

Table 18.--Estimated Annual Reporting Burden--First Year¹

	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), 1.232, 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

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

²Domestic facilities with Internet access.

³Domestic facilities without Internet access.

⁴Foreign facilities with Internet access and fluent in English.

⁵Foreign facilities without Internet access and fluent in English.

⁶Foreign facilities without Internet access and not fluent in English.