

(Comment 116) Several commenters state that the information in the registration goes beyond the information required by the Bioterrorism Act, thereby exceeding FDA's statutory authority. One of these commenters states that "there are no references, either in the Bioterrorism Act or the legislative history, to the inclusion of individual names in the registration."

(Response) As noted in section I of this document, in issuing this interim final rule, FDA is relying on the authority in section 305 of the Bioterrorism Act, as well as section 701(a) and (b) of the FD&C Act. Including information regarding both the facility's parent company and the emergency contact will facilitate the efficient enforcement of the act by enhancing FDA's ability to deter and respond quickly to a food-related emergency. Accordingly, the provisions of this interim final rule are consistent with FDA's statutory authority provided by the Bioterrorism Act and the FD&C Act.

The only required elements of the registration that the Bioterrorism Act does not specifically mention are the facility's parent company name, address, and phone number, and emergency contact information. Regarding the emergency contact information, the information will make it possible for FDA to respond quickly to emergencies that occur during nonworking hours by contacting facilities when an emergency occurs.

FDA is also requiring the parent company information for emergency situations. If an emergency occurs with respect to a particular facility or group of facilities, FDA will need to alert the parent company, as well as the affected facilities, because the parent company has ultimate responsibility for the facility. Moreover, in terms of inspections, the relationship between a facility and its parent company is vital for FDA in tracking and investigating incidents.

With regard to that portion of the comment asserting the Bioterrorism Act does not refer to individual names, the interim final rule does not require the submission of an individual's name except for the name of the authorized individual submitting the registration and, if the submitter is authorized by another individual, the name of the authorizing individual. Of course, if the owner, operator, agent in charge, or U.S. agent is an individual, the name of that individual must be submitted. If the emergency contact for a facility is an individual, that name must be submitted as well. However, as stated in responses to comments 124 and 137, the

interim final rule does not require an individual to be designated as the U.S. agent or an emergency contact.

(Comment 117) One commenter believes that, contrary to FDA's proposed use of the registration information to determine the source and cause of a bioterrorist event, the proposed requirements are geared to locating and contacting facilities that through some other means have already been associated with the event, thus facilitating further investigation.

(Response) FDA believes that registration both will help the agency contact facilities that already have been the target of an event, and will assist the agency in determining the source and cause of the event. First, registration will provide FDA with a more complete and up-to-date database of facilities to contact if the agency learns of an actual or potential threat to the food supply. The specific registration information, such as food product categories and geographic location, will enable FDA to narrow down the facilities that may be affected by a bioterrorist attack or other food-related emergency, thus saving precious time. Second, registration will assist FDA's implementation of the other regulations and guidance documents that FDA is developing to implement the Bioterrorism Act, namely prior notice, recordkeeping, records access guidance, and detention. Registration, prior notice, and recordkeeping enable FDA either to obtain information it does not currently have, or to obtain that information more quickly than FDA was able to do prior to the enactment of the Bioterrorism Act. This information gives FDA crucial tools to protect the U.S. food supply. For example, registration will enable FDA to fill in incomplete information for certain facilities derived through records about a source of a bioterrorist attack or other food related emergency, thus facilitating a traceback. In this example, registration information would also allow FDA to contact some facilities quickly during a traceback investigation.

(Comment 118) One commenter requests that FDA consider registrations submitted more than once on behalf of a particular facility as valid, since some foreign companies may register multiple times both at the facility and corporate levels.

(Response) Once a facility is registered with FDA, the electronic system will reject any additional registrations that are submitted on behalf of the same facility. To have the system do otherwise does not make sense, because each facility must only register with FDA once and will only be

assigned one unique registration number. Accepting multiple registrations would also create confusion in FDA's database of registered facilities, because FDA would not know who to contact in the event of an emergency if there is different emergency contact information in the registrations for the same facility. Once a facility is registered, FDA will send a confirmation to the facility by e-mail, mail, or fax, depending on how the facility registered. Thus, personnel at the facility will be aware that the facility is registered.

(Comment 119) A commenter requests that FDA clarify whether it requires a registrant to specify container/package size in its registration. The commenter states that such a requirement would be very time-consuming and introduce prohibitive costs both financially and in terms of resources. The commenter further states that this potentially could necessitate numerous and frequent updates to registration information.

(Response) Neither the proposed rule nor the interim final rule requires registrants to specify container or package sizes in its registration.

(Comment 120) One trade association believes that FDA should provide "full translation services for non-English speakers and the disabled as required under the Americans with Disabilities Act (ADA)."

(Response) Regarding translation services for non-English speakers, this comment is not clear about whether it is requesting these services for the registration itself, or for outreach activities related to registration. FDA intends to translate all outreach-related slide presentations and downlink transcripts for the interim final rule into French and Spanish, similar to what FDA did for the outreach for the proposed rule. As noted previously, FDA will require the registration to be submitted in English. The owner, operator, or agent in charge of a foreign facility that requires translation services may wish to authorize an English-speaking individual to register on its behalf.

FDA is in full compliance with section 508 of the Rehabilitation Act and provides an "Accessibility Statement" for disabled persons on its Web site. FDA cannot identify from this comment if other "translation services" are being requested for the disabled.

2. Name, Full Address, Phone Number, Fax Number, and E-mail Address

(Comment 121) Several commenters object to FDA's requirement that a registration include the facility's phone number, fax number, and e-mail