

address. These commenters state that the e-mail address of the facility is not likely to be that of an individual person, but one for the facility as a whole and is usually staffed by a facility's most junior employee, who would not be the appropriate person for FDA to contact in the case of a bioterrorism incident or other food-related emergency. The commenters also state that FDA will have the phone number and e-mail address of the emergency contact, so it should not be necessary also to require the phone number and e-mail address of the facility as a whole. Regarding the fax number, some commenters argue that they might not have fax machines. Therefore, these commenters request that FDA make the facility fax number and e-mail optional elements of registration.

(Response) FDA agrees with the commenter that a facility's fax number should be optional and that a facility's e-mail address also should be optional unless the facility registers electronically and provides an e-mail address for confirmation. Section two of the proposed registration form states that the registrant is required to provide its fax number and e-mail address "if available." However, to clarify in the rule that this information is optional, FDA has moved these registration elements to the section in the interim final rule entitled "What optional items are included in the registration form?" (§ 1.233). FDA has decided to retain the requirement that a facility's phone number be provided because having that number will facilitate routine communications with the facility. For domestic facilities, the emergency contact information will only be used in the event of an actual or potential emergency; the facility phone number will be used for all other communications (e.g., to schedule an inspection), unless the registration provides other contact information in the "Preferred Mailing Address" section of the form. For foreign facilities, the U.S. agent's information will be used for both routine and emergency contacts, unless the facility chooses to provide a different emergency contact. FDA, however, believes it is important to have a contact phone number for a foreign facility itself, in case FDA cannot contact the U.S. agent.

(Comment 122) Several commenters state that the fields in section 2 of the proposed registration form for facility name and address correspond to addresses in the United States, such as "zip code," and do not take into account address formats used in foreign countries. For example, in many Latin American countries, addresses are not

necessarily denoted by a street number and name, but may be identified by a crossing of streets or even by specific reference points that may involve other buildings or landmarks.

(Response) In the electronic registration, FDA intends to provide flexibility to enable a foreign facility to include its street address information in the format used in the foreign country. Regarding "zip codes," in the proposed registration form, FDA's electronic system is designed to request zip code information only for facilities located in the United States, and the postal code for countries that have postal codes. For identification of a country, the electronic system employs a pull-down menu that lists countries' two letter abbreviations as listed in the International Standards Organization 3166. The printed registration will also provide enough space for a registrant to enter the facility's address information in whatever format is used in its own country.

### 3. Name and Address of the Parent Company

(Comment 123) Several commenters believe that name and address of the parent company should not be required. Another commenter states that it does not object to this requirement.

(Response) The interim final rule retains the requirement that parent company information be provided in a registration if applicable. The parent company information enables FDA to ascertain the relationship between a facility and its parent company, if the facility is a subsidiary of the parent company, because not infrequently, a facility or subsidiary may have a different name than its parent company. 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.

### 4. Emergency Contact Information

(Comment 124) Several commenters believe that FDA should give facilities or their parent companies the option of identifying relevant emergency contact information (phone number, whether cell or land line, e-mail address) without necessarily identifying a specific individual. These commenters state that because the purpose of an

emergency contact is for FDA to communicate in an emergency situation with the facility, there is no need for FDA to contact a specific individual. Many facilities already have emergency contact procedures in place for responding to local emergencies; FDA's emergency contact information should provide flexibility for facilities to utilize these existing procedures. Also, requiring an individual to be identified by name may mean a facility would need to provide frequent updates to its registration, because the individual responsible for responding to emergencies may change on a frequent basis. Other commenters request that FDA allow a facility to designate an alternate emergency contact, or that FDA require the emergency contact to be located at the corporate headquarters, instead of at the facility.

Other commenters believe FDA has appropriately defined the scope of information necessary to accomplish the goal of quick response and notification in the case of a bioterrorist attack on the U.S. food supply.

(Response) FDA has considered these comments and in response, has modified the interim final rule so it does not require a facility to provide an individual's name as part of the emergency contact information. However, the facility must ensure that the information it provides will enable FDA to contact a live person representing the facility 24 hours a day, 7 days a week. FDA agrees that emergency contact information should be specific to the facility's already established emergency procedures; therefore, FDA will not necessarily require contact information for a corporate headquarters. However, a facility may designate the emergency contact information for its corporate headquarters, if that is appropriate for operations at that facility.

As noted, for foreign facilities, FDA will consider the facility's U.S. agent as the emergency contact unless specified otherwise in the registration. If a foreign facility designates someone other than its U.S. agent as the emergency contact, FDA will utilize that information to contact the facility instead of the facility's U.S. agent when an emergency occurs.

### 5. Trade Names

(Comment 125) Several commenters agree that trade names should be required as part of the registration. These commenters request that FDA define "trade names" and provide examples. One commenter states that requiring trade names for food