

statute requires the owner, operator, or agent in charge of those facilities to submit a registration to FDA. Obtaining existing registration information from other agencies would not guarantee that FDA has the information for all facilities required by the Bioterrorism Act's registration requirement because there is wide variation in the purposes and information required by other registration or permitting systems. For example, the laws administered by the Alcohol and Tobacco Tax and Trade Bureau (TTB) do not require foreign alcohol beverage producers to obtain permits, unless they are also engaged in the business of importing alcohol beverages into the United States. In addition, the information provided by alcohol beverage permittees to TTB is not entirely identical to the information that must be provided by facilities to FDA in accordance with the provisions of this interim final rule.

Although it is theoretically possible for FDA to obtain information from other agencies, the stringent timeframes for issuing this interim final rule do not provide FDA adequate time to reconcile the different information required or to work with the other agencies to have them amend their existing requirements to capture all the information FDA needs. We would also need to work with other agencies to ensure the confidentiality of nonpublic registration information under relevant information disclosure laws (e.g., §§ 20.85 and 20.88 (21 CFR 20.85 (Federal agencies), 20.88 (State agencies), and 20.89 (foreign governments))). Because the purpose of registration with FDA is to assist FDA in responding to threatened or actual bioterrorist incidents or other food-related emergencies, FDA must have the registration information readily accessible. If FDA has to coordinate with other agencies or governments to obtain from them the information necessary to respond to such an emergency, FDA may be prevented from responding to the emergency in a timely manner.

Regarding facilities that may be registered with FDA under existing regulations (e.g., low acid canned food), like the registrations of other agencies, these FDA registrations also do not contain all of the information required in this interim final rule, because the purposes of the regulations differ. FDA will continue to look for ways to minimize duplicative registrations in the future, but could not do so in the timeframe provided for developing this rule. On its own initiative, FDA has made several editorial changes to this section for the purpose of clarity.

L. Comments on "What Happens if You Fail to Register?" (Proposed § 1.241)

1. Revocation of Registration

(Comment 148) Several commenters submitted comments in response to FDA's request for comments regarding the circumstances under which a firm's registration should be cancelled and/or considered null and void. One commenter states that neither the FD&C Act nor the Bioterrorism Act authorize revocation of registration. One commenter states that because the Bioterrorism Act's Rule of Construction notes that registration is not a licensing or approval process, FDA cannot extend or withdraw approval. This commenter suggests that a registration may only be vacated through the ordinary criminal process to prove fraud if the registration is made fraudulently. Another commenter states that revocation should be reserved for extreme situations of bioterrorism, intentional contamination, and other criminal activity, and should afford a facility an opportunity for an adjudicative hearing, since revocation effectively prohibits a facility from manufacturing/processing, packing, or holding food for consumption in the United States. A foreign commenter suggests that any revocation of registration should occur only after a process that involves foreign authorities within the same locale as the foreign facility, in consultation with the U.S. Embassy. One commenter requests a clear delineation of the circumstances warranting registration suspension, suggesting that it should extend only to the parameters of the Bioterrorism Act. Another commenter suggests that revocation of registration should only be considered for facilities that have ceased trading, or no longer handle food products. A commenter suggests that FDA clarify the distinction between suspension and revocation: Revocation should only be for facilities that have gone out of business or that have submitted false information. FDA should employ the less drastic penalty of suspension for submission of inaccurate, incomplete, or untimely information. The commenter suggests that FDA notify a facility that failure to submit all of the required information within 15 days will result in suspension. Registration could be reinstated when this missing information is provided.

(Response) FDA does not agree that it should have a category of registrations that have been suspended. A facility either is registered by submitting a registration to FDA or it is not registered. Regarding registration cancellation, FDA has determined that

the only circumstances under which it will cancel a registration are if the agency independently verifies that a facility has gone out of business or is under a new ownership, or if FDA establishes that the submitted registration is for a facility that does not exist. FDA has clarified this in the interim final rule by adding the following paragraph to § 1.241:

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

As mentioned previously, a facility under new ownership is required to submit a new registration.

(Comment 149) One commenter asks that FDA not recall products already distributed into commerce if it determines after confirmation of the registration that the registration contains inadvertent errors.

(Response) Neither the proposed rule nor the interim final rule provide for the recall of food distributed into commerce because FDA subsequently determines that there are inaccuracies in the registration of a facility at which the food was manufactured/processed, packed, or held.

2. Prohibited Act for Domestic or Foreign Facility

(Comment 150) Several commenters request clarification on the penalties that may be imposed for failure to register and who may be subject to these penalties. One commenter states that failure to register may be a simple omission rather than a terrorist act; therefore, FDA should apply criminal actions according to the consequences and characteristics of the act. Another commenter asks FDA to clarify that although failure to register is a prohibited act, importing food from an unregistered facility is not. A commenter asks FDA to clarify that failure to register, although a prohibited act, will not result in debarment. This commenter asks FDA to maintain a public list of debarred individuals and firms, and make this list available on the Internet.

(Response) FDA agrees that § 1.241 was likely confusing and has clarified this provision in the interim final rule. Specifically, the interim final rule consolidates the two provisions relating to the prohibited act of failing to register (21 U.S.C. 331(dd)) and makes clear that