

update must include any changes to any information the facility previously submitted, including, but not limited to, changes to information regarding food product categories. This information, including these categories, will assist FDA in conducting investigations and surveillance operations in response to a bioterrorist incident. If this information is outdated it will interfere with FDA's ability to quickly ascertain the nature and scope of the problem and to alert affected facilities and prevent further distribution of harmful food. Therefore, for efficient and effective implementation of the Bioterrorism Act, FDA is proposing to require registrants to update previously submitted information in both the mandatory and optional categories, if the registrant originally submitted information in both categories and that information changes. FDA requests comments on this proposed requirement and how it will affect the submission of optional information.

A facility canceling a registration must do so on a separate cancellation form electronically or by mail.

D. Additional Provisions

1. What Other Registration Requirements Apply? (Proposed § 1.240)

In proposed § 1.240, FDA has included a provision reminding registrants that they must comply with all other applicable registration requirements, including those found in part 108 (21 CFR part 108), related to emergency permit control. FDA wants to ensure that registrants subject to the registration regulation being proposed to implement the Bioterrorism Act are aware that this registration does not take the place of that required in part 108, or any other registration requirements.

FDA seeks to minimize the burden of this rule on covered facilities and the submission of duplicative information. FDA is aware that existing registrations required by FDA and other federal agencies ask for information that may be duplicative of some of the information FDA is proposing be submitted under this rule. The Bioterrorism Act requires that certain facilities register with FDA. The Bioterrorism Act also specifies that certain information must be contained in the facilities' registration submissions. FDA seeks comments on whether there are registration requirements under which facilities must submit duplicative information to more than one Federal agency. If so, FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the

duplication of information required to be submitted under these registration requirements. In particular, FDA is interested in comments on whether it has authority, under the Bioterrorism Act or another regulatory mandate, to grant a partial or full exemption from the FDA registration requirement to facilities that have already registered with another Federal agency. If such authority exists, FDA is also interested in whether the goals of the Bioterrorism Act could be met if FDA does not have complete registration information.

2. What Happens if You Fail to Register? (Proposed § 1.241)

As provided in the Bioterrorism Act, two consequences may occur if a facility covered under these regulations fails to register. Failure of either domestic or foreign facilities to register is considered a prohibited act under section 301 of the act (21 U.S.C. 331). Under section 302 of the act (21 U.S.C. 332), 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 (21 U.S.C. 333), can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. Under section 305a of the Bioterrorism 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 seeks comment on circumstances under which a firm's registration should be considered null and void and on circumstances under which a firm's registration should be revoked. FDA also seeks comment on the process for such determinations.

For foreign facilities that fail to register and attempt to import food into the United States, the Bioterrorism Act requires the food be held at the port of entry unless FDA directs its removal to a secure facility. FDA is proposing in § 1.241(e) that 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. Perishables, however, may not be stored in U.S. Customs Service's bonded warehouses; thus FDA may direct fresh produce or seafood that requires storage to another facility. FDA and the U.S. Customs Service plan to issue guidance for their field offices that will identify locations of secure storage.

In order to minimize confusion about who is responsible for making arrangements if food is held under section 801(l) of the act (21 U.S.C. 381(l)), FDA is proposing in § 1.241(f) that the owner, purchaser, importer, or consignee must arrange for storage of the article of food, in an FDA-designated secure facility and must promptly notify FDA of the location. Any movement of the article to the facility must be accomplished under bond. We note that when section 801(l) of the act requires that food be held, it does not appear to mandate that the Government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making Government oversight straightforward. As described previously, U.S. Customs Service has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under section 801(l) of the act, it did not intend to require FDA or U.S. Customs Service to take custody of or pay for the holding of such food. We seek comment on this issue.

The article of food must be held at the port of entry or in the secure facility until the owner, operator, or agent in charge of the foreign facility has submitted its registration information to FDA, FDA has registered the facility, and FDA has notified the U.S. Customs Service and the person who submitted the registration that the facility is registered and the article of food no longer is subject to a hold under section 801(l)(1) of the act. Notwithstanding section 801(b) of the act, while any article of food is held at its port of entry or in a secure facility under section 801(l) of the act, it may not be delivered to any of its importers, owners, or consignees.

The Bioterrorism Act does not provide specific procedures for the disposition of food under hold under section 801(l) of the act when no subsequent registration is submitted. 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 calendar days after the food arrives in the United States. (See 19 CFR 142.2.) If entry is not made within this timeframe, the carrier or other authorized party is required to