

packaging is unworkable because “brand codes” and “grade names” change frequently, and would thus require continual updates.

(Response) The Bioterrorism Act specifically states that trade names should be a required part of the facility’s registration, and thus, FDA agrees with the comment that trade names should be a required registration element. FDA also agrees that it should define the term, “trade names,” and, as discussed previously, provides a definition of “trade names” in the interim final rule. In response to the comment stating that “brand codes” and “grade names” change frequently, FDA notes that the trade names definition does not include this information, but only information about names the facility itself uses.

#### 6. Product Categories Under § 170.3

(Comment 126) Many commenters assert that registrants should not be required to supply information regarding food product categories associated with a facility. A variety of reasons are offered, including that the categories are outdated and not relevant; the categories are difficult to understand and apply; use of the categories would lead to mistakes regarding a facility’s selection of appropriate categories; categories would require a facility to submit constant updates to FDA, as a facility continuously changes the food it produces in response to market demands; use of categories would impose an enormous burden and increased cost; use of categories would limit targeted communications because often one manufacturer’s finished product is another’s ingredient, which would confuse FDA’s efforts to notify affected facilities; facilities would be subject to criminal penalties if product category information is not correct or is outdated; under the Bioterrorism Act, FDA has the discretion to require this information and FDA should not exercise that discretion; use of categories introduces huge uncertainties as to whether the appropriate facilities would be contacted in the event of an emergency, which may lead either to causing unnecessary concern or inadequate notification of affected facilities; some categories overlap each other, yet many foods fall into gaps between categories; and requiring categories would increase the time to complete a registration. One commenter states that FDA should include food product categories, because these categories would help FDA to more closely focus inspection resources.

(Response) The interim final rule maintains the requirement that food product categories be specified in a

facility’s registration. As required by the Bioterrorism Act, FDA considered in guidance whether such categories should be included and determined that such information will be an important aid to the agency in the event of a foodborne emergency (68 FR 42415). The interim final rule requires each facility to submit the general food product category (as identified under § 170.3) of the food manufactured/processed, packed, or held at such facility. For ease of use, FDA lists the more common categories found in FDA’s product code builder at <http://www.fda.gov/search/databases.html> as the main categories on the registration form, referencing the relevant food product category in § 170.3 for each FDA product code category. To relieve some of the burden of frequent updates, FDA has added a “most/all human food product categories” option. Facilities that manufacture/process, pack, or hold food that does not fit into one of the § 170.3 categories are required to check “none of the above mandatory categories.” These facilities may also choose to check one or more of the optional boxes that correspond to the category of food manufactured/processed, packed, or held at the facility, as specified in section 11(a) or 11(b) of the registration form.

FDA continues to believe that information regarding food product categories is necessary for a quick, accurate, and focused response to a bioterrorism incident or other food-related emergency. The categories will help FDA to focus its response on the appropriate facilities, saving crucial time. Some threats may be specific to a certain facility type (e.g., a threat against beverage bottling facilities). Under these circumstances, being able to target communications will allow FDA to expedite and focus its response. The fact that in some instances a threat cannot be isolated to a finite set of facilities does not mean that this will be the case in all instances. Being able to focus communications as much as possible based on a particular threat through the use of food product categories will ensure that FDA is able to respond as effectively and efficiently as possible.

(Comment 127) One commenter notes that in the proposed registration form, FDA has stated that warehouses are not required to complete the section on food product categories. The commenter states that this exception for warehouses is not mentioned in the preamble or codified of the proposed regulations, and asks FDA to clarify this exception.

(Response) To ensure that facilities have fully completed the section on food product categories, FDA has

changed this section to require all facilities to check at least one box. As noted, as required by the Bioterrorism Act, FDA considered in guidance whether such categories should be included and determined that such information will be an important aid to the agency in the event of a foodborne emergency (68 FR 42415). Thus, this interim final rule requires registrants to identify the food product category under § 170.3 for food manufactured/processed, packed, or held at each facility. FDA has also provided that facilities that manufacture/process, pack, or hold food in many different food product categories (such as many warehouses) do not have to check every food product category, and may instead check the “most/all human food product categories.” Importantly, however, the interim final rule requires a warehouse that holds only one or a limited number of different food products to identify those categories listed in § 170.3. Because the proposed rule would not have required a facility to identify a food product category on the registration form if it was manufacturing/processing, packing, or holding food that did not fit into a category under § 170.3, FDA would not have been able to determine whether a registrant’s food product categories were not covered under § 170.3, or whether the registrant forgot to complete the section of the registration form on food product categories. Therefore, the interim final rule requires facilities that manufacture/process, pack, or hold food product categories not covered under § 170.3 to check “none of the above mandatory categories.” Because the revised version of the Form 3537 requires all facilities to check at least one box in the food product categories section, FDA has deleted the language in the form stating that warehouses are exempt from completing the food product categories section of the form.

#### 7. U.S. Agent

FDA addresses comments related to the U.S. agent requirement in section III.E.15 of this document.

#### 8. Certification Statement

(Comment 128) One commenter notes that the requirements for identifying personal information in the certification statement should relate to the individual making the certification, not the individual submitting the registration. This change would recognize that administrative personnel, not responsible parties of the company, may process the actual facility registration.