

Table 19.--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						
1.231(a), 1.232, 1.233 <sup>2</sup>	FDA 3537	15,255	1	15,255	2	30,510
1.231(b), 1.232, 1.233 <sup>3</sup>	FDA 3537	6,172	1	6,172	3	18,516
1.231(c), 1.232, 1.233 <sup>2</sup>	FDA 3537	100	1	100	2	200
1.231(c), 1.232, 1.233 <sup>3</sup>	FDA 3537	100	1	100	3	300
1.231(a), 1.232, 1.233 <sup>4</sup>	FDA 3537	3,186	1	3,186	2	6,372
1.231(b), 1.232, 1.233 <sup>5</sup>	FDA 3537	2,981	1	2,981	7	20,867
1.231(b), 1.232, 1.233 <sup>6</sup>	FDA 3537	14,173	1	14,173	12	170,076
1.231(c), 1.232, 1.233 <sup>4</sup>	FDA 3537	100	1	100	2	200
1.231(c), 1.232, 1.233 <sup>5</sup>	FDA 3537	100	1	100	7	700
Previously registered facilities						
1.234(c), <sup>2</sup> 1.235(c)	FDA 3537/3537a	99,159	1	99,159	1	99,159
1.234(d), <sup>3</sup> 1.235(d)	FDA 3537/3537a	40,117	1	40,117	1	40,117
1.234(e), <sup>2</sup> 1.235(e)	FDA 3537/3537a	650	1	650	1	650
1.234(e), <sup>3</sup> 1.235(e)	FDA 3537/3537a	650	1	650	1	650
1.234(c), <sup>4</sup> 1.235(c)	FDA 3537/3537a	20,711	1	20,711	1	20,711
1.234(d), <sup>5</sup> 1.235(d)	FDA 3537/3537a	19,377	1	19,377	1	19,377
1.234(d), <sup>6</sup> 1.235(d)	FDA 3537/3537a	92,125	1	92,125	1	92,125
1.234(e), <sup>4</sup> 1.235(e)	FDA 3537/3537a	650	1	650	1	650
1.234(e), <sup>5</sup> 1.235(e)	FDA 3537/3537a	650	1	650	1	650
Total						521,830

<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.

#### BILLING CODE 4160-01-C

The information collection provisions of this interim final rule have been submitted to OMB for review.

Prior to the effective date of this interim final rule, FDA will publish a

notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. 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.