

vi. *Foreign facility costs to hire a U.S. agent.* The U.S. agent is a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its agent. Only one U.S. agent per foreign facility is permitted. The U.S. agent acts as a communications link between the FDA and the facility and FDA would consider providing information to the U.S. agent the same as providing information directly to the foreign facility.

In option 7, facilities can designate their U.S. agent as their agent in charge of the facility for purposes of registration and the agent can register in behalf of the facility. The costs and benefits of permitting the U.S. agent to register on behalf of the facility are considered in option 7.

FDA has little information on how many foreign facilities already have a U.S. agent. Comments stated that many exporters do not currently have a U.S. agent; they would have to hire an agent in response to the regulation. FDA expects, however, that some foreign facilities already have a U.S. representative that can function as a U.S. agent. The U.S. representative may be a business partner, broker, U.S. lawyer, or parent company. FDA assumes that the likelihood that a foreign facility has an existing U.S. agent is related directly to the quantity of product the foreign facility exports to the United States.

To estimate the number of foreign facilities that already have a U.S. agent, FDA assumes that manufacturers/processors that do more business in the United States are more likely to have an existing U.S. agent. To estimate the amount of product a foreign manufacturer/processor exports to the United States, FDA estimates the number of line entries exported to the United States by foreign manufacturers. The term "line entry" refers to a group of products that are subject to the same FDA admissibility decision because they have the same FDA product code, brand name, size or packaging, manufacturer/processor, shipper, consignee, importer's product description, and country of production. One shipment may contain multiple line entries.

FDA used data from OASIS on the average number of line entries and the average number of manufacturers/processors (listed in OASIS under the category "manufacturers") by country and product code to estimate the number of line entries for foreign manufacturers/processors. A shortcoming of these data is that entries

are by product code; thus, manufacturers/processors that are exporting products in more than one product code are in the count of manufacturers/processors for every product code in which they export. A product code designates a category of product, such as cheese and cheese products. The OASIS data consequently have approximately twice as many manufacturers/processors as actually exist. To adjust for this double-counting, FDA assumed the average foreign manufacturer/processor exports in two product categories. To find an approximate number of line entries per manufacturer, FDA divided the total number of manufacturers/processors into the total number of line entries for each country and applied the average number of line entries per manufacturer/processor to all the manufacturers/processors from that country. This method will underestimate the number of very small and very large manufacturers/processors, because it removes the variation in number of line entries exported from countries with a large number of manufacturers/processors exporting to the United States.

To estimate the number of foreign facilities that would have to hire a U.S. agent, FDA assumed that foreign facilities that export more than 100 line entries each year into the United States, or 10 percent of foreign manufacturers/processors, already have a U.S. representative who can function as a U.S. agent. FDA also assumed that the 16 percent of manufacturers/processors that are exporting 10 or fewer line entries to the United States would stop exporting to the United States, rather than incur the expense of registering, hiring a U.S. agent, and providing prior notice under 21 CFR part 1, subpart I. FDA requests comments on these assumptions. Table 12 presents average numbers of line entries and the percent of foreign manufacturers/processors that export that number.

TABLE 12.—AVERAGE NUMBER OF LINE ENTRIES FROM FOREIGN MANUFACTURERS/PROCESSORS

Average Number of Line Entries	Percent of Total Number of Foreign Manufacturers/Processors	Cumulative Percent of Manufacturers/Processors
≤10	15.81	15.81
11–20	25.43	41.24
21–40	32.27	73.51

TABLE 12.—AVERAGE NUMBER OF LINE ENTRIES FROM FOREIGN MANUFACTURERS/PROCESSORS—Continued

Average Number of Line Entries	Percent of Total Number of Foreign Manufacturers/Processors	Cumulative Percent of Manufacturers/Processors
41–60	7.30	80.81
61–80	5.88	86.69
81–100	3.64	90.33
101–120	1.78	92.11
121–140	0.72	92.83
141–160	1.59	94.42
161–180	0.48	94.90
181–200	0.83	95.73
>200	4.27	100.00

FDA anticipates that foreign facilities would find U.S. agents through the Internet or business contacts. Finding and hiring an agent would result in labor costs for the facility. FDA requests comments on these assumptions.

FDA bases the estimated cost of hiring a U.S. agent on the fees charged by U.S. agents for foreign drug, biologic, and device manufacturers. The requirements for a U.S. agent for drugs, biologics, and devices (parts 207, 607, and 807, respectively) are very similar to the requirements for a U.S. agent for foods in this proposed regulation, and many of the U.S. agents began working as a response to the drug, biologic, and device foreign facility registration regulations. FDA contacted some active U.S. agents, whose annual cost estimates for their services ranged from \$700 to \$2,000 (Refs. 16 and 17).

vii. *Annual costs for foreign facilities.* Foreign facilities have to retain a U.S. agent. In the first year, the facility would incur costs to hire and retain an agent. In future years, the facility would have to pay an annual fee of approximately one thousand dollars to the agent.

Like domestic facilities, foreign facilities are required to update their registration when a change occurs in any of the information previously submitted. FDA estimates the frequency of registration updates for foreign facilities as 20 percent per year. FDA requests comments on this assumption. The cost to the facility of updating would be 1 hour to find and fill out the form, including translation if necessary, and to certify the changed registration.

New facilities would incur the same costs to learn about the regulation, hire a U.S. agent, and fill out the registration information in future years as existing facilities would incur in the first year.