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[Page 57505-57509]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket No. 2002N-0276] (formerly Docket No. 02N-0276)
RIN 0910-AC40

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that confirms the interim final rule entitled ``Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (68 FR 58894, October 10, 2003 (interim final rule) as corrected by a technical amendment (69 FR 29428, May 24, 2004), and responds to comments submitted in response to the request for

[[Page 57506]]

comments in the interim final rule. This final rule affirms the interim final rule's requirement that domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States be registered with FDA by December 12, 2003. The interim final rule implemented the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to be registered with FDA by December 12, 2003. This final rule does not make any changes to the regulatory requirements established by the interim final rule.

DATES: The interim final rule published at 68 FR 58894 was effective on December 12, 2003. The technical amendment to the interim final rule published at 69 FR 29428 was effective May 24, 2004. This final rule, which adopts as final the interim rule as amended, is effective October 3, 2005.

FOR FURTHER INFORMATION CONTACT: Catherine L. Copp, Center for Food Safety and Applied Nutrition (HFS-004), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1589.

SUPPLEMENTARY INFORMATION:

I. Background and Legal Authority

Section 305 of the Bioterrorism Act, which was enacted on June 12, 2002, amended the Federal Food, Drug, and Cosmetic Act (the act) to require the Secretary to establish regulations requiring domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to be registered with the Secretary (section 415 of the act (21 U.S.C. 350d)). Facilities were required to be registered by December 12, 2003. Failure to register a facility in accordance with section 415 of the act is a prohibited act (section 301(dd) of the act (21 U.S.C. 331(dd))). Section 305 of the Bioterrorism Act amended the act to prohibit the importation of food from a foreign facility that is required to register, but has not done so (section 801(l) of the act (21 U.S.C. 381(l))).

The Department of Health and Human Services (DHHS) and the Department of Treasury (Treasury) jointly published the proposed registration regulation in the Federal Register on February 3, 2003 (68 FR 5378), for comment (proposed rule). On October 10, 2003, DHHS and the Department of Homeland Security (DHS) jointly issued the interim final rule\1\. The interim final rule implemented section 305 of the Bioterrorism Act, and required domestic and foreign facilities to be registered with FDA by December 12, 2003. The interim final rule responded to comments from the public on the proposed rule, and established a 75-day comment period on a limited set of issues identified in the interim final rule and also set out below. In order to ensure that those commenting on the interim final rule had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the registration system, FDA reopened the comment period on the same limited set of issues for 30 days on April 14, 2004 (69 FR 19766). FDA requested comment only on the following issues:

\1\The authorities of Treasury under section 701(b) of the act to prescribe regulations for the efficient enforcement of section 801 of the act were transferred to DHS when it was created by an act of Congress in 2002.

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

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

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 the interim final rule, instead

of relying on an existing relationship with a person who qualifies as a U.S. agent;

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.

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

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 invited comment, and the submission of data or other information, on the following:

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

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

In addition to the provisions of the act amended by section 305 of the Bioterrorism Act, FDA is relying on section 701(a) and (b) of the act (21 U.S.C. 371(a) and (b)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and Treasury jointly to prescribe regulations for the efficient enforcement of section 801 of the act.

To the extent that 5 U.S.C. 553 applies to this action, the agency's implementation of this action with an immediate effective date comes within the good cause exception in 5 U.S.C. 553(d)(3) (21 CFR 10.40(c)(4)(ii)). As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

II. Comments on the Interim Final Rule

FDA received approximately 200 timely submissions in response to the interim final rule. Approximately three-quarters of the comments FDA received addressed issues outside the scope of the interim final rule's request for comments. FDA did not consider nonresponsive comments in developing this final rule, and this final rule does not address comments that are beyond the scope of the issues on which FDA requested comment. Relevant comments did not cause FDA to significantly revise its economic analysis of the requirement that each foreign facility designate a U.S. agent. Because FDA's responses to the comments below do not result in any changes to the regulatory requirements published in the interim final rule, the governing regulation continues to be set out in Sec. Sec. 1.225 through 1.243 and 20.100.

All of the issues on which FDA requested comment were related to the assumptions in the economic analysis section of the interim final rule. Accordingly, FDA is responding to all comments in section III of this document.

III. Analysis of Economic Impacts Benefit-Cost Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the

[[Page 57507]]

economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also considers a rule as a significant regulatory action if it raises novel legal or policy issues. In the interim final rule, FDA determined that the rule was a significant regulatory action as defined by Executive Order 12866. We have determined that this final rule is not a significant regulatory action as defined by Executive Order 12866, because it is not imposing any new requirement on any entity beyond the requirements of the interim final rule.

The scope of the analysis of economic impacts for this final rule is limited to the costs associated with the U.S. agent requirement. For a full discussion of all costs and benefits associated with the registration requirement, see the proposed and interim final rules.

Summary of U.S. Agent Costs

Section 415(a)(1)(B) of the act, as established by the Bioterrorism Act, requires that the owner, operator, or agent in charge of a foreign facility submit in the facility's registration the name of the U.S. agent for the facility. Section 1.232(d) requires that all foreign facility registrations include information about the facility's U.S. agent and implements the statutory requirement. Section 1.227(b)(13) requires that the U.S. agent be a person residing or maintaining a place of business in the United States, who is designated by the owner, operator, or agent in charge of a foreign facility as the facility's agent. FDA recognizes only one U.S. agent per foreign facility for purposes of registration. (See 68 FR 58894 at 58915.) 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 (Sec. 1.227(b)(13)(ii)). A U.S. agent may submit a facility's 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 (Sec. 1.225(c)).

In the economic analyses of the proposed and interim final rules, FDA estimated that more than 90 percent of foreign facilities did not currently have a U.S. agent and that foreign facilities currently without a U.S. agent would require 5 to 15 hours to find an agent and would pay an annual fee of $1,000 (68 FR 5378 at 5396 and 68 FR 58894 at 58943). The $1,000 fee estimated in the proposed rule was an

estimate of an average fee for a U.S. agent under FDA regulations for drugs, biologics, and devices (21 CFR parts 207, 607, and 807, respectively), based on fees quoted over the phone and in Internet advertisements. During the period from the publication of the proposed rule to publication of the interim final rule, a number of companies began advertising their services as a U.S. agent for foreign food facilities on the Internet. These companies specified a range of costs, some with discounts for multiple facilities under the same ownership, 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. Many of the U.S. agents charged fees for additional registration-related services, such as registration updates or cancellations. Based on these estimates of fees, FDA concluded that $1,000 represented a reasonable estimate of a U.S. agent fee, including registering the foreign facility (68 FR 58894 at 58945). The total first year cost for foreign facilities was estimated to be $306 million, and annual costs were estimated to be $229 million with a U.S. agent fee of $1,000. However, because there was a wide range of fees charged by U.S. agents, FDA also presented in the interim final rule an estimate of the cost of the rule with a U.S. agent fee of $700. Assuming this $700 fee, FDA estimated that the total first year cost for foreign facilities would be $247.6 million and annual costs would be $164.5 million (68 FR 58894 at 58945).

To improve the analysis involving the costs of hiring and retaining a U.S. agent, FDA requested comments on a number of specific components of the cost calculations, as summarized below.

A. The Costs to a Foreign Facility of Hiring and Retaining a U.S. Agent

(Comment 1) FDA received a number of comments about the costs of hiring and retaining a U.S. agent. FDA received estimates of U.S. agent fees ranging from $95 to $1400. Many comments mentioned a very wide range of fees, with differences as large as $800 between the lowest and highest fees cited in a single comment. None of the comments stated whether there were differences in services between the low and high fee agents, other than lower fees for ``farm'' registrations. (The comments did not elaborate on the meaning of ``farm'' registrations.) The majority of the comments that estimated U.S. agent fees mentioned $700 or $750 or included $700 in the range of fees. Some comments also noted that U.S. agents charged an hourly fee for any additional, but unspecified, services provided to the foreign facility. Some comments did not provide a dollar estimate of the U.S. agent fee, but asserted that FDA had underestimated the cost of a U.S. agent, while others claimed that FDA had overestimated the cost of hiring and retaining a U.S. agent.

(Response) In the interim final rule, FDA estimated total costs using average U.S. agent fees of $700 and $1,000. Given the wide range of fees reported in the comments, we now conclude that the average fee for a U.S. agent is probably closer to $700, giving a total first year cost for foreign facilities of $247.6 million and annual costs of $164.5 million. Table 1 presents the revised present value and

annualized total costs of the interim final rule for a U.S. agent fee of $700.

Table 1.--Present value and annualized costs over 20 years for a U.S. agent fee of $700 (in millions)

Discount Rate	Present Value	Annualized
7%	$2,144.1	$107.2
3%	$2,861.5	$143.1

[[Page 57508]]

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 the Interim Final Rule, Instead of Relying on an Existing Relationship With a Person Who Qualifies as a U.S. Agent

(Comment 2) FDA did not receive any comments estimating the number of facilities that have hired a U.S. agent or have negotiated additional duties from someone with whom they have an existing relationship. However, we did receive individual comments from facilities and industry representatives reporting that some facilities have hired a new U.S. agent. FDA also received comments reporting that some facilities have used U.S. business partners, U.S. customers, or U.S. brokers as U.S. agents.

(Response) From the comments we received it is clear that foreign facilities are complying with the U.S. agent requirement both by hiring new U.S. agents and by negotiating new duties with someone with whom they have an existing relationship. However, it was not possible to extrapolate from the comments how many facilities were hiring new U.S. agents or utilizing existing relationships. Therefore, FDA has not altered its analysis on this point. (See 68 FR 58894 at 58945.)

C. The Number of Foreign Facilities That Have Ceased Exporting to the United States Because They Have Decided Not to Hire or Retain a U.S. Agent for Registration Purposes

(Comment 3) FDA did not receive any estimates of the number of foreign facilities that have ceased exporting to the United States due to the U.S. agent requirement. FDA did receive comments from governmental agencies and industry groups reporting that some exporters of small value shipments may stop exporting or have stopped exporting

to the United States as a result of the cost of hiring a U.S. agent. Other comments stated that they were unaware of any facilities that had stopped exporting to the United States in response to the cost of hiring a U.S. agent.

(Response) Although some comments confirmed the assumption of the interim final rule economic analysis that some facilities would stop exporting to the United States due to costs associated with hiring a U.S. agent, the comments did not provide any information to estimate how many facilities would stop exporting. Therefore, FDA has not altered this portion of its analysis. (See 68 FR 58894 at 58943.)

D. The Distribution of Costs Between Submitting Registrations and Other Services Offered by the U.S. Agent

(Comment 4) FDA received some comments separating the fee paid to a U.S. agent for registration services from fees paid for ongoing services. One comment assumed that the U.S. agent fees would be in addition to any existing fee for services the agent may be providing for the facility. Another comment stated that the fee to register a facility was $350 with an additional charge of $199 per year for acting as a facility's U.S. agent, for a total fee of $549. Most comments that provided a U.S. agent fee did not specify what services were provided for the fee.

(Response) FDA was unable to estimate based on the information in the comments the distribution of costs between submitting registrations and other services offered by the U.S. agent. Therefore, FDA has not altered this portion of its analysis. (See 68 FR 58894 at 58945.)

E. The Assumptions Underlying FDA's Estimates of the Costs of Hiring and Retaining a U.S. Agent

(Comment 5) FDA received comments questioning whether FDA had included all costs associated with hiring a U.S. agent. One comment stated that a firm had spent $1,800 per facility to register its foreign affiliates.

(Response) The comment that provided specific costs of registration included many activities that FDA considered in other parts of its analysis, such as reading and understanding the rule and understanding the implications of the requirements for their business. If only activities related to the U.S. agent were considered, the comment's cost estimates were consistent with FDA's cost estimates for a U.S. agent. (See 68 FR 58894 at 58945.)

(Comment 6) Other comments that mentioned costs stated that FDA had failed to include costs associated with entering into a legal agreement with the U.S. agent.

(Response) FDA did include an estimate of costs to find and hire a U.S. agent in the interim final rule, which would include the costs of establishing an agreement between the U.S. agent and the facility. Accordingly, FDA has not altered its assumptions about costs associated with entering into an agreement with the U.S. agent. (See 68 FR 58894 at 58945.)

F. 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 invited comment, and the submission of data or other information, on the following: 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.

FDA received no comments on the number of U.S. small businesses adversely affected by the loss of their trading partners, and thus, has not altered this portion of its analysis. (See 68 FR 58894 at 58954 to 58955.)

G. 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 invited comment, and the submission of data or other information, on the following: The costs incurred by these domestic small businesses due to the loss of these trading partners.

(Comment 7) Some comments agreed that there was a potential for some foreign facilities to stop exporting to the United States as a result of the U.S. agent requirement. One comment listed the following several possible consequences for U.S. small businesses if foreign facilities stopped exporting: (1) Need to find new suppliers; (2) inability to supply existing customer base; (3) increase in cost of goods; and (4) increase in cost of goods that may be passed on to U.S. consumers. However, no comments provided any estimate of the costs of these effects.

(Response) In the economic analysis of the interim final rule, FDA considered the impacts on small businesses. Because no comment provided an estimate of the costs to domestic small businesses if some foreign facilities cease exporting to the United States due to the U.S. agent requirement, FDA has not altered its estimate of the number of facilities that will stop exporting to the United States or its expectations of possible consequences for U.S. facilities. (See 68 FR 58894 at 58954 to 58955.)

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because this final rule

[[Page 57509]]

does not make any changes to existing requirements, and thus, does not impose any new costs on facilities, the agency certifies that this final rule will not have a significant impact on a substantial number of small entities. Full analysis of the effect of the registration requirement on small entities is provided in the analysis of economic impacts set out in the preceding analysis of economic impacts and in the preamble to the interim final rule at 68 FR 58894 at 58954.

V. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ``any rule that includes any 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 (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

VI. Federalism Analysis

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions and an estimate of the annual reporting burden were provided in the interim final rule issued October 10, 2003 (68 FR 58894). Included in the estimate was the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The final rule requires no new information collection. Individuals and organizations may submit comments on the burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the contact person identified in the FOR FURTHER INFORMATION CONTACT section of this document. The information collection provisions in this final rule have been approved under OMB control number 0910-0502. This approval expires October 31, 2006. 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.

VIII. Analysis of Environmental Impact

The agency has determined 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.

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.

PART 1--GENERAL ENFORCEMENT REGULATIONS

PART 20--PUBLIC INFORMATION

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the interim rule amending 21 CFR parts 1 and 20, which was published at 68 FR 58894 (October 10, 2003) and amended at 69 FR 29428 (May 24, 2004), is adopted as a final rule without change.

Dated: August 28, 2005.
Michael Chertoff,
Secretary of Homeland Security.

Dated: September 20, 2005.
Michael O. Leavitt,
Secretary of Health and Human Services.
[FR Doc. 05-19730 Filed 9-28-05; 1:53 pm]

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