

definition of "retail food establishment" if they meet the other criteria of the "retail food establishment" definition. FDA notes, however, that many of these establishments may also manufacture/process, pack, or hold food that is subsequently sold to consumers. Unless the establishment's primary function is to sell food, including the food it manufactures/processes, directly to consumers, it must register with FDA.

(Comment 83) One commenter asks FDA to clarify whether warehouses that hold food for sales in U.S.-based duty-free stores are required to register. The commenter indicates that products stored in a duty-free enterprise warehouse and sold in an airport duty-free store are purchased solely by travelers departing from the United States, and therefore, are not for consumption in the United States.

(Response) FDA's understanding of duty-free shops is that purchased goods (including food) must be taken out of the United States by the traveler before such goods may be consumed or used. Thus, the agency agrees with the commenter that warehouses holding food for sale in duty-free stores are not required to register as long as the food is not for consumption or actually consumed in the United States.

In addition to the previous comments, FDA has made several editorial changes in this section for clarity.

15. U.S. Agent

(Comment 84) Some commenters claim that FDA's requirements for U.S. agents, and the responsibilities and liabilities of U.S. agents, are not clear. The commenters state that because FDA's proposed requirements are so general, it is difficult for a foreign facility to know what qualifications its U.S. agent should have.

(Response) FDA has retained the criteria for U.S. agent as proposed. As stated in the proposed rule, there are only two qualifications for a U.S. agent: The agent is required to reside or maintain a place of business in the United States and to be physically present in the United States. As far as U.S. agent liability, FDA generally does not intend to hold the U.S. agent responsible for violations of the Bioterrorism Act that are committed by the foreign facility, a position consistent with that articulated in the preamble to the agency's drugs, biologics, and device registration regulations (66 FR 59142, November 27, 2001). FDA, however, would consider legal action against a U.S. agent where the agent knowingly submitted false information to FDA or the agent and the foreign facility were effectively the same entity. Liability

issues between the facility and its U.S. agent must be resolved between the private parties (*i.e.*, the facility and its U.S. agent), most likely through the terms of their contractual relationship.

(Comment 85) Some commenters ask FDA to clarify whether it will notify the U.S. agent or a facility's emergency contact in the event of a bioterrorist attack or other food-related emergency that affects a foreign facility.

(Response) Because the role of the U.S. agent is to act as a communications link between the facility and FDA, FDA will communicate with the U.S. agent in both routine and emergency situations. This means that the U.S. agent needs to be accessible to FDA 24 hours a day, 7 days a week, unless the foreign facility opts to designate a different person other than the facility's U.S. agent to serve as the facility's emergency contact by providing the information specified in § 1.233(e) in the facility's registration. If a facility's registration includes an emergency contact person provided under § 1.233(e), FDA will notify this person instead of the U.S. agent during emergencies, but will continue to use the U.S. agent for routine communications with the facility.

(Comment 86) Some commenters argue that FDA's requirement that facilities have a single U.S. agent is contrary to usual business practices. The commenters state that a facility may have several U.S. agents for different business functions, such as separate product lines or different geographic areas.

(Response) FDA believes that it would be unreasonably complex to allow facilities to have several U.S. agents for purposes of FDA registration, as FDA would then have to determine with which agent to communicate for each product line or geographic distribution area. This would likely hinder communication between FDA and the facility and thereby, thwart a chief purpose of the Bioterrorism Act—facilitating a quick and effective response to a terrorist attack or other public health emergency related to the U.S. food supply. Also, section 305 of the Bioterrorism Act is written in the singular—that is, it states that a foreign facility must include the name of its "U.S. agent." Thus, allowing facilities to designate more than one U.S. agent would be inconsistent with the plain language in the Bioterrorism Act.

FDA is clarifying in § 1.227(b)(13)(iii) that having a single U.S. agent for FDA registration purposes does not preclude a facility from having multiple agents (such as foreign suppliers) for other business purposes and that FDA is not requiring that all of a firm's commercial

business in the United States be conducted through the U.S. agent designated for purposes of registration.

(Comment 87) Several commenters argue that the U.S. agent requirement is onerous and potentially trade-restrictive. The commenters state that there is no requirement for a third-party go-between for domestic facilities; thus, this requirement is more restrictive on foreign facilities than on U.S. producers.

(Response) FDA believes that it has structured the U.S. agent requirement to be consistent with the statutory mandates of the Bioterrorism Act. The rule sets out only two qualifications for a U.S. agent: The agent is required to reside or maintain a place of business in the United States and to be physically present in the United States. Therefore, many foreign facilities are able to use existing contacts in the United States as their U.S. agents. Moreover, FDA has clarified in the interim final rule that the requirement of a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes.

(Comment 88) Some commenters argue against the U.S. agent requirement because they believe the requirement will hinder, not enhance, communication with the foreign facility.

(Response) As discussed in the preamble to the proposed rule, the purpose of the U.S. agent is to serve as a communications link between FDA and an individual facility for a number of purposes, including both emergency situations and day-to-day registration issues. These routine issues may include FDA's need for information about that facility and arranging both routine inspections and inspections or communications with the facility due to a potential bioterrorism threat or other public health emergency.

(Comment 89) Several commenters argue that FDA should allow the U.S. agent to be located outside the United States. They state that many foreign facilities do not have contacts within the United States, so it will be difficult for them to locate a U.S. agent.

(Response) Section 305 of the Bioterrorism Act (which amends the FD&C Act) states that the registration of a foreign facility "shall include with the registration the name of the United States agent for the facility." Thus, requiring a foreign facility's U.S. agent to reside or maintain a place of business in this country is consistent with the plain language of the Bioterrorism Act. This approach is also consistent with FDA's implementation of the statutory requirement for drug, biologics, and device registration (21 U.S.C. 360(i)(1)),