

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS¹—Continued

21 CFR Part 1	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1.244(b) ⁶	FDA 3537/3537a	42,519	1	42,519	1	42,519
Grand total						366,717

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

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

IX. 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.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 tentatively concludes that the proposed 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.

XI. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measures of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 305 of the Bioterrorism Act requires FDA to propose and issue final regulations requiring the registration of food facilities within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 305 of the Bioterrorism Act also provides that if FDA does not issue final regulations by this date, facilities still must register with FDA by December 12, 2003, subject

to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. In addition, section 801 of SBREFA (5 U.S.C. 801), states that a major final rule may not take effect until 60 days after the agency has published the rule and submitted it to Congress for review. A major rule for this purpose is defined in 5 U.S.C. 804 as one that the Administrator of the Office of Information and Regulatory Affairs of OMB has determined has resulted in or is likely to result in: (a) An annual effect on the economy of \$100 million or more; or (b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

OMB has determined that this proposed rule, when finalized, will be a major rule. Accordingly, FDA must publish the final registration rule no later than October 12, 2003, for it to be effective by the statutory deadline of December 12, 2003. For these reasons, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.