

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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