

Table 53.--Estimated Annual Reporting Burden

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.279-1.285 ¹	77,427	1	77,427	40	\$6,194,000	\$743,000	3,097,080
1.279-1.285 ¹	7,743	1	7,743	40	\$620,000	\$74,400	309,715
1.280-1.281 ²	77,427	84	6,500,000	0.384	\$0	\$0	2,500,000
1.282 ²	77,427	3.36	260,000	0.5	\$0	\$0	130,000
1.283(a)(2)(iv), 1.285(c)(4) ²	77,427	0.168	13,000	0.25	\$0	\$0	3,250
1.283(a)(5)(ii) ²	77,427	1.26	97,500	1	\$0	\$0	97,500
1.283(a)(7) ²	77,427	0.105	8,125	0.25	\$0	\$0	2,031
1.283(a)(6)(i)- (a)(6)(iv), 1.285(f)(1)-(f)(4) ²	77,427	0.168	13,000	8	\$0	\$0	104,000
Total one time burden hours							3,406,795
Total recurring burden hours							2,836,781

¹ One time burden.² Recurring burden.*B. Hour Burden Estimate*

1. Number of Establishments Affected

Using 2001 fiscal year information from OASIS (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food imported or offered for import into the United States. FDA does not have specific information on who will submit prior notice since there are no restrictions on who can submit prior notice. Therefore, FDA estimates prior notice submission information based on the 77,427 importers of food in OASIS.

2. New and Closing Importers

In addition to the U.S. importers currently in existence, in future years new import businesses will open and some existing import businesses will close. These new submitters would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA assumes that on a yearly basis 7,743 importers will leave the

market and 7,743 importers will enter the market.

3. Hour Burden Estimate Researching the Prior Notice Requirement

a. *Learning the interim final rule.* To become familiar with the requirements for this interim final rule, FDA estimates that one manager and two subordinates from each importing business will attend an 8-hour training session on the prior notice regulation. This one-time research burden for the existing importers is about 1,858,248 hours (3 people per firm × 8 hours × 77,427 importers). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 1 of table 53 of this document.

In the years that follow the startup year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. In addition to the first year burden to research prior notice, it is expected that 185,832 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice (3 people per firm × 8 hours × 7,743 new importers). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 2 of table 53 of this document.

b. *Coordinating the information.* FDA assumes it will take about 2 business days (16 hours) for an administrative employee of the prior notice-submitting

firm to coordinate with others to establish new business practices required to receive the information needed for prior notice. We assume this set-up time is sufficient to coordinate information for existing importing accounts. The total hours needed to gather information for existing accounts is 1,238,832 (77,427 importing firms × 16 hours per firm). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 1 of table 53 of this document. Thus, the total burden listed in row 1 is 1,858,248 hours + 1,238,832 hours = 3,097,080 one-time burden hours to learn the rule and coordinate information.

In addition to the first year coordination burden, we expect importing businesses to see a 10 percent turnover in their accounts. Thus, in future years, importing firms will spend 123,883 hours to gather information on their new accounts. This portion of the estimate is for 21 CFR part 1, subpart I, 1.276 through 1.285 and is shown in row 2 of table 53 of this document. Thus, the total burden listed in row 2 is 185,832 hours + 123,883 hours = 309,715 one-time burden hours for new firms to learn the rule and coordinate information.

4. Submitting Prior Notice

To estimate the repetitive effort of submitting a prior notice, FDA assumes the activity takes 1 hour each time an import entry is submitted. An import