Table 3.--Final Count of Domestic Facilities Required to Register From CBP

NAICS Code	Type of Industry	PRIA No. of Facilities	Revised Count No. of Facilities
3111	Animal food manufacturing	1,710	1,710
3112	Grain and oilseed milling	913	913
3113	Sugar and confectionery product manufacturing	1,689	1,689
3114	Fruit and vegetable preserving and specialty food manufacturing	1,796	1,796
3115	Dairy product manufacturing	1,769	1,769
3117	Seafood product preparation and packaging	854	854
3118	Bakeries and tortilla manufacturing	10,644	10,644
3119	Other food manufacturing	2,994	2,994
3121	Beverage manufacturing	2,748	2,748
4224	Grocery and related product wholesale	39,721	39,721
4225	Farm product raw material wholesale	9,546	9,546
4228	Beer, wine, distilled alcoholic beverage wholesale	4,630	4,630
49312	Refrigerated warehousing and storage	945	945
49313	Farm product warehousing and storage	516	516
		80,475	80,475

Table 4.--Final Count of Domestic Facilities Required to Register From Nonemployer Statistics

NAICS Code	Nonemployer businesses Type of Industry	PRIA No. of Facilities	Revised count No. of Facilities
3111	Animal food manufacturing	642	642
3112	Grain and oilseed milling	287	287
3113	Sugar and confectionery product manufacturing	1,439	1,439
3114	Fruit and vegetable preserving and specialty food manufacturing	2,000	2,000
3115	Dairy product manufacturing	594	594
3117	Seafood product preparation and packaging	693	693
3118	Bakeries and tortilla manufacturing	6,271	6,271
3119	Other food manufacturing	4,725	4,725
3121	Beverage manufacturing	1,608	1,608
4224	Grocery and related product wholesale	32,050	32,050
4225	Farm product raw material wholesale	4,795	4,795
4228	Beer, wine, distilled alcoholic beverage wholesale	2,578	2,578
4931	Warehousing and storage	964	964
		58,646	58,646
	Food contact	9,778	0
		68,424	58,646

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TABLE 5.—REVISED COUNT OF DOMESTIC FACILITIES REQUIRED TO REGISTER OF FACILITIES FROM OTHER SOURCES

	PRIA	Revised count
Mixed-type facilities	30,497	30,497
Food contact substances	22,650	0
Transportation holders		33,666
Ingredient suppliers		272
Direct sales marketers		12,400
U.S. outlying islands		315
	53,147	77,150

TABLE 6.—COUNT OF FOREIGN MANUFACTURERS/PROCESSORS REQUIRED TO REGISTER FROM OASIS

Type of product	No. of facilities
Foods	110,392
Food additives	2,979
Color additives	378
Infant formula	235
Vitamins	7,986
Animal feeds	3,330
Medicated animal foods	150
	125,450

TABLE 7.—NO. OF AFFECTED FACILITIES

Domestic facilities:	
CBP	80,475
Nonemployer statistics	58,646

TABLE 7.—NO. OF AFFECTED FACILITIES—Continued

Other sources	77,150
Total domestic	216,271
Foreign facilities:	
Foreign manufacturers/processors	125,450
Percent that will stop exporting	16%
Adjusted number of manufacturers/processors	105,378
Foreign packers and holders	100,027
Total foreign	205,405
Total	421,676

4. Costs

a. *Time estimates.*

In the PRIA, FDA anticipated that it would take four steps for a domestic facility to comply with the regulation: (1) The facility becomes aware of the regulation; (2) the facility learns what the requirements are; (3) an administrative worker fills out the form; and (4) the owner, operator, or agent in charge of the facility confirms the submission is correct. FDA also anticipated that facilities with Internet access that research and register online will have lower registration costs than facilities without Internet access. The interim final rule permits the owner, operator, agent in charge, or an individual authorized by the owner, operator, or agent in charge to submit the registration. Although the owner, operator, or agent in charge is not required to make the actual submission, the owner, operator, or agent in charge is still legally responsible for the registration. Therefore, FDA expects that in cases in which the owner, operator, or agent in charge authorizes an individual to submit the registration on its behalf, the owner, operator, or agent in charge will still take time to confirm that the information on the form is correct before it is submitted to FDA by the authorized individual.

FDA anticipated that foreign facilities would follow the same four steps to comply with the regulation as domestic facilities: (1) The facility must become aware of the regulation, (2) the facility learns the requirements, (3) an administrative worker fills out the form, and (4) the owner, operator, or agent in charge of the facility or the U.S. agent authorized by a foreign facility confirms the submission is correct. In addition, foreign facilities could have fifth and sixth steps to find and then hire a U.S. agent. To estimate the cost of registration for foreign facilities, FDA assumed that they would incur the same per facility costs as domestic facilities, plus additional costs. Similar to domestic facilities, FDA estimated that facilities that research and register electronically would incur lower costs than facilities that do not. Tables 9 through 13 of this document summarize the costs in the PRIA and the revised costs for the interim final rule. Similar to domestic facilities, the interim final rule permits the owner, operator, agent in charge of a foreign facility, or an individual authorized by the owner, operator, or agent in charge to submit the registration. While the owner, operator, or agent in charge is not required to make the actual submission, the owner, operator, or agent in charge is still legally responsible for the registration. Therefore, FDA expects that in cases in which the owner, operator, or agent in charge authorizes an individual to submit the registration on its behalf, the owner, operator, or agent in charge will still take time to confirm that the information in the form is correct before it is submitted to FDA by the authorized individual.

(Comment 173) A number of comments stated that FDA underestimated the time necessary to comply with the proposed rule. One comment provided an estimate of 40 hours to read the proposed rule, submit comments to FDA, implement any final rule internally, and verify registrations of business partners. With 40 percent of these hours managerial time and 60 percent administrative time, the approximate cost was $1,500. The commenter also estimated that additional research for any final rule would require another 4 hours. Another comment estimated that the initial registration would take 3 hours, that managerial expertise would be necessary to gather the information for the registration, and that it would take a manager more than 15 minutes to fill out the form.

Another comment stated that a manager or lead counsel would be responsible for reviewing any final rule and formulating a plan for implementation. This comment estimated that this process would take 10 hours of a manager's time at a cost of $567.40, in addition to 1 hour of an administrative assistant's time. This comment also suggested legal counsel may review the regulation for 5 hours at a total cost of $1,500. Finally, another comment stated it would take 20 hours of staff time to read, comprehend, gather the necessary data, and complete the form. All of the estimates provided in these comments were for facilities with Internet access and workers fluent in English. Several of the comments suggested that FDA increase the time estimates for facilities without Internet access and without staff fluent in English.

(Response) FDA estimated that domestic facilities with Internet access and fluent in English would need, on average, 2 hours to research the regulation and complete and certify the form; domestic facilities without Internet access would need 3 hours. A facility would require approximately 1 or 2 hours, depending on the availability of the Internet, to find the requirements and determine if the facility is required to register, 15 minutes to categorize products and enter them in the appropriate food product categories, 30 minutes to find the remaining registration information and enter it onto the form, and 15 minutes for confirming all the registration information is correct. This estimate is on a per facility, not a per firm, basis. Also, this estimate is approximate; some facilities may require more or less time. FDA anticipates and estimated in the PRIA that firms with multiple facilities will spend 2 hours per facility, if Internet is available, researching and submitting registration information. The facility, or the firm on behalf of the facility, is required to enter the registration data; however, the facility, firm, or an industry or trade group may research the regulation. Firms with many facilities or industry groups representing hundreds or thousands of facilities submitted all of the comments listed previously.

In the PRIA, a large firm composed of 1,000 facilities would spend 2,000 hours researching and registering all its facilities. Given the estimates provided by the comments, this estimate is likely an overestimate. FDA expects that firms composed of many facilities will have lower per facility registration costs than single-facility firms. Multifacility firms will learn from their experience gained while registering their first facility and will be more efficient at registering additional facilities. Also, the registration system has built-in features that will allow common information to be transferred easily from one facility to another within the same firm. FDA was not able to estimate the reduction in time to register for these multifacility firms on a per facility basis, and so retains its original estimates. However, for this reason, FDA's time estimates are likely overestimates for multifacility firms.

FDA does not anticipate that small facilities will read the **Federal Register**. Instead, they will learn of their obligation to register from trade groups, the press, or FDA outreach efforts, then go to the registration Web site and using the information provided at the Web site, including the interactive features of the registration system, complete and submit their registration. The time estimates included in the economic analysis represent an average facility time estimate across small, medium, and large facilities, and thus, for some individual facilities, the average time estimate will be too high and for some it will be too low. Therefore, FDA did not alter its estimates of the time to complete the registration process.

FDA was persuaded by the comments that managerial staff, rather than administrative staff, would do any necessary research. FDA has re-estimated the analysis using managerial time for researching and administrative time for entering the registration data. Several comments suggested that FDA underestimated the managerial wage, one giving an alternative wage rate of $75 per hour. In the PRIA, FDA used the Bureau of Labor Statistics estimate from the National Compensation Survey (Ref. 16), doubled to include overhead costs. This estimate is an average across many facilities. The higher wage estimate provided was from a very large firm with over 1,000 facilities that FDA would anticipate would have higher wages than most facilities. Therefore FDA did not change its estimate of the average managerial wage.

FDA did not receive any specific estimates of the additional time to register for facilities that lack Internet access and staff who do not speak English. Therefore, because FDA has not increased the base time for registration and has no new information to increase the additional time for foreign language translation or mail submissions, FDA has not increased its estimate of time costs for facilities without Internet access and staff who do not speak English.

(Comment 174) One comment suggested that FDA ignores the effort that will be required of large companies to identify all of the manufacturing and holding facilities covered by the registration requirement. The comment stated that one large supplier might have as many as 1,000 facilities that would have to register.

(Response) FDA included in its cost estimate one hour of research time for each facility to learn about the registration requirements, including whether it needs to be registered. This time may not be used by each facility, but by the firm that registers all its facilities. Multifacility firms are likely to require less time on a per-facility basis than FDA estimates. For a firm with 1,000 facilities, the PRIA estimated the firm would spend 1,000 hours to learn about the registration requirements, which is probably an overestimate of the time required by the firm, as a large, multifacility firm should learn from experience and become more efficient at registering additional facilities.

b. *Other costs.*

(Comment 175) Many commenters were concerned about potential port delays arising from FDA's failure to process registrations in a timely manner, facilities not being aware of the registration requirements prior to shipping food to the United States, or the receiver of the shipment not being aware that the foreign facility is not registered. Commenters mentioned costs associated with port delays including the lost value of perishable goods, storage costs, and the need for larger inventories for domestic facilities that receive imports.

(Response) FDA considered qualitatively in the PRIA potential costs associated with port delays due to foreign facilities not being aware of the registration requirement until their shipment reaches the port. This included costs such as lost value of perishables, storage costs, and transaction costs. Commenters did not provide any quantitative data about the size of these costs. Therefore, FDA has not changed its estimate of port delay costs.

(Comment 176) FDA received a number of comments that FDA underestimated the cost of the proposed rule, because it failed to include time for facilities to write and submit comments.

(Response) The function of the Regulatory Impact Analysis is to measure the costs and benefits of the requirements of the rule. Submitting comments is part of the rulemaking process, not a requirement of the rule. Therefore, FDA did not include in the PRIA costs associated with commenting on the proposed rule.

(Comment 177) FDA received comments stating that registration would require changes in business activities to prevent comingling of product or coding on product to reflect where it was manufactured/processed, packed and held.

(Response) FDA disagrees with this comment. The interim final rule requires all facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA. However, the interim final rule does not require any additional labeling of food or restriction of comingling of product.

(Comment 178) FDA received comments that FDA failed to include the cost to facilities of confirming that trading partners are registered.

(Response) FDA did not explicitly include this cost because confirming registrations of trading partners is not a requirement of the interim final rule. However, FDA did include higher costs for foreign facilities to learn about the interim final rule and comply with the requirements, and this includes the higher transaction costs for foreign trading partners. These costs may be borne in part by domestic facilities that inform foreign facilities of the requirement to register.

5. Alternative Options

In the PRIA, FDA considered eight different regulatory options. FDA received many comments that suggested additional options. Suggestions included accepting multiple submissions on a CD–ROM, deleting the requirement to include product categories, different requirements for time allowed to update registrations, different requirements for the U.S. agent, and using other registration systems to gather information for the FDA facility database.

a. *Accept CD–ROM submissions.*

(Comment 179) A number of comments requested that FDA accept multiple registrations on a single submission, such as a specially formatted CD–ROM with the registrations for all the facilities of a

single firm. Comments stated that this would lower the burden of registration, particularly for firms with many facilities, and would improve the accuracy of the registrations.

(Response) The interim final rule allows the submission of multiple registrations on a single CD–ROM. The registrant must use a specially formatted CD–ROM with a PDF version of the registration form. The registrant then enters the facilities' registration information on the CD–ROM and mails the CD–ROM to FDA. FDA will process CD–ROM submission, along with paper submissions, in the order received. CD–ROM submissions will be entered electronically into the registration system. This option will result in additional costs to FDA for processing submissions and training staff to process the submissions. FDA estimates it will take an additional 100–150 hours to develop the automated workflow process for CD–ROM submissions, integrate the process into the existing process, and include the process in the testing phases. At a labor cost of $100 per hour, the total cost for the process control would be approximately $10,000 to $15,000. Additional training costs for staff processing the CD–ROM submissions would be about $8,000 to $10,500. These costs are incorporated into the total FDA cost estimate.

FDA anticipates that this option will lower costs for some large, multifacility firms. Only firms that can lower their costs by using this option will do so. However, FDA does not quantitatively estimate the cost savings.

b. *Food product categories.*

FDA proposed to require the inclusion of food product categories in the registration information. Food product categories are necessary for FDA to communicate directly with subgroups of facilities and to help verify prior notices from facilities that are subject to both registration and the prior notice requirements. FDA estimated that including food product category information in the registration would increase the time to complete each facility's registration by 15 minutes. Including food product categories in the registration form also increases the number of updates facilities will have to submit to FDA.

(Comment 180) FDA received numerous comments stating that including the food product categories as a registration requirement would add to the costs of the rule, without providing any benefits. Some comments stated that the additional 15 minutes for facilities to include food product categories underestimated the time needed to provide this information. Also, large facilities may manufacture/process, pack, or hold thousands of products and determining the food product categories for all these products would be very difficult.

(Response) In responding to these comments, FDA breaks the comments into three categories: (1) The time to research the food product categories for the initial registration, (2) the effect of including food product categories on the frequency of updates, and (3) the benefits of including food product categories. FDA addresses the impact on updates in the section on frequency of updates, and addresses the last category of comments in the benefits section.

FDA does not agree with the comments that suggested FDA underestimated the time to include food product categories as a registration element. For facilities that handle many different types of food, such as warehouses the registration form includes a "most/all human food categories" to alleviate the burden of providing information on each specific category of food at the facility. This will allow facilities that handle a large variety of foods to fill out the food product category section of the form very quickly. Also, the electronic registration form includes extensive online help, with descriptions of the food product categories and a link to the FDA product code builder, which will interactively categorize foods. This will simplify identification of the appropriate food product category. For example, pudding is a product that some may believe may be relatively difficult to categorize. On the registration form, it may be unclear to a registrant whether pudding should be characterized as a bakery product/dough/mix/icing or a gelatin/rennet/pudding mix/pie filling. The online registration provides a link to the FDA product code builder, which has a search function. Searching on "pudding" gives three possible categories, the two categories already given and baby food, all with drop down menus. By using the drop down menus, a list of products in those categories is provided. The registrant can then find its product in the drop down menu. Moreover, most products, such as alcoholic drinks, fruits, vegetables, and eggs, can simply be characterized by reading the food product categories.

As previously mentioned, most facilities are small and do not produce a large number of products. Therefore, FDA has not altered its 15 minute estimate of the time to fill in the food product categories.

c. *Frequency of updates.*

The proposed rule would have required registered facilities to submit updates or cancellations of their registration information within 30 days of a change in information previously submitted to FDA. The interim final rule changes this requirement to 60 days. Facilities that close or transfer ownership are required to cancel their registrations. New facilities and facilities that change ownership must register. Based on data from the Small Business Administration (Ref. 17), FDA estimated that 10 percent of facilities will cancel registrations and 10 percent of facilities have to submit a new registration each year. FDA also estimated that 20 percent of facilities would have to update their registrations each year. Updates and cancellations were estimated to take 1 hour. First-time registrations in subsequent years were estimated to be as costly as first-time registrations in the first year.

(Comment 181) FDA received many comments about how often facilities will have to update their registrations. As noted, FDA estimated 20 percent of facilities would have to update their registrations each year. Comments provided a number of other estimates of how frequently updates would be required. Multiple comments estimated that 50 percent of facilities would have to update their registrations each year. Other comments did not provide an estimate of how often updates would be required, but suggested that FDA require annual updates. Others commented that facilities would have to update registration information many times a year. Another comment did not provide an alternative estimate of the frequency of updates, but disagreed with the 20 percent per year estimate provided by FDA. Various comments suggested that the most frequently changing components of the registration would be the name of the emergency contact and, if "trade name" were defined broadly, it would be the most frequently changing registration information element.

Some comments suggested including food product categories in the registration would lead to monthly registration updates. Comments stated that there is constant fluctuation in the nature of products produced at large facilities, which would require frequent updates. One comment suggested that one in four large facilities that manufacture/process food would have to submit updates each month. Comments stated that the cost of maintaining the food product categories would exceed the cost of the initial registration.

Comments most frequently suggested that FDA require updates every 6 to 12 months or annually. However, some comments suggest that to allow update periods longer than 30 days would reduce the usefulness of the database.

(Response) As stated in the definitions section of this rule, trade names mean the terms under which the facility conducts business, or additional names by which the facility is known. Trade names are terms associated with the facility, as opposed to brand names, which are terms associated with products. Therefore, comments that stated that names associated with products change frequently, which would result in the need for frequent updates, overestimate the frequency with which facilities will have to update their registrations because brand names are not included as an element of registration. FDA has also removed the requirement that an individual be identified as the emergency contact, another registration element that commenters mentioned was likely to change frequently.

FDA does not agree that the cost of updates resulting from changes in product lines will require facilities to submit monthly updates. Some types of facilities, such as warehouses or wholesalers, are likely to select the most/all human food category due to the large variety of products handled at the facility. Manufacturers/processors are the most likely facilities to have frequent changes in product lines. However, the majority of these facilities are small. The 18,259 manufacturers in the Nonemployer Statistics have only 1 employee, and due to their small size, should not have frequent changes in product lines. In the CBP data, 80 percent of the 29,149 manufacturers have fewer than 50 employees. It is unlikely facilities of this size will produce many different product lines and that these product lines will change frequently. This leaves a small number, approximately 3,700 large manufacturers, that may have more frequent changes in product lines. Also, the product categories included in the registration form include many individual products; thus, a product line change may not change the food product category. For example, a facility may change pudding flavors or the level of fat in the pudding without changing food product categories.

FDA does agree with the comments that the frequency of updates will be greater than estimated in the PRIA. FDA has re-estimated the frequency with which updates will occur for 60-day updates by using the suggested frequency of updates in the comments for the 30-day update period. For large manufacturing/processing facilities, FDA has used the estimate provided by some commenters that one in four facilities would have to submit an update each month with a 30-day update period. Large manufacturing/processing facilities would then submit two updates per year with a 60-day update period, rather than 3 times per year with a 30-day update period. For other facilities, FDA has used the estimate that 50 percent of facilities would have to update each year (or facilities would update once every 2 years) with a 30-day update. FDA assumes that the number of updates will still be once every 2 years with a 60-day requirement for updates. A weighted average of the two estimates gives 55 percent of facilities updating each year. FDA has also applied this estimate for domestic facilities to foreign facilities.

FDA has also considered an alternative option in which facilities are required to update their registration within a year of a change. FDA assumes that for facilities that are not large manufacturers/processors, updates by 50 percent of facilities per year is equivalent to one change every 2 years. Under this approach, the frequency of updates for facilities that are not large manufacturers/processors would still be 50 percent of facilities each year, but no updates would occur in the first year. Large manufacturers/processors would have to update once a year, with no updates the first year. Without incorporating zero updates in the first year, adopting this option would give a weighted average of 51 percent of facilities updating each year. To incorporate the lack of updates for the first year, we included zero updates for 1 year in 20 years of the registration system. This lowers the average for percent of facilities submitting updates each year to 48 percent. See tables 11 and 12 of this document for cost estimates for these options.

FDA also considers an option in which facilities are not required to include food product categories in their registrations. FDA estimates that it would take only 45 minutes to fill out and certify the registration form and that 50 percent of all facilities would have changes in their registration information each year.

Comments received in response to the proposed rule assumed that changes in optional elements would result in updates. In the interim final rule, FDA does not require a facility to update its registration when changes occur in optional items. FDA does not have information to adjust the estimates of frequency of update in response to changes in optional information. However, FDA does believe that the estimate of frequency of updates is an overestimate, as it is based on changes in both optional and required information.

d. *U.S. agent.*

The Bioterrorism Act and the interim final rule require that all foreign facilities required to register have a U.S. agent. The interim final rule requires the U.S. agent to be 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. FDA will recognize only one U.S. agent for purposes of registration per foreign facility. The U.S. agent acts as a communications link between FDA and the facility and FDA considers providing information to the U.S. agent the same as providing information directly to the foreign facility. A U.S. agent may submit a registration to FDA, if the owner, operator, or agent in charge of the foreign facility authorizes the U.S. agent (if an individual) to register on behalf of the owner, operator, or agent in charge of the facility.

U.S. Agent Assumptions

In the PRIA, FDA assumed, based on preliminary comments, 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.

FDA used data from OASIS on the average number of line entries and the average number of manufacturers by country and product code to estimate the number of line entries for foreign manufacturers (Ref. 2). A shortcoming of these data is that entries are by product code, thus, manufacturers that are exporting products in more than one product code are in the count of manufacturers for every product code in which they export. The OASIS data consequently have approximately twice as many manufacturers as actually exist. To adjust for this double-counting, FDA assumed the average foreign manufacturer exports in two product categories. To find an approximate number of line entries per manufacturer, FDA divided the total number of manufacturers into the total number of line entries for each country and applied the average number of line entries per manufacturer to all the manufacturers from that country. This method will underestimate the number of very small and very large

manufacturers, because it removes the variation in number of line entries exported from countries with a large number of manufacturers 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 80 line entries each year into the United States, or 10 percent of foreign manufacturers, already have a U.S. representative who can function as a U.S. agent. FDA acknowledges that this is an uncertain estimate; the true number of facilities that have an existing business representative that would be willing to serve as their U.S. agent may be much higher. FDA will test the impact of overall U.S. agent costs under different assumptions.

For foreign facilities that do not have an existing business representative willing to act as their U.S. agent for little or no extra cost to the U.S. agent or facility, FDA estimated it would take between 5 and 15 hours to hire a U.S. agent, depending on whether the facility had Internet access and its personnel were fluent in English. Additionally, FDA estimated an annual U.S. agent fee of $1,000 per year, based on estimates of agent fees provided by U.S. agents for other FDA-regulated products. This estimate of the U.S. agent fee contemplates that the U.S. agent will register the foreign facility. If the foreign facility chooses to register on its own behalf, the U.S. agent fee may be lower; however, the facility itself will have higher costs associated with registering. These costs include time to enter the registration information, translate the registration information if the facility is not fluent in English, and additional time for mailing a postal registration if the facility does not have Internet access.

FDA acknowledges that these assumptions are uncertain. Accordingly, as explained more fully in the following paragraphs, FDA provides alternative assumptions regarding U.S. agent fees, based on U.S. agents currently proffering their services as U.S. agents for the purposes of the Bioterrorism Act. In general, current prices for other U.S. agent activities (such as serving as a U.S. agent for drug or device foreign establishments) and published prices for an emerging market may not be precise predictors of the actual prices charged for this service.

FDA also assumed that the 16 percent of manufacturers 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 includes the effect of prior notice on foreign facilities ceasing trade with the United States, because both will represent an increase in the cost of importing to the United States. FDA is unable to separate the effects on foreign facilities ceasing to export to the United States and so considers them both here. These estimates are also uncertain as the value of and the return on food shipments are variable and the cost for an individual food facility to comply with the Bioterrorism Act regulations is uncertain. Some facilities may ship very few shipments to the United States each year, but may earn a very high return; these facilities will likely continue to export to the United States. Conversely, some facilities may ship many, low value, low return shipments to the United States and may stop exporting to the United States as a result of the regulations under the Bioterrorism Act. Foreign facilities may also have existing business relationships with facilities in the United States. If a domestic facility is willing to absorb the cost of registering and providing U.S. agent services to a foreign facility, the facility may continue to export to the United States. In the proposed rule, FDA requested comments on these assumptions. No comments provided quantitative estimates of the number of facilities that would stop exporting or that already have U.S. agents. These estimates are uncertain, as the value of and the return on food shipments are variable and the cost for an individual facility to comply with the Bioterrorism Act regulations is uncertain. Some facilities may ship very few shipments to the United States each year, but may earn a very high return; these facilities will likely continue to export to the United States. Conversely, some facilities may ship many, low value, low return shipments to the United States and stop exporting to the United States as a result of the regulations under the Bioterrorism Act. In the proposed rule, FDA requested comments on these assumptions. No comments provided quantitative estimates of the number of facilities that would stop exporting or that already have U.S. agents. Table 8 presents average numbers of line entries and the percent of foreign manufacturers that export that number.

If 16 percent of foreign manufacturers/processors do choose to cease exporting to the United States, the total effect on trade will be much smaller than 16 percent. The facilities projected to cease exporting to the United States represent a small fraction of total trade. The 16 percent of facilities represents approximately 20,000 facilities exporting between 1 and 10 line entries to the United States each year. If, on average, each would have exported 5 line entries, the total number of line entries affected would be approximately 100,000, which is less than 2 percent of all lines.

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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.

(Response) FDA does not require a legal agreement between the U.S. agent and the foreign facility, but the estimated total cost for foreign facilities does include the costs of finding and hiring a U.S. agent.

FDA agrees that many facilities do not already have a U.S. agent. In the PRIA, FDA estimated that more than 90 percent of foreign facilities do not currently have a U.S. agent. Again, if more than 10 percent of foreign food facilities already have a relationship to a domestic entity that could serve as an equivalent to the role of the U.S. agent as required in this interim final rule, the impact of this rulemaking would be lower. FDA tests the sensitivity of this estimate in the following paragraphs.

In the PRIA, FDA estimated that foreign facilities currently without a U.S. agent would require 5 to15 hours to find an agent and would pay an annual fee of $1,000. FDA's estimate of the U.S. agent fee was based on the fees charged by U.S. agents for other FDA regulated products with similar responsibilities to those required in the proposed rule. Therefore, given the foundation for the fees cited in the PRIA and the lack of evidence for higher fees, FDA does not increase its estimate of the U.S. agent fee.

No comments suggested that FDA overestimated the fee that would be charged by a U.S. agent. The $1,000 fee estimated in the proposed rule was an estimate of an average fee for a U.S. agent under other FDA regulations, based on fees quoted over the phone and Internet advertisements. However, since publication of the proposed rule, a number of companies have begun Internet advertising of their services as a U.S. agent for foreign food facilities that are required to register with FDA. These companies specify a range of costs, some with discounts for multiple facilities under the same ownership or fees that are a function of the number of shipments each year or additional fees for registration updates. Based on the requirements in the proposed rule, the lowest fee quoted was $399 for representation by a U.S. agent for 1 year; other U.S. agents charged initial fees between $599 and $1,400 (Ref. 18). Many of the U.S. agents intend to charge fees for additional registration-related services, such as registration updates or cancellations. Based on these new estimates of fees, FDA believes that $1,000 still represents a reasonable estimate of a U.S. agent fee. Ultimately, the fee that a foreign facility will pay to hire and retain a U.S. agent will be a function of several factors; whether the facility has Internet access, whether its employees are fluent in English, whether it has existing relationships with potential U.S. agents, and individual facility preferences.

Sensitivity Analyses

Many facilities will choose lower-priced U.S. agents; therefore, FDA presents an estimate of the cost of the rule with a U.S. agent fee of $700. In this situation, the total first year cost for foreign facilities would be $247.6 million and annual costs would be $164.5 million. In addition, the assumed number of entities that would no longer export to the United States would fall under this scenario; if U.S. agent costs are lower, it would continue to make economic sense for a larger number of foreign facilities to continue importing into the United States. FDA does not provide an estimate of the decrease in the number of facilities that will cease exporting to the United States.

FDA also considers a higher U.S. agent cost of $1,200. This represents the higher range of Internet estimates; however, fees offered by facilities over the Internet may not represent the full range of U.S. agent fees. Also, foreign facilities that do not have Internet access or are not fluent in the languages commonly used in trade may face higher fees. This gives a first year cost of $345.0 million and annual costs of $271.7 million.

As discussed previously, the assumption that 10 percent of foreign facilities have an existing relationship that is equivalent to a U.S. agent is uncertain. FDA considers as an alternative assumption that those facilities that export 40 or more line entries per year, or 26 percent of facilities, already have a business partner in the United States that serves the function of a U.S. agent and the foreign facility will only incur the costs of registering. This lowers that cost to foreign facilities to $283.9 million in the first year and $209.7 in future years.

Alternatively, FDA considers that only facilities that export more than 120 line entries per year, or 8 percent of facilities have a U.S. business partner that will fulfill role of the U.S. agent. This will increase the cost to foreign facilities to $308.8 million in the first year and $231.2 million, annually.

Given the uncertainty surrounding the percent of facilities that will stop exporting to the United States, FDA also considers two alternative options. Eight percent stop exporting and 24 percent stop exporting. If eight percent of foreign facilities that ship very small numbers of line entries to the United States each year stop exporting to the United States, then the quantified cost of the interim final rule will increase to $320.4 million per year and $239.4 million in subsequent years. However, this estimate does not account for a decrease in the nonquantified costs. Foreign facilities that stop exporting to the United States due to the Bioterrorism Act regulations will earn lower returns on their product because they will shift to a market with a lower return. Additionally, domestic facilities that receive product from these facilities will not incur costs to find new suppliers. Alternatively, if facilities that ship 20 or fewer line entries per year to the United States, or 24 percent of facilities, stop exporting, the quantified costs will decrease to $291.7 million in the first year and $218.2 million in subsequent years. However, the increase in nonquantified costs will offset these cost savings.

FDA considers the total cost for foreign facilities under the combination of lowest and highest cost alternatives. The lowest cost combination gives a total cost of $220.5 million for the first year and $144.6 million in subsequent years. The highest cost combination gives a total cost of $364.6 million in the first year and $267.4 million annually.

Distribution of Costs

FDA has chosen to use the facility as its unit of analysis for two reasons: (1) The Bioterrorism Act requires registration on a facility basis, and (2) most information available to FDA is at the facility level. For these reasons, costs are reported as average per facility costs and total costs for facilities. However, FDA expects that all of the costs will not be borne by the facilities. Economic theory shows that, in the case of new costs, a portion of the costs will be borne by the producer and a portion by the consumer. In this case, the costs may be spread among the foreign facility, importers, exporters, domestic food producers and distributors, and consumers. However the costs are distributed, the total social cost of the rule will be unchanged. Although the distribution of these costs is uncertain, the total cost of submitting a facility's registration and U.S. agent services are both costs of the requirements of this interim final rule for foreign facilities. FDA requests comments on the distribution of costs between submitting registrations and other services offered by the U.S. agent and comments on the overall cost of hiring and retaining a U.S. agent and the assumptions underlying FDA's estimates of these costs.

Table 9.--Sensitivity analysis of foreign facility costs (in millions)

Alternative U.S. agent costs	First year costs	Annual costs
Baseline estimate	$306.0	$228.8
U.S. agent fee of $700	$247.6	$164.5
U.S. agent fee of $1200	$345.0	$271.7
26% already have a U.S. agent	$283.9	$209.7
10% already have a U.S. agent	$310.2	$232.4
8% already have a U.S. agent	$308.8	$231.2
8% stop exporting	$320.4	$239.4
24% stop exporting	$291.7	$218.2
Lowest estimate	$220.5	$144.6
Highest estimate	$364.6	$267.4

(Comment 184) Several comments predict that some foreign facilities would cease exporting to the United States due to the cost of procuring a U.S. agent. Comments mention this as a cost to both foreign facilities and domestic facilities. For foreign facilities that ship small quantities to the United States, some comments assert that the cost of a U.S. agent could exceed the profits from shipping to the United States. For these facilities, it would make economic sense to stop exporting to the United States. Other comments assert that some domestic facilities, particularly small businesses, might lose important suppliers. These comments state that the loss of foreign suppliers could have a significant negative impact on their businesses. FDA also received comments on the effect of requiring a U.S. agent on domestic small businesses.

(Response) FDA agrees that some foreign facilities may choose to stop exporting to the United States because the cost of registering and procuring a U.S. agent will exceed the benefits to the facility of exporting food to the United States. As mentioned previously, the number of foreign facilities that will choose to stop exporting to the United States is uncertain, as it will depend on the cost of registration for the individual facility and the return on the shipment in the United States versus its return in other markets. No comments provided any quantitative estimates of the number of facilities that would stop exporting to the United States. These costs were included qualitatively in the PRIA. The effect of requiring a U.S. agent on domestic small businesses will be considered in the Regulatory Flexibility Analysis.

(Comment 185) Several alternatives to the proposed requirement for a U.S. agent are suggested by commenters, including making the U.S. agent requirement optional, requiring a U.S. agent only if the facility does not have an e-mail contact, and requiring that the U.S. agent reside or maintain a place of business in North America.

(Response) FDA is constrained by the Bioterrorism Act, which requires all foreign facilities subject to this rule to have a U.S. agent. Also, FDA believes that the statute requires that the U.S. agent reside or maintain a place of business in the U.S. proper, not North America generally. Therefore, choosing not to require a U.S. agent or having the person reside or maintain a place of business outside the United States is not consistent with congressional intent. However, while not a legally available option, FDA does provide an estimate of the cost for an option in which a U.S. agent is not required.

e. *Duplicate requirements with other licensing or registering authorities.*

(Comment 186) FDA received many comments that the registration requirement duplicates other registration requirements for FDA, other U.S. government agencies, other governments, and State and local authorities. These comments suggest that FDA obtain the registration information from these other authorities rather than require an additional registration. Specific registration requirements mentioned by commenters included FDA low acid canned foods, FDA feed manufacturers, FDA seafood Hazard Analysis and Critical Control Point importers, TTB, EPA, USDA, Australia, Iceland, New Zealand, Chile, California, and FIRMS.

(Response) FDA has determined that it is most cost-effective for FDA to require registration by all affected facilities under this rule. Using data from other registration systems would be cost-effective, if FDA could collect the data from other systems at a total lower cost, to both facilities and FDA, than original collection of the data. For FDA to use another regulatory agency's registration system, FDA needs to: (1) Be able to get the data from the other agency; (2) capture all of the required information; (3) avoid duplicate registrations; (4) verify that the data are correct; (5) update the registration in a timely manner; and (6) issue a new registration number and confirmation to the registered facility.

Using other registration systems would likely increase costs for FDA to get the data from the other system. This would require interagency cooperation and compatibility of IT systems by the statutory deadline of December 12, 2003. In addition to creating the existing IT system, FDA would have to develop the ability to accept large transfers of data from other systems. Additionally, accepting data from other registration systems will require facilities to provide any data elements not included in those registration systems to FDA separately, which will also result in higher costs for FDA.

Using other registration systems would not lower the cost of registration for covered facilities. Even if another registration system is used, facilities will still incur research costs to learn about the registration requirements to determine whether they need to register or if they had already fulfilled the requirements, so research costs for facilities will be unchanged under both

systems. Costs for submitting the data will be different if other registration systems are used. For the costs of accepting duplicate registrations to be lower for facilities, the alternate registration system must include all the data elements required by the FDA registration. The system that initially seemed most likely to match FDA's requirements and most frequently mentioned in comments involved the permit requirements applicable to the alcohol beverage industry under laws enforced by TTB. FDA met with TTB to determine whether it was feasible to use TTB's basic permit system. FDA and TTB determined that TTB's regulations do not apply to all facilities required to register under this interim final rule. For example, the laws administered by TTB do not require foreign alcohol beverage producers to obtain permits, unless they are also engaged in the business of importing alcohol beverages into the U.S. FDA and TTB also determined that several of the required data elements for FDA registration are not mandatory information for alcohol beverage permittees, including some of the emergency contact information required by this interim final rule. Accordingly, even facilities with TTB permits would still have to file immediately a registration update with FDA to provide missing data elements. FDA concluded that accepting registrations in alternative registration systems would not lower costs for facilities. If accepting registrations does not lower costs for FDA or for facilities, it is not a cost-effective alternative.

FDA assumes that if original data collection is not cost-effective for domestic facilities, it will be less cost-effective for foreign facilities, because foreign facilities will still have to obtain a U.S. agent and submit to FDA the information for their U.S. agent.

f. *FDA costs.*

FDA costs include creating and maintaining a database, processing paper submissions, and sending an annual mailing to registrants. Developing and maintaining a database includes automatically entering registrations into the database that arrive electronically and sending an electronic receipt and facility registration number back to the registrant. FDA estimates that four full-time equivalent employees (FTEs) will be needed to oversee the database. Additionally, paper submissions (*i.e.* those received by mail, fax, or on CD-ROM) will have to be entered manually. Costs are presented for the first 5 years of the system in table 9 of this document. Annual costs are discounted at 7 and 3 percent. No comments were received on FDA's cost estimates in the PRIA. However, cost numbers were revised based on new information obtained by FDA.

Tables 10 through 12 provide details of the components of total costs for FDA, domestic facilities, and foreign facilities. For tables 11 and 12, FDA provides the estimate of the costs from the PRIA, and from 4 options; the interim final rule, the interim final rule with longer updates, the interim final rule without product categories, and the interim final rule with no U.S. agent requirement. Details of the costs that have not changed in response to comments may be found in the proposed rule. Tables 13 and 14 summarize the total costs over the first four years and provide a present value for a 20 year horizon for a 7 percent and 3 percent discount rate, respectively. FDA acknowledges uncertainty in these estimates; please see the proposed rule for a fuller discussion of all sources of uncertainty, and the discussion and sensitivity analysis under comment 192 regarding the uncertainty of the U.S. agent estimate.

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Table 10.--FDA Costs

FDA Costs	Year One	Year Two	Year Three	Year Four	Year Five
Development/modification/enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/steady state	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$97,000	$97,000	$97,000	$97,000	$97,000
Processing paper submissions	$2,900,000	$1,600,000	$1,600,000	$1,600,000	$1,600,000
Mailing costs	$180,000	$35,000	$35,000	$35,000	$35,000
New hardware	$0	$0	$0	$650,000	$0
Total	$13,228,000	$8,523,000	$9,623,000	$9,079,000	$8,429,000
Total discounted at 7%	$13,228,000	$7,965,000	$8,405,000	$7,411,000	$6,430,000
Total discounted at 3%	$13,228,000	$8,275,000	$9,071,000	$8,309,000	$7,489,000

Table 11.--Computation of Costs for Domestic Facilities

	Proposed	Interim Final	Longer Updates	No Product categories	No U.S. Agent
Number of domestic facilities	202,046	216,271	216,271	216,271	216,271
Time to research requirements with Internet (hours)	1	1	1	1	1
Time to research requirements without Internet (hours)	2	2	2	2	2
Time to complete the form (hours)	1	1	1	1	1
Percent of facilities with Internet	71%	71%	71%	71%	71%
Manager wage (hourly)	$56.74	56.74	56.74	56.74	56.74
Administrative wage (hourly)	$25.10	25.1	25.1	25.1	25.1
First year domestic costs	$13,200,000	$23,000,000	$23,000,000	$21,600,000	$23,000,000
Annual facility costs					
Percent of businesses going out of business	10%	10%	10%	10%	10%
Percent of businesses entering	10%	10%	10%	10%	10%
Percent of businesses with changes	20%	55%	48%	50%	55%
Time to update or cancel registration (hours)	1	1	1	1	1
Annual facility costs	$3,300,000	$6,900,000	$6,400,000	$6,400,000	$6,900,000

Table 12.--Computation of Costs for Foreign Facilities

	Proposed	Interim Final	Longer Updates	No Product Categories	No U.S. Agent
Number of foreign holders and packagers	100,027	100,027	100,027	100,027	100,027
Number of foreign facilities manufacturers/ processors	125,450	125,450	125,450	125,450	125,450
Percent of facilities stops exporting	16%	16%	16%	16%	16%
Total facilities	205,405	205,405	205,405	205,405	205,405
Speaks English	16%	16%	16%	16%	16%
Has Internet access	31%	31%	31%	31%	31%
Has U.S. Agent	10%	10%	10%	10%	10%
Hourly wage rate	$25.10	$25.10	$25.10	$25.10	$25.10
Time to find agent (hours)	5	5	5	5	0
Additional time to find a U.S. agent if not fluent in English (hours)	5	5	5	5	0
Additional time to find a U.S. agent without Internet access (hours)	5	5	5	5	0
Agent fee (annual cost)	$1,000	$1,000	$1,000	$1,000	$0
Time to research requirements (hours)	1	1	1	1	1
Additional time to research requirements if not fluent in English (hours)	5	5	5	5	5
Additional time to research requirements without Internet access (hours)	5	5	5	5	5
Time to complete the form (hours)	1	1	1	0.75	1
Additional time to complete if not fluent in English (hours)	0	0	0	0	1
Additional time to submit registration without Internet access (hours)	0	0	0	0	1
Total first year costs	$306,000,000	$306,000,000	$306,000,000	$304,800,000	$73,100,000
Annual costs					
Agent fee	$1,000	$1,000	$1,000	$1,000	$0
Percent of businesses going out of business	10%	10%	10%	10%	10%
Percent of businesses entering	10%	10%	10%	10%	10%
Percent of businesses with changes	20%	55%	48%	50%	55%
Total annual costs	$227,000,000	$228,800,000	$228,500,000	$228,400,000	$10,600,000

Table 13.--Summary of Costs (in Millions) Discounted at 7 Percent

	Interim Final	Longer Updates	No Product Categories	No U.S. Agent
Domestic first year costs	$23.0	$23.0	$21.6	$23.0
Foreign first year costs	$306.0	$306.0	$304.8	$73.1
FDA first year costs	$13.2	$13.2	$13.2	$13.2
Total first year costs	$342.2	$342.2	$339.6	$109.3
Domestic second year costs	$6.5	$6.0	$6.0	$6.0
Foreign second year costs	$213.8	$213.5	$213.5	$10.0
FDA second year costs	$8.0	$8.0	$8.0	$8.0
Total second year costs (7% discount)	$228.3	$227.5	$227.5	$24.0
Domestic third year costs	$6.0	$5.6	$5.6	$6.0
Foreign third year costs	$199.8	$199.5	$199.5	$9.0
FDA third year costs	$8.4	$8.4	$8.4	$8.4
Total third year costs	$214.2	$213.5	$213.5	$23.4
Domestic fourth year costs	$5.6	$5.2	$5.2	$6.0
Foreign fourth year costs	$186.8	$186.4	$186.4	$9.0
FDA fourth year costs	$7.9	$7.9	$7.9	$7.9
Total fourth year costs	$200.3	$199.5	$199.5	$22.9
Present value	$2,942.0	$2,932.0	$2,928.0	$398.0

Table 14.--Summary of Costs (in Millions) Discounted at 3 Percent

	Interim Final	Longer Updates	No Product Categories	No U.S. Agent
Domestic first year costs	$23.0	$23.0	$21.6	$23.0
Foreign first year costs	$306.0	$306.0	$304.8	$73.1
FDA first year costs	$13.2	$13.2	$13.2	$13.2
Total first year costs	$342.2	$342.2	$339.6	$109.3
Domestic second year costs	$6.7	$6.0	$6.2	$7.0
Foreign second year costs	$222.1	$221.7	$221.7	$10.0
FDA second year costs	$8.3	$8.3	$8.3	$8.3
Total second year costs (7% discount)	$237.1	$236.0	$236.2	$25.3
Domestic third year costs	$6.5	$6.0	$6.0	$7.0
Foreign third year costs	$215.7	$215.3	$215.3	$10.0
FDA third year costs	$9.1	$9.1	$9.1	$9.1
Total third year costs	$231.2	$230.4	$230.4	$26.1
Domestic fourth year costs	$6.3	$5.9	$5.9	$6.0
Foreign fourth year costs	$209.3	$209.0	$209.0	$10.0
FDA fourth year costs	$8.8	$8.8	$8.8	$8.8
Total fourth year costs	$224.4	$223.7	$223.7	$24.8
Present value	$3,992.0	$3,976.0	$3,972.0	$512.0

6. Benefits

In the PRIA, FDA asserted that requiring registration of manufacturers/processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways. One, by requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain. Two, if FDA is aware of a specific food threat, a registration database would make FDA better able to inform the facilities potentially affected by the threat. Three, FDA would be able to deploy more efficiently its domestic compliance and regulatory resources. Four, FDA inspectors, using prior notice and registration, would be better able to identify shipments for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. Persons who might attempt to intentionally contaminate the U.S. food supply would be deterred, by the creation of additional evidence that might be used against them, from starting a business in the food supply chain. Persons who might intentionally contaminate the food supply but refuse to register would be subject to criminal and civil sanctions and, if foreign, would risk having their product held at

a U.S. port. With emergency contact information and product categories, FDA can quickly call or e-mail the emergency contact at both domestic and foreign facilities that may be targeted by a specific food threat. If FDA suspects a particular product is at risk, we can quickly identify which facilities to contact. This quick communication will allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination of food. In the past, FDA field personnel (Ref. 19) have had difficulty notifying facilities of recalls and other enforcement actions due to incomplete information in existing agency records. In the past, for foreign facilities, FDA has attempted to disseminate recall information through foreign embassies. Contacting foreign facilities through their U.S. agent (or their designated emergency contact) will be more efficient and increase the probability that the facility will receive the information in a timely fashion and act on it.

A complete list of facilities in the food supply chain will also aid FDA in scheduling inspections and undertaking compliance activities. FDA currently uses an OEI that we developed by obtaining lists from State governments and adding firms to the OEI through surveillance activities, such as reviewing phone books. The OEI is incomplete and frequently out of date (Ref. 20). FDA has even less information about foreign facilities that manufacture/process, pack, or hold food for consumption in the United States. A complete list of domestic facilities with correct contact information and food product categories would aid inspectors in contacting facilities, and with product information available, would help the agency to identify facilities for inspections. Because of the turnover in the food industry and the ratio of inspectors to food facilities, FDA never has had a complete list of foreign or domestic facilities that provide food for consumption in the United States. Also, a complete list of facilities will aid FDA in understanding which facilities will be affected by a future regulation, which will increase the agency's effectiveness in targeting communication and outreach to these facilities.

In conjunction with the prior notice requirements in part 1, subpart I, this rule will make it possible for FDA to better identify imported food shipments that require inspection prior to admission. The registration will confirm the identity of the country of production, which may not be the same as the country from which the product has been shipped. This information will assist FDA in identifying specific shipments to inspect, if, for example, we have information that a particular type of food or shipments from a particular country may be adulterated. Additionally, the database of registrants and products also will aid FDA in verifying that a product is correctly identified by where and by whom it was produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice purportedly from the facility for a shipment identified as nuts, FDA can decide whether to target that shipment for verification based on the discrepancy.

FDA has conducted its own evaluation of the vulnerability of the U.S. food supply and has also commissioned two threat assessments, one through the Batelle Memorial Institute and a second through the Institute of Food Technologists. These assessments determined the most serious risks of intentional contamination during various stages of food production and distribution. The results of these assessments are classified. We have also received intelligence information regarding threats to the food supply that are guiding our food security efforts. However, to understand possible costs of an intentional strike on the U.S. food supply, FDA presents in table 15 outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods. These outbreaks do not represent all possible forms that a terrorist attack might take, but merely illustrate the public health costs of foodborne emergencies. It is likely that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be more costly. However, the probability of an attack occurring and the exact reduction in risk resulting from registration is unknown.

Table 15.--Summary of Five Foodborne Outbreaks

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost
Salmonella enteritidis (Ref. 20)	Minnesota, 1994	Ice cream	150 cases, 30 hospitalized	29,100 in Minnesota 224,000 Nationwide	$3,187,700,000 to $5,629,800,000
Shigella sonnei (Ref. 21)	Michigan, 1988	Tofu salad	3,175 cases	Not available	$45,200,000 to $79,800,000
Outbreaks Resulting From Deliberate Contamination					
S. Typhimurium (Ref. 22)	Dalles, Oregon, 1984	Salad bars	751 cases, 45 hospitalized	Not available	$10,700,000 to $18,900,000
S. dysentreriae type 2 (Ref. 23)	Texas, 1996	Muffins and doughnuts	12 cases, 4 hospitalized	All cases identified	$83,000
Outbreaks Resulting From Imported Foods					
Cyclospora cayaetanensis (Ref. 24)	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1,465 cases identified, less than 20 hospitalized	Not available	$3,900,000

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a. *Food-contact substances.*

(Comment 187) Some comments stated that there would be no benefits to requiring the registration of articles that contact food and their components. Commenters noted that none of the foodborne outbreaks included in the benefits section resulted from articles that contact food. However, other comments noted the potential for articles that contact food to leach into and contaminate food and concluded that it was necessary to require the registration of articles that contact food.

(Response) FDA has revised the interim final rule to exclude facilities that manufacture/process, pack, or hold food-contact substances, as defined in section 409(h)(6) of the FD&C Act. Accordingly, FDA does not need to address these comments, because these facilities are not subject to the interim final rule.

b. *Food product categories.*

(Comment 188) Many comments claim that, for several reasons, including food product categories would have no benefits: One, facilities would be unable to categorize their products correctly; two, FDA would fail to communicate with facilities that use as ingredients potentially affected foods; and three, the food product categories do not make useful distinctions between categories. Comments claimed that these limitations would make food product code categories useless and even have a negative impact on FDA's ability to communicate with facilities by diverting resources that could be better used elsewhere.

(Response) FDA disagrees with these comments. Consultations with FDA field personnel identify food product categories as an essential part of registration. FDA field personnel state that they would use food product category information to identify facilities potentially affected by a particular emergency, such as a terrorist threat or class 1 recall and for planning inspections. For example, needing to contact only 200 facilities with information about a threat instead of 20,000 will enhance FDA's speed and the reliability of the message. FDA believes that facilities can correctly categorize their products, and FDA will provide interactive help menus as part of the electronic registration system to aid facilities in correctly identifying the appropriate food product categories for their products. Also, FDA will provide a link to the agency's product code builder, which will allow facilities to search for their particular products.

FDA staff have experience using food product categories in their current enforcement activities and have found them to make useful distinctions between foods. FDA is also aware that some products may be ingredients in other food products and will use that information in selecting which facilities

to inform of a threat. While FDA recognizes that in some instances and depending on the nature of the threat, it may not be able to target only certain facilities with which to communicate (*e.g.*, a threat against a food product used as an ingredient in many finished products), this does not mean that having product category information would not help FDA focus its resources in other situations (*e.g.*, a threat specifically against soft drink beverage facilities).

(Comment 189) Some comments stated that including food product categories was necessary for the registration system to have any utility.

(Response) FDA agrees with these comments and has chosen to include product categories as a required element in the registration.

c. *U.S. agent.*

(Comment 190) Many comments state that requiring a U.S. agent would generate no benefits and might even inhibit communications between the facility and FDA. Comments offer alternatives such as not requiring the U.S. agent to reside or maintain a place of business in the United States, exempting facilities that provide an e-mail address from the U.S. agent requirement, and making the U.S. agent optional.

(Response) FDA does not agree that a U.S. agent will inhibit communications with FDA. The facility may opt to register with FDA directly and have FDA communicate directly with the facility in case of an emergency. Therefore, requiring a U.S. agent will not lower the expected benefits, as FDA still would have a contact in the United States for each facility with which the agency can communicate on routine matters (*e.g.* issuance of new regulations or guidance applicable to the facility). For some facilities that lack the ability to communicate easily with the United States, due, for example, to language barriers or lack of telephone or Internet access, the U.S. agent will be an important link for both registering the facility, if the owner, operator, or agent in charge authorizes the U.S. agent (if an individual) to register the facility, and communicating with FDA. For a facility that prefers to register and communicate with FDA itself, the U.S. agent still provides additional benefits, such as of being in the same, or nearby, time zone.

d. *Frequency of updates.*

(Comment 191) Many comments request that FDA require less frequent updates of registration information on the basis of high costs to update registration, without generating offsetting benefits.

(Response) FDA has lengthened the update period to 60 days, but has not extended it to the 6 to 12 months requested in many comments. The usefulness of the registration database depends in large part on its accuracy. Allowing longer times for updates will considerably reduce the accuracy of the database, while, as shown in the analysis of costs, will not significantly lower the costs. For most facilities, there will be little difference in costs for updates for 60 days versus annually. The largest costs will be to large manufacturers/processors, which are estimated to update twice a year, at a cost of approximately 2 hours of labor. However, allowing yearly updates would mean that more than 50 percent of the registrations in the database would contain incorrect information at any given point in time, versus less than 10 percent with 60 day updates. Although, FDA is unable to quantify the benefit of a more accurate database, the functionality of the database will be substantially better with a smaller percentage of registrations containing inaccurate information.

Additionally, when foreign food facilities attempt to import their product into the United States, their prior notice will be checked against the registration database. If there are discrepancies between the registration database and information in the prior notice, the shipment will be flagged for followup by FDA personnel, as deemed appropriate. Discrepancies confirmed by FDA border inspections may cause FDA or CBP to examine the shipment.

Table 16.--Summary of Annualized Costs and Qualitative Benefits

	Discount Rate	Final Rule	Longer Updates	No Product Categories	No U.S. Agent
Domestic costs	3%	$6.3	$5.9	$5.8	$6.3
Foreign costs	3%	$185.5	$185.2	$185.1	$11.5
FDA costs	3%	$6.5	$6.5	$6.5	$6.5
Total costs		$198.3	$197.6	$197.4	$24.3
Domestic costs	7%	$4.8	$4.5	$4.5	$4.8
Foreign costs	7%	$136.5	$136.3	$136.2	$9.3
FDA costs	7%	$4.9	$4.9	$4.9	$4.9
Total costs		$146.2	$145.7	$145.6	$19.0
Benefits			lower	lower	lower

V. Interim Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA has concluded that this interim final rule would have a significant economic impact on a substantial number of small entities. The following analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis under the Regulatory Flexibility Act.

(Comment 192) Several comments state that FDA underestimated the impact of the registration on small entities. Small domestic facilities may be adversely affected if their foreign trading partners stop exporting to the United States and small entities may incur higher costs than estimated in the

PRIA. Particularly, small facilities that operate in small niche markets may incur large expenses finding new suppliers.

(Response) FDA did not include in the Preliminary Regulatory Flexibility Analysis the cost of small entities losing foreign suppliers. FDA has estimated that 16 percent of foreign facilities may stop exporting to the United States to avoid the registration requirements. FDA estimates that the impact of registration on the number of line entries submitted for import into the United States will be less than 2 percent of all food entries. This may result in a significant impact on a substantial number of small entities. However, FDA is not able to predict how many small entities will be adversely affected or the size of the impact, and none of the comments provided a basis from which to estimate this impact.

Of the 216,271 domestic entities covered under the interim final rule, 99 percent are small according to the Small Business Administration's (SBA's) regulations. The expected burden for small entities is low, between $90 and $147. For some small facilities, however, costs may be much higher than the expected burden. As stated previously, there is a potential for large transaction costs associated with finding new trading partners. Also, some small facilities may experience unusual difficulties in registering, such as difficulty understanding the requirements, difficulty finding the registration form or website, or confusion over whether they are required to register. With such a large number of facilities affected, if a meaningful percentage of small entities experience a much larger burden, a substantial number of small entities will experience a significant economic effect. A discussion of options considered for small entities was included in the proposed rule. Additional options are also considered in the final regulatory impact analysis, which may also be considered an analysis of options for small businesses because the vast majority of affected entities are small.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $113 million. FDA has determined that this interim final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of Congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the SBREFA, the Office of Management and Budget (OMB) has determined that this interim final rule is a major rule for the purpose of Congressional review.

VIII. Paperwork Reduction Act of 1995

This interim final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown later with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Registration of Food Facilities.

Description: The Bioterrorism Act contains a provision requiring the Secretary to issue a regulation requiring that domestic and foreign facilities that manufacture/process, pack, or hold food intended for consumption in the United States register with FDA by December 12, 2003. Under the Bioterrorism Act, a foreign facility is one that manufactures/processes, packs, or holds food for consumption in the United States without further processing or packaging outside the United States. Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3, unless "most/all" human food categories "or none of the above mandatory categories" is checked; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, under the interim final rule, facilities would be encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal. Under the interim final rule, facilities would also be required to submit timely updates within 60 days of a change to any required information on their registration form, and are required to cancel their registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States.

Description of Respondents: Domestic facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register. Foreign facilities are required to register if they manufacture/process food for consumption in the United States that is not further processed or packaged before being shipped to the United States or if they pack or hold such food. A food is not considered to have been further processed solely because labeling was added or other *de minimis* activity was performed with respect to the food.

TABLE 17.—NO. OF RESPONDENTS

Domestic facilities	216,271
Foreign facilities	205,405
Total	421,676

Burden: In the PRA analysis of the proposed rule, FDA estimated that it would take an administrative worker with Internet access 1 hour to read and understand the registration requirements; this time was doubled to 2 hours of an administrative worker's time for those facilities without Internet access. In response to comments, FDA has revised this estimate to 1 or 2 hours of a manager's time to read and understand the regulations. Foreign facilities' workers would need 1 hour to read and understand the registration requirements, if they have access to the Internet and can read and write in English. An additional 5 hours would be needed if they do not have Internet access, and an additional 5 hours would be needed if they do not read or understand English. In subsequent years, facilities that enter the industry would have to register, facilities that close would have to notify FDA of their closure, and facilities that have changes in their registration information would have to provide updates to FDA. FDA estimated that annually 10 percent of covered facilities would close, 10 percent would open (SBA Small Businesses by the Numbers), and 20 percent of registered facilities would have changes to their registration information.

Next, FDA estimates that filling out a registration form would take a total of 1 hour: 45 minutes of an administrative worker's time and 15 minutes of an owner, operator, or agent in charge's time to verify that the registration information is correct before submitting the form to FDA. Foreign facilities' workers would need 1 hour to fill out the form, if they have access to the Internet and can read and write in English. An additional 1 hour would be needed if they do not have Internet access and an additional 1 hour would be needed if they do not read or understand English. Table 18 of this document shows the burden by domestic and foreign facilities, availability of the Internet, and fluency in English. FDA has information on the percentages of foreign facilities without Internet access and without employees fluent in English, but no information on the percentages of facilities with a particular combination of these characteristics. To compute the burden hours, for ease of computation and reporting, FDA assigned to zero facilities the condition of Internet access and no employees fluent in English and used the percentages of facilities without Internet access and with no employees fluent in English to report numbers of facilities with Internet and English-speaking employees, without Internet and without English-speaking employees, and without Internet and with English-speaking employees. FDA believes that facilities will only use the CD–ROM option, if it will require the same, or fewer hours, than another option.

In the following years, new facilities will have to register with FDA. These new facilities will bear the same burden to register that facilities incurred in the first year. Based on estimates by SBA that 10 percent of all businesses are new (SBA, Small Business by the Numbers), FDA estimates that the number of new facilities each year will be equal to 10 percent of the total number of facilities. Also, a facility that goes out of business, changes ownership, or stops manufacturing/processing, packing, or holding food for consumption in the United States will have to cancel its registration. FDA estimated that 10 percent of the total number of facilities will have to cancel their registration, also based on SBA statistics. FDA estimated that it would take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Finally, facilities for which there is a change of information submitted in their registration will have to update their registration. FDA estimated that each year 20 percent of facilities will have to update the information submitted in their registration. This estimate is revised to 55 percent based on comments. It will take these facilities approximately 1 hour to locate the correct form, enter the updated information, and send it to FDA. Table 19 of this document presents an estimate of the burden hours for new facilities, and updates and cancellations for previously registered facilities in future years.

Additionally, facilities that are not registered and are required by FDA to move their food shipment to secure storage must also notify FDA of the location of the secure storage. This paperwork burden is already estimated in Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 FR 5428), which requires imports that fail to give adequate notice, including failure to provide a required registration number, to place their shipment in secure storage.

In response to comments, FDA added the option of submitting registrations by CD–ROM. FDA believes that registrants will only use this option if it will take them as the same as or less time than submitting their registrations by Internet or mail. Therefore, the total number of burden hours will remain the same or be decreased by the availability of the CD–ROM option.

(Comment 193) FDA received numerous comments about the usefulness of the information, number of respondents, and the hourly burden for the respondents.

(Response) FDA has responded to comments relating to the usefulness of the information collection in section IV. A.6 of this document (Benefits). Similarly, the agency has responded to comments relating to the number of respondents in section IV.A.3 of this document (number of facilities affected). Finally, the agency has responded to comments regarding the hourly burden in section IV.A.4.a of this document (time costs).

(Comment 194) FDA received numerous comments that the PRA analysis was incorrect, because it failed to include duplicative registration requirements for many facilities.

(Response) The PRA analysis counts the burden hours resulting from the provisions of the interim final rule. Burden hours for other registration provisions would be counted in the PRA analyses for those rules. Including burden hours for other registration provisions would result in double counting of the burden hours. Therefore, FDA does not agree with this comment.

(Comment 195) FDA received comments that FDA had underestimated the frequency with which facilities would need to update their registrations.

(Response) As noted, the interim final rule changes the requirement for timely update from 30 to 60 days. FDA re-estimated the frequency with which facilities would update their registrations. Instead of 20 percent, 55 percent of facilities will update their registrations each year. A full discussion of how this estimate was reached is included in the response to comment 197 (section IV.A.5.c of this document).

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Table 18.--Estimated Annual Reporting Burden--First Year[1]

	FDA Form No.	No. of respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
21 CFR Part 1						
1.231(a), 1.232, 1.233[2]	FDA 3537	152,552	1	152,552	2	305,104
1.231(b), 1.232, 1.233[3]	FDA 3537	61,719	1	61,719	3	185,157
1.231(c), 1.232, 1.233[2]	FDA 3537	1,000	1	1,000	2	2,000
1.231(c), 1.232, 1.233[3]	FDA 3537	1,000	1	1,000	3	3,000
1.231(a), 1232, 1.233[4]	FDA 3537	31,864	1	31,864	2	63,728
1.231(b), 1.232,1.233,[5]	FDA 3537	29,811	1	29,811	7	208,677
1.231(b), 1.232, 1.233,[6]	FDA 3537	141,730	1	141,730	12	1,700,760
1.231(c), 1.232, 1.233[4]	FDA 3537	1,000	1	1,000	2	2,000
1.231(c), 1.232, 1.233[5]	FDA 3537	1,000	1	1,000	7	7,000
Total hours						2,477,426

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Domestic facilities with Internet access.
[3]Domestic facilities without Internet access.
[4]Foreign facilities with Internet access and fluent in English.
[5]Foreign facilities without Internet access and fluent in English.
[6]Foreign facilities without Internet access and not fluent in English.

Table 19.--Estimated Annual Reporting Burden--Subsequent Years[1]

21 CFR Part 1	FDA form number	Number of respondents	Annual frequency per respondent	Total annual responses	Hours per response	Total Hours
New Facilities						
1.231(a), 1.232, 1.233[2]	FDA 3537	15,255	1	15,255	2	30,510
1.231(b), 1.232, 1.233[3]	FDA 3537	6,172	1	6,172	3	18,516
1.231(c), 1.232, 1.233[2]	FDA 3537	100	1	100	2	200
1.231(c), 1.232, 1.233[3]	FDA 3537	100	1	100	3	300
1.231(a), 1.232, 1.233[4]	FDA 3537	3,186	1	3,186	2	6,372
1.231(b), 1.232, 1.233[5]	FDA 3537	2,981	1	2,981	7	20,867
1.231(b), 1.232, 1.233[6]	FDA 3537	14,173	1	14,173	12	170,076
1.231(c), 1.232, 1.233[4]	FDA 3537	100	1	100	2	200
1.231(c), 1.232, 1.233[5]	FDA 3537	100	1	100	7	700
Previously registered facilities						
1.234(e),[2] 1.235(e)	FDA 3537/ 3537a	99,159	1	99,159	1	99,159
1.234(d),[3] 1.235(d)	FDA 3537/ 3537a	40,117	1	40,117	1	40,117
1.234(e),[2] 1.235(e)	FDA 3537/ 3537a	650	1	650	1	650
1.234(e),[3] 1.235(e)	FDA 3537/ 3537a	650	1	650	1	650
1.234(c),[4] 1.235(c)	FDA 3537/ 3537a	20,711	1	20,711	1	20,711
1.234(d),[5] 1.235(d)	FDA 3537/ 3537a	19,377	1	19,377	1	19,377
1.234(d),[6] 1.235(d)	FDA 3537/ 3537a	92,125	1	92,125	1	92,125
1.234(e),[4] 1.235 (e)	FDA 3537/ 3537a	650	1	650	1	650
1.234(e),[5] 1.235 (e)	FDA 3537/ 3537a	650	1	650	1	650
Total						521,830

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Domestic facilities with Internet access.
[3]Domestic facilities without Internet access.
[4]Foreign facilities with Internet access and fluent in English.
[5]Foreign facilities without Internet access and fluent in English.
[6]Foreign facilities without Internet access and not fluent in English.

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The information collection provisions of this interim final rule have been submitted to OMB for review.

Prior to the effective date of this interim final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Request for Comments

FDA is issuing this rule as an interim final rule, with an opportunity for public comment on specific issues identified below. Although the agency is seeking comment on this interim final rule, it is effective December 12, 2003. This means that the rule's requirements will be in effect and have the force and effect of law from that date until any subsequent modification by the issuance of a final rule. Accordingly, as required by section 305 of the Bioterrorism Act, all covered facilities must be registered with FDA by December 12, 2003.

As noted, elsewhere in this issue of the **Federal Register**, FDA is publishing an interim final rule concerning prior notice of imported food shipments. Given the relatedness of the prior notice and food facilities registration rules, FDA is establishing a comment period for the registration rule that coincides with the comment period on the prior notice interim final rule. Thus, the comment period for the registration interim final rule will open today for a period of 75 days. Moreover, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days in March 2004.

As noted elsewhere in this issue of the **Federal Register**, FDA's economic analysis is based on a number of assumptions. To improve this analysis, FDA invites public comment on the following issues:

1. The cost to foreign facilities of hiring and retaining a U.S. agent. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship in response to this interim final rule, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes.

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent;

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

FDA will seriously consider all comments submitted. FDA is dedicated to updating this estimate with the best available information in order to inform decision makers who may be considering regulatory alternatives in developing a final rule.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) written or electronic comments regarding this interim final rule by December 24, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit one electronic copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation is effective on December 12, 2003. The agency will address comments received and confirm or amend the interim final rule in a final rule. The agency, however, will not consider any comments that have been previously considered during this rulemaking.

X. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the interim final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the interim final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Brown, Bradley, Memorandum to the file, July 21, 2003.
2. U.S. Census Bureau, 2000 County Business Patterns, available at *http://www.census.gov/epcd/cbp/view/cbpview.html*.
3. U.S. Census Bureau, 1999 Nonemployer Statistics, available at *http://www.census.gov/epcd/nonemployer/index.html*.
4. U.S. Food and Drug Administration, Field Accomplishments and Compliance Tracking System (FACTS), fiscal year 2002.
5. U.S. Department of Agriculture, National Agriculture Statistics Service, 1997 Census of Agriculture-United States Data, available at *http://www.nass.usda.gov/census/*.
6. U.S. Census Bureau, 1997 Economic Census of Transportation and Warehousing, available at *http://www.census.gov/svsd/www/97trans.html*.
7. Direct Selling Association, Direct Selling by the Numbers, accessed at *http://www.dsa.org/research/numbers.htm#DISTTYPE*, 7/10/2003.
8. Direct Sales World, Facts and Figures and Comment of the World of Direct Sales, accessed at *http://www.nmworld.com/pages/Countries/USA/index.html*, 7/10/2003.
9. U.S. Census Bureau, Guam: 1997 Census of the Outlying Areas, available at *http://www.census.gov/prod/ec97/oa97e-6.pdf*.
10. U.S. Census Bureau, Northern Mariana Islands: 1997 Census of the Outlying Areas, available at *http://www.census.gov/prod/ec97/oa97e-7.pdf*.
11. U.S. Census Bureau, Puerto Rico: 1997 Census of the Outlying Areas, available at *http://www.census.gov/prod/ec97/oa97e-4.pdf*.
12. U.S. Census Bureau, Virgin Islands: 1997 Census of the Outlying Areas, available at *http://www.census.gov/prod/ec97/oa97e-5.pdf*.
13. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), fiscal year 2002.

14. RTI, Survey of Manufacturing Practices in the Dietary Supplement Industry, Prepared for FDA, May 17, 2003.
15. Brown, Bradley, Memorandum to file, November 22, 2002.
16. U.S. Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01–04, available at *http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf*.
17. U.S. Small Business Administration, Office of Advocacy, Small Business by the Numbers May 2002, available at *http://www.sba.gov/advo/stats/sbfaq.html*.
18. Cato, Todd, Memo to the record, May 23, 2003.
19. Gripp, Russell, Memo to the record, May 14, 2003.
20. Hennessy T. W., Hedberg C. W., Slutsker L, *et al.*, and the Investigation Team, "A National Outbreak of *Salmonella enteritidis* Infections From Ice Cream," *The New England Journal of Medicine*, May 16, 1996, pp. 1281–1286.
21. Kolavic S. A., Kimura A, Simons S. L., *et al.*, "An Outbreak of Shigella Dysenteriae Type 2 Among Laboratory Workers Due to Intentional Food Contamination," *The Journal of the American Medical Association*, 278:5:396–403.
22. Trook T. J., Tauxe R. V., Wise R.P., *et al.* "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *The Journal of the American Medical Association*, 278:5:389–397.
23. Lee L. A., Ostroff S. M., McGee H. B., *et al.* "An Outbreak of Shigellosis at an Outdoor Music Festival," *American Journal of Epidemiology*, 133:6:608–615.
24. Herwaldt B. L., Ackers M. L., and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, pp. 1548–1556.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 20 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Subpart H (§§ 1.225 through 1.243) is added to part 1 to read as follows (subparts F and G are reserved):

Subparts F–G [Reserved]

Subpart H—Registration of Food Facilities

General Provisions

Sec.

Procedures for Registration of Food Facilities

Additional Provisions

General Provisions

§ 1.225 Who must register under this subpart?

(a) You must register your facility under this subpart if you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for one of the exemptions in § 1.226.

(b) If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.

(c) If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.

§ 1.226 Who does not have to register under this subpart?

This subpart does not apply to the following facilities:

(a) A foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States. A facility is not exempt under this provision if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a *de minimis* nature;

(b) Farms;

(c) Retail food establishments;

(d) Restaurants;

(e) Nonprofit food establishments in which food is prepared for, or served directly to, the consumer;

(f) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. However, those fishing vessels otherwise engaged in processing fish are subject to this subpart. For the purposes of this section, "processing" means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel;

(g) Facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

§ 1.227 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Facility* means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(i) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(ii) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

(3) *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:

(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

(4) *Food* has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)),

(i) Except for purposes of this subpart, it does not include:

(A) *Food* contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)), or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(5) *Holding* means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(6) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

(7) *Nonprofit food establishment* means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

(8) *Packaging* (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

(9) *Packing* means placing food into a container other than packaging the food.

(10) *Restaurant* means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(i) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(ii) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

(11) *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

(12) *Trade name* means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

(13) *U.S. agent* means a person (as defined in section 201(e) of the act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent cannot be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(i) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies under § 1.233(e) another emergency contact.

(ii) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility.

(iii) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

(14) *You* or *registrant* means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Procedures for Registration of Food Facilities

§ 1.230 When must you register?

The owner, operator, or agent in charge of a facility that manufactures/processes, packs or holds food for consumption in the United States must register the facility no later than December 12, 2003. The owner, operator, or agent in charge of a facility that begins to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must register before the facility begins such activities. An owner, operator, or agent in charge of a facility may authorize an individual to register the facility on its behalf.

§ 1.231 How and where do you register?

(a) *Electronic registration.* (1) To register electronically, you must register at *http://www.fda.gov/furls*, which is available for registration 24 hours a day, 7 days a week. This website is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. An individual authorized by the owner, operator, or agent in charge of a facility may also register a facility electronically.

(2) FDA strongly encourages electronic registration for the benefit of both FDA and the registrant.

(3) Once you complete your electronic registration, FDA will automatically provide you with an electronic confirmation of registration and a permanent registration number.

(4) You will be considered registered once FDA electronically transmits your confirmation and registration number.

(b) *Registration by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in paragraph (a) of this section, you may register by mail or fax.

(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1–877–FDA–3882 (1–877–332–3882).

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301–210–0247.

(3) If any required information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed registration submissions into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the registration as entered, confirmation of registration, and your registration number. When responding to a registration submission, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(7) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(c) *Registration by CD–ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under paragraph (a) of this section, you may register by CD–ROM.

(1) Registrants submitting their registrations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(2) These files must be submitted on a portable document format (PDF) rendition of the registration form (Form 3537) and be accompanied by one signed copy of the certification statement that appears on the registration form (Form 3537).

(3) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) A CD–ROM may contain registrations for as many facilities as needed up to the CD–ROM's capacity.

(5) The registration on the CD–ROM for each separate facility must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD–ROM to the U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the submitter unprocessed.

(8) FDA will enter CD–ROM submissions that comply with these specifications into its registration system, along with the complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the registration(s) as entered, confirmation of registration, and each facility's assigned registration number.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately update your facility's registration as specified in § 1.234.

(11) Your facility is considered registered once FDA enters your facility's registration data into the registration system and the system generates a registration number.

(d) *Fees.* No registration fee is required.

(e) *Language.* You must submit all registration information in the English language except an individual's name, the name of a company, the name of a street, and a trade name may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

§ 1.232 What information is required in the registration?

Each registrant must submit the following information through one of the methods described in § 1.231:

(a) The name, full address, and phone number of the facility;

(b) The name, address, and phone number of the parent company, if the facility is a subsidiary of the parent company;

(c) For domestic and foreign facilities, the names, addresses, and phone numbers of the owner, operator, and agent in charge.

(d) For a foreign facility, the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated under § 1.233(c));

(e) For a domestic facility, an emergency contact phone number;

(f) All trade names the facility uses;

(g) Applicable food product categories as identified in § 170.3 of this chapter, unless you check either "most/all human food product categories," according to § 1.233(e), or "none of the above mandatory categories" because your facility manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

(h) The name, address, and phone number for the owner, operator, or agent in charge;

(i) A statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate. If the individual submitting the form is not the owner, operator, or agent in charge of the facility, the registration must also include a statement in which the individual certifies that the information submitted is true and accurate, certifies that he/she is authorized to submit the registration, and identifies by name, address, and telephone number, the individual who authorized submission of the registration. Each registration must include the name of the individual registering the facility submitting the registration, and the individual's signature (for the paper and CD–ROM options).

§ 1.233 What optional items are included in the registration form?

FDA encourages, but does not require, you to submit the following items in your facility's registration. These data will enable FDA to communicate more quickly with facilities that may be the target of a terrorist threat or attack, or otherwise affected by an outbreak of foodborne illness. This information includes:

(a) Fax number and e-mail address of the facility;

(b) Preferred mailing address, if different from that of the facility;

(c) Fax number and e-mail address of the parent company, if the facility is a subsidiary of the parent company;

(d) For a domestic facility, emergency contact name, title, and e-mail address;

(e) For a foreign facility, an emergency contact name, title, phone number and e-mail address. FDA will consider the facility's U.S. agent the facility's emergency contact unless the facility chooses to designate another person to serve as an emergency contact under this section;

(f) For a foreign facility, title, fax number, and e-mail address of the U.S. agent;

(g) Type of activity conducted at the facility (e.g., manufacturing/processing or holding);

(h) Food categories not identified in § 170.3 of this chapter, which are provided in Form 3537 sections 11a (e.g., infant formula, animal byproducts and extracts) and 11b (e.g., grain products, amino acids);

(i) Type of storage, if the facility is primarily a holding facility;

(j) A food product category of "most/all human food product categories," if the facility manufactures/processes, packs, or holds foods in most or all of the categories identified in § 170.3 of this chapter;

(k) Approximate dates of operation, if the facility's business is seasonal;

(l) The fax number and e-mail address of the owner, operator, or agent in charge; and

(m) The fax number and e-mail address of the individual who authorized submission of the registration.

§ 1.234 How and when do you update your facility's registration information?

(a) *Update requirements.* The owner, operator, or agent in charge must submit an update to a facility's registration within 60 calendar days of any change to any of the information previously submitted under § 1.232 (*e.g.*, change of operator, agent in charge, or U.S. agent), except a change of the owner. The owner, operator, or agent in charge may authorize an individual to update a facility's registration.

(b) *Cancellation due to ownership changes.* If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as specified in § 1.235 within 60 calendar days of the change and the new owner must re-register the facility as specified in § 1.231. The former owner may authorize an individual to cancel a facility's registration.

(c) *Electronic update.* (1) To update your registration electronically, you must update at *http://www.fda.gov/furls.*

(2) Once you complete your electronic update, FDA will automatically provide you with an electronic confirmation of your update.

(3) Your registration will be considered updated once FDA transmits your update confirmation, unless notified otherwise.

(d) *Update by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a)), you may update your facility's registration by mail or by fax:

(1) You must update your registration using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting the form by phone at 1–877–FDA–3882 (1–877–332–3882).

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–210–0247.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a registration form for revision, FDA will use the means by which the registration was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible updates into its registration system, along with CD–ROM submissions, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the registration form a copy of the update as entered and confirmation of the update. When responding to an update submission, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(7) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

(e) *Update by CD–ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods provided under § 1.231(a), you may update your facilities' registrations by CD–ROM.

(1) Registrants submitting their updates in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(2) Update files must be submitted on a PDF rendition of FDA's registration form (Form 3537) and be accompanied by one signed copy of the certification statement on the registration form (Form 3537).

(3) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD–ROM may contain updates for as many facilities as needed up to the CD–ROM's capacity.

(5) The update for each facility on the CD–ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD–ROM to U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives an update CD–ROM that does not comply with these specifications, it will return the CD–ROM to the registrant unprocessed.

(8) FDA will enter CD–ROM update submissions into its registration system, along with the complete and legible mailed and faxed update submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the update(s) as entered and confirmation of the update.

(10) If any update information you previously submitted was incorrect at the time of submission, you must immediately resubmit your update.

(11) Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.

§ 1.235 How and when do you cancel your facility's registration information?

(a) *Notification of registration cancellation.* A facility canceling its registration must do so within 60 calendar days of the reason for cancellation (*e.g.*, facility ceases operations, ceases providing food for consumption in the United States, or the facility is sold to a new owner).

(b) *Cancellation requirements.* The cancellation of a facility's registration must include the following information:

(1) The facility's registration number;

(2) Whether the facility is domestic or foreign;

(3) The facility name and address;

(4) The name, address, and e-mail address (if available) of the individual submitting the cancellation; and

(5) A statement certifying that the information submitted is true and accurate, and that the person submitting the cancellation is authorized by the facility to cancel its registration.

(c) *Electronic cancellation.* (1) To cancel your registration electronically, you must cancel at *http://www.fda.gov/furls.*

(2) Once you complete your electronic cancellation, FDA will automatically provide you with an electronic confirmation of your cancellation.

(3) Your registration will be considered cancelled once FDA transmits your cancellation confirmation.

(d) *Cancellation by mail or fax.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facility's registration by mail or fax.

(1) You must cancel your registration using Form 3537a. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857, or by requesting the form by phone at 1–877–FDA–3882 (1–877–332–3882).

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in paragraph (d)(1) of this section or fax it to 301–210–0247.

(3) If the information on the form is incomplete or illegible when FDA receives it, FDA will return the form to you for revision, provided that your mailing address or fax number is legible and valid. When returning a cancellation form for revision, FDA will use the means by which the cancellation was received by the agency (*i.e.*, by mail or fax).

(4) FDA will enter complete and legible mailed and faxed cancellations into its registration system, along with CD–ROM cancellations, as soon as practicable, in the order FDA receives them.

(5) FDA will then mail to the address or fax to the fax number on the cancellation form a copy of the cancellation as entered and confirmation of the cancellation. When responding to a cancellation, FDA will use the means by which the form was received by the agency (*i.e.*, by mail or fax).

(6) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(7) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

(e) *Cancellation by CD–ROM for multiple submissions.* If, for example, you do not have reasonable access to the Internet through any of the methods described in § 1.231(a), you may cancel your facilities' registrations using a CD–ROM.

(1) Registrants submitting their cancellations in CD–ROM format must use ISO 9660 (CD–R or CD–RW) data format.

(2) Cancellation files must be submitted on a PDF rendition of the cancellation form (Form 3537a) and be accompanied by one signed copy of the certification statement on the cancellation form.

(3) Each submission on the CD–ROM must contain the same preferred mailing address in the appropriate block on Form 3537.

(4) The CD–ROM may contain cancellations for as many facilities as needed up to the CD–ROM's capacity.

(5) The cancellation for each facility on the CD–ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company.

(6) You must mail the CD–ROM to U.S. Food and Drug Administration (HFS–681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD–ROM that does not comply with these specifications, it will return the CD–ROM to the registrant unprocessed.

(8) FDA will enter CD–ROM submissions that meet the specifications into its registration system, along with complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD–ROM, FDA will mail to the preferred mailing address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

Additional Provisions

§ 1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of it's facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure

under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

PART 20—PUBLIC INFORMATION

Subpart F—Availability of Specific Categories of Records

■ 3. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2562; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 4. Section 20.100 is amended by adding paragraph (c)(42) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(42) Registration of food facilities, in § 1.243 of this chapter.

Dated: October 2, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

Dated: October 8, 2003.

Tom Ridge,

Secretary of Homeland Security.

BILLING CODE 4160–01–P

Note: The following appendix will not appear in the Code of Federal Regulations.

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

FDA USE ONLY

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

USE BLUE OR BLACK INK ONLY

Date: _____ (MM/DD/YYYY)

Section 1 - TYPE OF REGISTRATION

1a. ○ DOMESTIC REGISTRATION	○ FOREIGN REGISTRATION
1b. ○ INITIAL REGISTRATION	○ UPDATE OF REGISTRATION INFORMATION

If update, provide the following:
Facility Registration Number: _____ PIN _____

Check all that apply and further identify changes in the applicable sections.	○ United States Agent Change – Foreign facilities only
○ Facility Name Change	○ Seasonal Facility Dates of Operation Change
○ Facility Address Change (see instructions)	○ Type of Activity Change
○ Preferred Mailing Address Change	○ Type of Storage Change
○ Parent Company Change	○ Human Food Product Category Change
○ Emergency Contact Change	○ Animal Food Product Category Change
○ Trade Name Change	○ Operator or Agent in Charge Change

1c. ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY? Yes ○ No ○
If "yes", provide the following information, if known.

Previous owner's name:	Previous owner's registration number:

Section 2 - FACILITY NAME / ADDRESS INFORMATION

FACILITY NAME:	
FACILITY STREET ADDRESS, Line 1:	
FACILITY STREET ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

Form 3537 (1/03)

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 3 - PREFERRED MAILING ADDRESS INFORMATION complete this section only if different from Section 2, Facility Name/Address Information (OPTIONAL)	
NAME:	
ADDRESS, Line 1:	
ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/ Country Code):
FAX NUMBER (Include Area/ Country Code):	E-MAIL ADDRESS:

Section 4 - PARENT COMPANY NAME / ADDRESS INFORMATION (IF APPLICABLE AND IF DIFFERENT FROM SECTIONS 2 AND 3). IF INFORMATION IS THE SAME AS ANOTHER SECTION, CHECK WHICH SECTION: SECTION 2 ○ or SECTION 3 ○	
NAME OF PARENT COMPANY:	
STREET ADDRESS OF PARENT COMPANY, Line 1:	
STREET ADDRESS OF PARENT COMPANY, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/ Country Code):
FAX NUMBER (OPTIONAL; Include Area/Country Code):	E-MAIL ADDRESS (OPTIONAL):

Section 5 - FACILITY EMERGENCY CONTACT INFORMATION (OPTIONAL FOR FOREIGN FACILITIES. FDA WILL USE YOUR U.S. AGENT AS YOUR EMERGENCY CONTACT UNLESS YOU CHOOSE TO DESIGNATE A DIFFERENT CONTACT HERE.)	
INDIVIDUAL'S NAME (OPTIONAL):	
TITLE (OPTIONAL):	EMERGENCY CONTACT PHONE (Include area/ country code):
E-MAIL ADDRESS (OPTIONAL):	

Form Approval: OMB No. 0910-xxxx
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DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 6 - TRADE NAMES (IF THIS FACILITY USES TRADE NAMES OTHER THAN THAT LISTED IN SECTION 2 ABOVE, LIST THEM BELOW (E.G., "ALSO DOING BUSINESS AS," "FACILITY ALSO KNOWN AS")
ALTERNATE TRADE NAME #1:
ALTERNATE TRADE NAME #2:
ALTERNATE TRADE NAME #3:
ALTERNATE TRADE NAME #4:

Section 7 - UNITED STATES AGENT (TO BE COMPLETED BY FACILITIES LOCATED OUTSIDE ANY STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.)		
NAME OF U.S. AGENT:		
TITLE (OPTIONAL):		
ADDRESS, Line 1:		
ADDRESS, Line 2:		
CITY:	STATE:	ZIP CODE:
U.S. AGENT PHONE NUMBER (Include Area Code):	EMERGENCY CONTACT PHONE NUMBER (Include Area Code):	
FAX NUMBER (OPTIONAL; Include Area Code):	E-MAIL ADDRESS (OPTIONAL):	

Section 8 - SEASONAL FACILITY DATES OF OPERATION (GIVE THE APPROXIMATE DATES THAT YOUR FACILITY IS OPEN FOR BUSINESS, IF ITS OPERATIONS ARE ON A SEASONAL BASIS) (OPTIONAL)
DATES OF OPERATION:

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See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 9 - TYPE OF ACTIVITY CONDUCTED AT THE FACILITY
(CHECK ALL TYPES OF OPERATIONS THAT ARE PERFORMED AT THIS FACILITY REGARDING THE MANUFACTURING/PROCESSING, PACKING OR HOLDING OF FOOD) (OPTIONAL)

O Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	
O Acidified / Low Acid Food Processor	O Labeler / Relabeler
O Interstate Conveyance Caterer/Catering Point	O Manufacturer / Processor
O Molluscan Shellfish Establishment	O Repacker / Packer
O Commissary	O Salvage Operator (Reconditioner)
O Contract Sterilizer	O Animal food manufacturer / processor / holder

Section 10 - TYPE OF STORAGE (FOR FACILITIES THAT ARE PRIMARILY HOLDERS) (OPTIONAL)

O Ambient (neither frozen nor refrigerated) Storage	O Refrigerated Storage	O Frozen Storage

Section 11a - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION
To be completed by all food facilities. Please see instructions for further examples.
IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.

O 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)]	O 7. CHEESE AND CHEESE PRODUCTS [21 CFR 170.3 (n) (5)]
O 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula (Optional Selection)	O 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)]
O 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)]	O 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)]
O 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (16), (35)]	O 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)]
O 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALITIES & CHEWING GUM [21 CFR 170.3 (n) (6), (9), (25), (38)]	O 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (includes Medical Foods) [21 CFR 170.3 (n) (31)]
O 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING/INSTANT CEREALS [21 CFR 170.3 (n) (4)]	

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DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 11a - GENERAL PRODUCT CATEGORIES - FOOD FOR HUMAN CONSUMPTION (CONTINUED)
To be completed by all food facilities. Please see instructions for further examples.
IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.

12. DIETARY SUPPLEMENTS O Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3 (o) (20)] O Vitamins and Minerals [21 CFR 170.3 (o) (20)] O Animal By-Products and Extracts (Optional Selection) O Herbals and Botanicals (Optional Selection)	O 23. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)]
O 13. DRESSINGS AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)]	O 24. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11), (14), (17), (18), (23), (24), (29), (34), (40)]
O 14. FISHERY/SEAFOOD PRODUCTS [21 CFR 170.3 (n) (13), (15), (39), (40)]	O 25. NUT AND EDIBLE SEED PRODUCTS [21 CFR 170.3 (n) (26), (32)]
O 15. FOOD ADDITIVES, GENERALLY RECOGNIZED AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)	O 26. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)]
	O 27. SHELL EGG AND EGG PRODUCTS [21 CFR 170.3 (n) (11), (14)]
	O 28. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)]
	O 29. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)]
O 16. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9), (41), 21 CFR 170.3 (o) (21)]	O 30. SOUPS [21 CFR 170.3 (n) (39), (40)]
O 17. FRUITS AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)]	O 31. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)]
O 18. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)]	O 32. VEGETABLES AND VEGETABLE PRODUCTS [21 CFR 170.3 (n) (19), (36)]
O 19. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)]	O 33. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)]
O 20. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)]	O 34. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)]
O 21. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)]	O 35. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS),OR STARCH [21 CFR 170.3 (n) (1), (23)]
O 22. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)]	O 36. MOST/ALL HUMAN FOOD PRODUCT CATEGORIES (Optional Selection)
	O 37. NONE OF THE ABOVE MANDATORY CATEGORIES

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DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 11b - GENERAL PRODUCT CATEGORIES – FOOD FOR ANIMAL CONSUMPTION (OPTIONAL)

○ 1. GRAIN PRODUCTS (E.G., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE AND WHEAT)	○ 14. MILK PRODUCTS
○ 2. OILSEED PRODUCTS (E.G., COTTONSEED, SOYBEANS, OTHER OIL SEEDS)	○ 15. MINERALS
○ 3. ALFALFA AND LESPEDEZA PRODUCTS	○ 16. MISCELLANEOUS AND SPECIAL PURPOSE PRODUCTS
○ 4. AMINO ACIDS	○ 17. MOLASSES
○ 5. ANIMAL-DERIVED PRODUCTS	○ 18. NON-PROTEIN NITROGEN PRODUCTS
○ 6. BREWER PRODUCTS	○ 19. PEANUT PRODUCTS
○ 7. CHEMICAL PRESERVATIVES	○ 20. RECYCLED ANIMAL WASTE PRODUCTS
○ 8. CITRUS PRODUCTS	○ 21. SCREENINGS
○ 9. DISTILLERY PRODUCTS	○ 22. VITAMINS
○ 10. ENZYMES	○ 23. YEAST PRODUCTS
○ 11. FATS AND OILS	○ 24. MIXED FEED (POULTRY, LIVESTOCK, AND EQUINE)
○ 12. FERMENTATION PRODUCTS	○ 25. PET FOOD
○ 13. MARINE PRODUCTS	○ 26. MOST/ALL ANIMAL FOOD PRODUCT CATEGORIES

Section 12 – OWNER, OPERATOR, OR AGENT IN CHARGE INFORMATION

NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE

PROVIDE THE FOLLOWING INFORMATION, IF DIFFERENT FROM ALL OTHER SECTIONS ON THE FORM. IF INFORMATION IS THE SAME AS ANOTHER SECTION OF THE FORM, CHECK WHICH SECTION:

SECTION 2 ○ SECTION 3 ○ SECTION 4 ○ SECTION 7 ○

STREET ADDRESS, Line 1:

STREET ADDRESS, Line 2:

CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

Form 3537 (1/03)

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

DHHS/FDA - FOOD FACILITY REGISTRATION FORM

Section 13 - CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

SIGNATURE OF SUBMITTER

PRINT NAME OF THE SUBMITTER

CHECK ONE BOX: ○ A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

○ B. INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION (FILL IN BELOW)

IF YOU CHECKED BOX B ABOVE, INDICATE WHO AUTHORIZED YOU TO SUBMIT THE REGISTRATION:

○ OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

○ _____ NAME OF INDIVIDUAL WHO AUTHORIZED REGISTRATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN ADDRESS BELOW)

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL:

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 1:

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line 2:

CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):
FAX NUMBER (OPTIONAL; Include Area/ Country Code):	E-MAIL ADDRESS (OPTIONAL):

MAIL COMPLETED FORM TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5600 FISHERS LANE, ROCKVILLE, MD 20857, OR FAX IT TO (301) 210-0247.

FDA USE ONLY	
DATE REGISTRATION FORM RECEIVED	DATE NOTIFICATION SENT TO FACILITY

Public reporting burden for this collection of information is estimated to average between 1 and 12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN (HFS-024)
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number

Form 3537 (1/03)

Form Approval: OMB No. 0910-xxxx
Expiration Date:
See OMB Statement at end of form

FDA USE ONLY

USE BLUE OR BLACK INK ONLY

DHHS/FDA CANCELLATION OF FOOD FACILITY REGISTRATION FORM

FACILITY REGISTRATION NUMBER:	PIN:
O DOMESTIC REGISTRATION	O FOREIGN REGISTRATION

FACILITY NAME / ADDRESS INFORMATION

FACILITY NAME:	
FACILITY STREET ADDRESS, Line 1:	
FACILITY STREET ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	

CERTIFICATION STATEMENT

The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator, or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the cancellation on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the cancellation. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

SIGNATURE OF SUBMITTER

PRINT NAME OF THE SUBMITTER

CHECK ONE BOX: O A. OWNER, OPERATOR OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

O B. INDIVIDUAL AUTHORIZED TO SUBMIT THE CANCELLATION (FILL IN BELOW)

IF YOU CHECKED BOX B ABOVE, INDICATE WHO AUTHORIZED YOU TO SUBMIT THE CANCELLATION:

O OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

O _____ NAME OF INDIVIDUAL WHO AUTHORIZED CANCELLATION ON BEHALF OF OWNER, OPERATOR, OR AGENT IN CHARGE (FILL IN BELOW)

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL:

AUTHORIZING INDIVIDUAL ADDRESS, Line 1:	
AUTHORIZING INDIVIDUAL ADDRESS, Line 2:	
CITY:	STATE:
ZIP CODE (POSTAL CODE):	PROVINCE/TERRITORY:
COUNTRY:	PHONE NUMBER (Include Area/Country Code):

FDA USE ONLY:

DATE CANCELLATION FORM RECEIVED	DATE CONFIRMATION SENT TO FACILITY

MAIL COMPLETED FORM TO U.S. FOOD AND DRUG ADMINISTRATION, HFS-681, 5600 FISHERS LANE, ROCKVILLE, MD 20857, OR FAX IT TO (301) 210-0247.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CFSAN (HFS-024)
5100 Paint Branch Parkway
College Park, MD 20740

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

Form 3537a (1/03)

[FR Doc. 03-25849 Filed 10-9-03; 8:45 am]
BILLING CODE 4160-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N-0278]

RIN 0910-AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin on December 12, 2003, even in the absence of a final regulation. The interim final rule requires that the prior notice be submitted to FDA electronically via either the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PN System Interface). The information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6230.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

In the **Federal Register** of February 3, 2003 (68 FR 5428), the Department of Health and Human Services (FDA) and the Department of Treasury (U.S. Customs Service) issued a joint notice of proposed rulemaking requiring submission to FDA of prior notice of human and animal food that is imported or offered for import into the United States. The events of September 11, 2001, had highlighted the need to ensure that FDA had additional tools to help prevent a food-related bioterrorism event or other public health emergency. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A'Protection of Food Supply, section 307, which changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Under

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

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1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

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2. Section 1.231 is amended by revising paragraph (b)(1) to read as follows:

Sec. 1.231 How and where do you register?

* * * * *
(b) * * *
(1) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting a copy of this form by phone at 1-800-216-7331 or 301-575-0156.
* * * * *

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3. Section 1.232 is amended by revising paragraphs (d) and (g) to read as follows:

Sec. 1.232 What information is required in the registration?

* * * * *
(d) For a foreign facility, the name, address, phone number, and, if no emergency contact is designated under Sec. 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent;
* * * * *
(g) Applicable food product categories as identified in Sec. 170.3 of this chapter, unless you check either ``most/all human food product categories,'' according to Sec. 1.233(j), or ``none of the above mandatory categories'' because your facility manufactures/processes, packs, or holds a food that is not identified in Sec. 170.3 of this chapter;
* * * * *

Dated: May 10, 2004.
William K. Hubbard,
Associate Commissioner for Policy and Planning.
[FR Doc. 04-11598 Filed 5-21-04; 8:45 am]
BILLING CODE 4160-01-S

Interim Final Rule on Registration of Food Facilities (68 FR 58894)

[Federal Register: May 24, 2004 (Volume 69, Number 100)]
[Rules and Regulations]
[Page 29428]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr24my04-2]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N-0276]
RIN 0910-AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published an interim final rule in the Federal Register of October 10, 2003 (68 FR 58894). The interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States, to register with FDA by December 12, 2003. Due to several errors in Sec. Sec. 1.231 and 1.232 (21 CFR 1.231 and 1.232), the interim final rule contains some incorrect information. This document corrects those errors.

DATES: Effective May 24, 2004.

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1720.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 10, 2003 (68 FR 58894), FDA published an interim final rule on Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Since that time, FDA has discovered that the interim final rule contains several errors.

First, FDA is correcting the phone number to which registration form requests and other technical questions should be directed. The appropriate phone numbers are 1-800-216-7331 or 301-575-0156.

Second, Sec. 1.232 of the interim final rule contains several editorial errors. Section 1.232(d) currently states that each foreign facility must submit ``the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated under Sec. 1.233(c)).'' To improve the clarity of this provision, FDA is also revising Sec. 1.232(d). The reference to Sec. 1.233(c) in this sentence is incorrect; the proper reference is to Sec. 1.233(e). Also, the reference in Sec. 1.232(g) to Sec. 1.233(e) is incorrect; the proper reference is to Sec. 1.233(j).

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.