

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. agent 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