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)),

66 FR 59138 (November 27, 2001).) It is reasonable to impute to Congress knowledge of FDA's implementation of this provision, which specifies that the ''U.S. agent'' be a person in the United States, when Congress incorporated this concept and language into the Bioterrorism Act.

(Comment 90) Several commenters ask whether a foreign government official in the United States, such as a representative from the foreign country's embassy, may act as the U.S. agent for a foreign facility.

(Response) The agency has concerns that acting as a U.S. agent may conflict with the duties of foreign government representatives. Whether it is proper for a foreign government representative to act as a U.S. agent is a fact-specific inquiry, depending on the title and status of the foreign government representative and the functions that the representative assumes as a U.S. agent. FDA believes that the propriety of a foreign government official acting as the U.S. agency of a foreign facility is a determination best made in conjunction with the State Department. If the issue arises after implementation, FDA will discuss the particular situation with the State Department.

(Comment 91) A few commenters suggest that FDA allow registrants to omit U.S. agent information if FDA uses information available from a foreign government agency.

(Response) The Bioterrorism Act requires the owner, operator, or agent in charge of a facility engaged in the manufacturing, processing, packing, or holding food—both domestic and foreign—to register the facility with FDA. The Bioterrorism Act also requires registrants of foreign facilities to provide the name of their U.S. agent. Thus, FDA is not permitted to use information maintained by foreign government agencies or other domestic Federal or State agencies in lieu of having the owner, operator, or agent-in-charge of a facility submit the information to FDA.

(Comment 92) One commenter asks whether a U.S. agent must be one individual or can it be a ''person'' consistent with the act's definition of ''person'' as an ''individual, partnership, corporation, or association.''

(Response) FDA agrees with the commenter and has clarified in the definition of ''U.S. agent'' that a foreign facility's U.S. agent can be a ''person'' as defined by the FD&C Act. This interpretation is consistent with the drug, biologics, and device registration regulations in 21 CFR 207.3(a)(11) and (b), 607.3(i) and (j), and 807.3(h) and (r).

(Comment 93) One commenter asks how FDA intends to ensure that a person identifying itself as a U.S. agent does, in fact, meet the requirements for a U.S. agent. The commenter states that some foreign facilities may use a false U.S. agent name, address, or phone number when registering. This commenter suggests that FDA confirm a registration only through a facility's designated U.S. agent, via postal mail.

(Response) FDA believes that there are several checks that will help ensure that registrations are truthful and accurate. The facility's owner, operator, or agent in charge who submits a registration must certify that the registration information is true and accurate. In addition, FDA has revised the interim final rule so that an individual (other than the owner, operator, or agent in charge of the facility) may be authorized to submit the registration on behalf of the owner, operator, or agent. An individual (other than a facility's owner, operator, or agent in charge) who submits the registration form to the FDA must certify that he/she is authorized to submit the registration on the facility's behalf and must identify by name the individual who authorized submission of the registration. The certification statement also states that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. As an additional means to verify the identity of the person submitting the registration, the interim final rule requires that for the paper and CD–ROM registration options, the registration include the signature of the person submitting the registration. FDA believes that the combination of the signed certification statement and federal criminal liability will be a powerful incentive for truthful registrations. Further, because the Bioterrorism Act provides that an owner, operator, or agent in charge is responsible for registering a facility, it would be improper for FDA to confirm that registration only through a facility's U.S. agent if the U.S. agent did not originally submit the registration.

In addition to the changes noted previously, FDA has made several editorial changes to this section on its own initiative.

16. Other Definitions Included in the Interim Final Rule

(Comment 94) One commenter requests that FDA define ''trade names'' in the interim final rule. This commenter states that the term ''trade names'' is mentioned in both the Bioterrorism Act and the proposed rule several times, yet is not defined. The commenter requests that ''trade names'' be defined, ''to ensure that the scope of registration reflect[s] the intent and objectives of the statute.'' The commenter suggests that ''trade names'' be defined as ''the terms relating to the business activity of the facility that denote the names under which the facility conducts business or additional names by which the facility is known.'' The commenter also requests that FDA clarify that ''trade names'' ''denote terminology associated with the business of the facility, and does not necessarily signify a brand name, which is terminology associated with a product.'' The commenter provides some examples of trade names, such as: ''Facility name: Jones Foods Corporation; Trade Names: doing business as Joe Jones Fruit Processors, doing business as Jones Family Pie Company.''

(Response) FDA agrees with the comment, and has added the following definition for ''trade names'' to the interim final rule (§ 1.227(b)(12)): ''*Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.''

(Comment 95) Several commenters request that FDA clarify who is required to register if a facility has multiple individuals who may qualify as the owner, operator, or agent in charge.

(Response) The Bioterrorism Act and the interim final rule place the responsibility for registering a facility on the owner, operator, and agent in charge of the facility. If a facility has multiple owners, operators, or agents-in-charge, all are collectively responsible for registering the facility and any one of these individuals may register the facility, or as noted in the response to comment 93, authorize an individual to submit the registration for the facility. Although these persons may decide themselves how, as a practical matter, their facility will be registered, the existence of multiple owners, operators, or agents in charge does not affect the legal obligation each has under the rule to register relevant facilities.

(Comment 96) One commenter states that although FDA uses the terms ''owner,'' ''operator,'' or ''agent in charge'' throughout the proposed rule and the draft registration form, in section 1b (Update of Registration Information) and section 12 (Certification Statement) but these terms are not defined. The commenter also states that although FDA requests changes to the ''owner, operator, or agent in charge'' in section 1b of the