

facilities, but for ease of computation excluded a category of facilities that are not fluent in English and have Internet access. FDA requests comments on the number of facilities not fluent in English and without Internet access.

TABLE 49.—ESTIMATED ANNUAL REPORTING BURDEN—FIRST YEAR<sup>1</sup>

21 CFR Part	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1.241(a) <sup>2</sup>	FDA 3537	143,453	1	143,453	2	286,906
1.241(b) <sup>3</sup>	FDA 3537	58,593	1	58,593	3	175,779
1.241(a) <sup>4</sup>	FDA 3537	32,864	1	32,864	2	65,728
1.241(b) <sup>5</sup>	FDA 3537	30,811	1	30,811	7	215,677
1.241(b) <sup>6</sup>	FDA 3537	141,730	1	141,730	12	1,700,760
Total hours						2,444,850

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Domestic facilities with Internet access

<sup>3</sup> Domestic facilities without Internet access

<sup>4</sup> Foreign facilities with Internet access and fluent in English

<sup>5</sup> Foreign facilities without Internet access and fluent in English

<sup>6</sup> Foreign facilities without Internet access and not fluent in English

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 (Ref. 8), FDA estimates that the number of new facilities each year will be equal to 10 percent of the total number of facilities. Also, facilities that go out of business will have to notify FDA to cancel their registration. FDA estimates

that 10 percent of the total number of facilities will go out of business each year, also based on SBA statistics. Facilities exiting the business will have to send FDA a cancellation of their registration. FDA estimates that it will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Finally, facilities that have a material change of information submitted in their registration will have to notify FDA of

the new information. FDA estimates 20 percent of facilities will have a material change in the information submitted in their registration each year. It will take these facilities approximately 1 hour to locate the correct form, enter their information, and send it to FDA. Table 50 presents an estimate of the burden hours for new facilities, and updates and cancellations for existing facilities in future years.

TABLE 50.—ESTIMATED ANNUAL REPORTING BURDEN—SUBSEQUENT YEARS<sup>1</sup>

21 CFR Part 1	FDA Form Number	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New facilities						
1.241(a) <sup>2</sup>	FDA 3537	14,345	1	14,345	2	28,690
1.241(b) <sup>3</sup>	FDA 3537	5,859	1	5,859	3	17,577
1.241(a) <sup>4</sup>	FDA 3537	3,286	1	3,286	2	6,572
1.241(b) <sup>5</sup>	FDA 3537	3,081	1	3,081	7	21,567
1.241(b) <sup>6</sup>	FDA 3537	14,173	1	14,173	12	170,076
Previously registered facilities						
1.244(a) <sup>2</sup>	FDA 3537/3537a	43,036	1	43,036	1	43,036
1.244(b) <sup>3</sup>	FDA 3537/3537a	17,578	1	17,578	1	17,578
1.244(a) <sup>4</sup>	FDA 3537/3537a	9,859	1	9,859	1	9,859
1.244(b) <sup>5</sup>	FDA 3537/3537a	9,243	1	9,243	1	9,243