time, we included in the proposed rule implementing the prior notice requirements of section 307 of the Bioterrorism Act, a provision requiring the registration number of certain facilities to be provided as part of the required prior notice information. In the prior notice proposal, we also discussed the consequences of failure to provide required information, including required registration information, when importing food. We believe that including consequences of failing to register for foreign facilities in two different regulations may be confusing. Therefore, we have revised § 1.241 to include simply a cross reference to subpart I (Prior Notice of Imported Food), which sets out how food imported or offered for import from facilities not registered as required will be handled. Thus, we have deleted § 1.241(e) through (h). Although we no longer have provisions regarding imported food in this interim final rule, we are addressing the comments we received.

With regard to this comment, before the enactment of the Bioterrorism Act, FDA's role was to make admissibility decisions as to whether food imported or offered for import into the United States should be refused admission under section 801(a) of the FD&C Act. Any storage and transportation costs associated with FDA's refusal process were borne by the relevant private parties according to their contractual agreements. Nothing in the Bioterrorism Act changes who bears the costs related to food that may not be admitted into the United States. Although § 1.241(f) has been removed from this interim final rule, the prior notice interim final rule states that neither FDA nor CBP are liable for transportation, storage, or other expenses. The proposed registration rule and the proposed prior notice rule provided for costs to be borne by the owner, purchaser, importer, or consignee. FDA has reconsidered and believes that it would not be appropriate to specify which parties are responsible for costs as this is a commercial rather than a regulatory matter. Accordingly, the interim final prior notice rule merely provides that FDA or CBP is not liable for the costs.

(Comment 152) Several commenters request that FDA ensure that appropriate and sufficient storage

facilities (including climate controlled storage) exist before the Bioterrorism Act is enforced and that FDA release the food immediately once relevant facilities register. One commenter requests that FDA not hold food based on simple problems or errors in registration, such as misspelling. One commenter asks if the "secure location" must be a Customs bonded facility. Another commenter asks FDA to clarify the procedure it will follow to notify a foreign facility when its products have been held at the U.S. port because of failure to register. A commenter asks FDA to permit prompt registration, ideally electronic, when failure to register is discovered at the port of arrival. A commenter argues that if a shipment appears likely to be held, the exporter should have the option of taking it back or sending it to another country. This commenter argues that if FDA delays a shipment too long for administrative reasons, FDA should provide compensation. Another commenter states that the proposed regulations should be amended to specifically provide for release of compliant articles mixed with noncompliant articles. This commenter argues that FDA should not hold compliant articles while it is waiting for registration of the facilities that are associated with the noncompliant articles.

(Response) As stated previously, a facility may register either electronically (the preferred and fastest method) by mail (using paper or CD-ROM), or by fax. A facility that is registered electronically will receive its registration number almost instantaneously. FDA will process registrations received by mail or fax in the order received. It is the responsibility of the owner, operator, or agent in charge of each facility subject to the requirements of this rule to register before December 12, 2003, and before food from the facility is imported or offered for import into the United States. The Bioterrorism Act prohibits food from an unregistered foreign facility from being delivered for distribution in the United States.

As explained in more detail in the preamble to the interim final prior notice rule, the electronic systems for submission of prior notice will not provide confirmation that prior notice has been accepted by FDA for review unless the required registration information is complete and facially correct. Thus, the transmitter of the prior notice may be informed when there is a problem with the registration numbers.