

Table 8.--Average number of line entries from foreign manufacturers

Average number of line entries	Percent of total number of foreign manufacturers	Cumulative percent of manufacturers
1-10	15.81	15.81
11-20	25.43	41.24
21-40	32.27	73.51
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

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(Comment 182) FDA received many comments on requiring U.S. agents for foreign facilities required to register with FDA. Comments centered around five issues: (1) The role of the U.S. agent, (2) the cost of a U.S. agent, (3) facilities choosing to cease exporting to the United States, (4) alternatives suggested to the proposed U.S. agent requirements, and (5) the benefits of requiring a U.S. agent. The benefits of a U.S. agent are addressed in the benefits section VI.C of this document; the remaining comments are summarized and responded to in the following paragraphs.

Many comments were unclear about the role of the U.S. agent. A common misperception was that the U.S. agent must be the importer or broker the facility works with and that the facility would not be able to import through other brokers. Another common misperception was that the U.S. agent

was required to have information about all the food products the facility exports to the United States.

(Response) FDA believes that many foreign entities did not correctly understand the role of the U.S. agent and how narrow are the U.S. agent's responsibilities. The U.S. agent may be an importer or broker if the facility chooses; however, the only requirement for a U.S. agent in the proposed and interim final rule is that the U.S. agent reside or maintain a place of business in the United States. In this rulemaking, FDA does not place any new restrictions on foreign facilities using import brokers, which may have been the source of some of the confusion regarding the true impact of the agent requirement. The U.S. agent is also not expected to have information about all the shipments a facility sends to the United States. The U.S. agent's responsibility is to be able to contact the facility and pass on information from

FDA in both emergencies and routine operations. A U.S. agent may also register with FDA on behalf of the facility, if the facility so chooses. The U.S. agent is considered to be the facility's emergency contact, unless the facility designates an alternative contact in accordance with § 1.233(e). Therefore, FDA does not include any costs due to changes in business practices, such as using a single broker.

(Comment 183) FDA also received comments about costs of the U.S. agent. One comment states that the costs of requiring a U.S. agent were underestimated by a factor of 5 to 10. However, this comment provides no basis for this cost estimate. Many comments also state that most facilities do not already have a U.S. agent and would incur costs to procure a U.S. agent. Finally, some comments state that FDA should include the cost of a legal agreement between the foreign facility and the U.S. agent.