

facilities after the first registration form, and each subsequent registration form, is completed.

FDA is proposing in § 1.231(b) that a registrant may register by mail if none of the means of electronic access mentioned previously are reasonably available. In registering by mail, a registrant also may fill out one or more forms on behalf of one or more facilities. A registrant registering by mail must pick up a copy of the form from FDA headquarters, call FDA at a toll-free number (that will be provided in the final rule) to request a copy of the form, or send FDA a written request for the form. Once the registrant receives the mailed copy of the form, the form must be filled out completely and legibly, and mailed back to FDA at the address provided in the final rule. Once FDA receives the form, an agency employee will check to make sure all mandatory fields are filled out completely and legibly. If the form is not complete or is illegible, it will be returned to the registrant for completion, provided that the registrant's mailing address is legible and valid. If the form is complete and legible, FDA will manually enter the data on the form into the system as soon as practicable, which will depend on the number of other registration forms awaiting manual entry into the system.

The Bioterrorism Act requires FDA to notify the registrant that it has received the facility's registration and to assign the facility a unique registration number. Accordingly, FDA is proposing the following: If a facility registers electronically, FDA will provide the registrant with an automatic electronic confirmation of registration, along with the facility's registration number. This notification will be similar to an automatic electronic receipt many companies provide consumers when they purchase products online (i.e., via the Internet). If the facility registers by mail, FDA will be able to provide the registrant with confirmation of registration and the facility's registration number only after FDA manually enters the registration information into the system. Depending on the number of other paper registrations FDA receives, this entry process could take several weeks to several months. After the registration information is entered into the system, FDA will mail a copy of the information entered to the registrant, along with confirmation of registration and the registration number. If any of the information that was entered into the system is incorrect, the registrant must mail an update to correct the information within 30 calendar days.

For electronic registrations, FDA is proposing in § 1.231 to consider the facility registered when FDA electronically transmits the facility's registration number. If a registration is done by mail, the facility is registered once the data are entered into the registration system and the system generates a registration number. This means that the facility information will be entered into the registration system before the facility receives its registration number, if registration is done by mail. FDA strongly encourages all facilities, both foreign and domestic, to register electronically, as that minimizes the delay in having FDA mail the registrant a form, the registrant returning the completed form to FDA, FDA entering the facility's data manually into the registration system, and FDA subsequently mailing the registration number and receipt of registration to the facility. To the extent possible, all covered facilities should make every effort to register electronically or send in their registration form as far in advance as possible of the date they are intending to import their products into the United States (but not sooner than the announced date) since the Bioterrorism Act requires FDA to hold imported products of any unregistered facility at the U.S. port of entry until the facility is registered with FDA.

The Bioterrorism Act precludes FDA from requiring facilities to register electronically. Given FDA's preference for electronic registration and the ease of electronic registration for both registrants and FDA, FDA is requesting comments regarding what other means FDA should use to encourage electronic registration. FDA also is requesting comments from facilities that believe they will be unable to register electronically, as well as comments regarding data on the number of these facilities.

No registration fee is required for either the electronic or paper registration. FDA is proposing that registrants must submit all registration information in the English language. FDA is proposing to require submissions to be in English in order for FDA to understand the content of submissions and ensure that registration data are entered accurately.

### 3. What Information is Required in the Registration? (Proposed § 1.232)

FDA is proposing in § 1.232 that registrants must submit to FDA certain information, including: The name, full address, phone number, fax number, and e-mail address of the facility (paragraph (a)); the name and address of

the parent company (paragraph (b)), if the facility is a subsidiary of the parent company; emergency contact information, including the contact's name, title, office phone, home phone, cell phone (if available), and e-mail address (if available) (paragraph (c)); all trade names the facility uses (paragraph (d)); and the name, address, phone number, fax number (if available), and e-mail address (if available) of the U.S. agent for foreign facilities (paragraph (f)). FDA is planning to include all of this information in the mandatory section of the registration form. At the end of the form, FDA is planning to provide a statement in which the registrant will certify that the information submitted is true and accurate, and that the individual submitting the registration is authorized by the facility to do so (paragraph (g)). This statement also will require the phone number, e-mail address (if available), and fax number (if available) of the person submitting the registration.

Section 305 of the Bioterrorism Act also states that FDA may require registrants to submit the general food categories of food produced at the facility, if FDA determines through guidance that such information is necessary. FDA plans to issue such guidance, and make it available for comment in accordance with good guidance practices (21 CFR 10.115). The guidance will address FDA's finding that such food categories are necessary. Section 305 of the Bioterrorism Act specifically provides that the food categories to be used are those provided in § 170.3. FDA tentatively concludes that information on the category of food manufactured, processed, packed, or held at each facility that must register is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food related emergency, FDA would be able to alert soft drink manufacturers/processors, packers, and holders about this information. Additionally, the food categories, in conjunction with the prior notification requirements in 21 CFR part 1, subpart I, would aid FDA in verifying that