

entry, on average, constitutes 2.6 different articles of food; a prior notice must be submitted for each article of food. Therefore we estimate that submitting prior notice for each article of food will take 23 minutes to complete (23 minutes per line = 60 minutes/2.6 lines per entry). On an annual basis, submitting prior notice will take about 2.5 million hours (23 minutes (or 0.384 hours) per prior notice \times 6.5 million notices). This estimate is for 21 CFR part 1, subpart I, 1.280 through 1.281 and is shown in row 3 of table 53 of this document.

FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 6.5 million prior notices will be submitted annually based on fiscal year 2002 OASIS information and estimates of prior notice capacity. We divide 6.5 million lines by the 77,427 importers to get an average annual response frequency per importer of 84 notices.

5. Changes to a Confirmed Prior Notice

The annual total number of changes made by importers to confirmed prior notices will vary depending on the minimum prior notice submission time required. For example, more confirmed prior notices will likely have to be changed if the minimum prior notice submission time is noon the calendar day before arrival as opposed to a minimum submission time of 2 hours before arrival. FDA's interim final rule requires a minimum prior notice submission time for each of the following situations: 2 hours before arrival for articles of food imported by vehicle, 4 hours before arrival for articles of food imported by rail and air, and 8 hours before arrival for articles of food imported by vessel.

By combining the percentages by mode of transport and taking into account the location of the exporting country, we assume that about 4 percent of all prior notices (260,000 notices) will have to be resubmitted after confirmation is received from FDA. We assume that changes in the prior notices will be minor adjustments; therefore, both the cancellation of the original notice and the resubmission of the new notice are estimated to take about 30 minutes. This estimate is for 21 CFR part 1, subpart I, 1.282 and is shown in row 4 of table 53 of this document.

6. Refused Admission

Although FDA at this time does not have enough information to estimate a percent of refusals under the new prior notice program, for the purposes of this analysis FDA estimates the reporting

burden assuming a 2 percent refused admission rate.

An imported food product is subject to refusal under section 801(m)(1) of the FD&C Act if it arrives at the port of arrival with untimely, inaccurate, or no prior notice. FDA estimates that about 130,000 of the annual prior notices will be subject to refusal (2 percent of 6.5 million prior notices).

If an article of food is refused under section 801(m)(1) of the FD&C Act, the food must be held until the prior notice has been correctly submitted or until the product is exported. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal.

In many cases, the location notice will be given as part of a correction and resubmission, as described in the next section. FDA estimates that 13,000 out of the 130,000 annual refusals will give the location notice separately and that it will take about 15 minutes per prior notice to notify FDA of the shipment's location. This will result in about 3,250 hours (13,000 notices \times 0.25 hours).

This estimate is for 21 CFR part 1, subpart I, 1.283(a)(2)(iv) and 1.285(c)(4) and is shown in row 5 of table 53 of this document.

7. Correction and Resubmission of Prior Notice

FDA estimates that 97,500 out of the 130,000 annual refusals will be because of inaccurate prior notice requiring resubmission, or because no prior notice was submitted. FDA estimates that it will take an hour to cancel, correct, and resubmit, or submit (in the case of no notice) each of these 97,500 notices. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(5)(ii) and is shown in row 6 of table 53 of this document.

8. Exportation of Products Refused Admission

Some importers of articles of food that have been refused admission into the United States will decide to export their product rather than try to submit or resubmit prior notice. FDA estimates that this will occur for only about 25 percent of the 130,000 articles refused admission for inaccurate, untimely, or no prior notice. If an article of food is refused admission under section 801(m)(1) of the FD&C Act and exported, FDA requests, but does not require, that prior notice be cancelled. FDA estimates that for these 32,500 articles of food, prior notice will be cancelled 25 percent of the time and that this cancellation will take 15 minutes per article. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(7) and

is shown in row 7 of table 53 of this document.

9. FDA Review Request

If an article of food to be imported is refused under section 801(m)(1) of the FD&C Act or placed under hold under section 801(1), a request may be submitted asking for an FDA review. FDA estimates that of the 130,000 articles of food that are refused admission under section 801(m)(1) of the FD&C Act or placed under hold under section 801(1) of the FD&C Act yearly, 10 percent will request an FDA review (13,000 reviews). FDA estimates that it will take the requestor about 8 hours to prepare the factual and legal information necessary to request a review. Thus, importers will spend about 104,000 hours on review requests annually. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(6)(i) through (a)(6)(iv) and 1.285(f)(1) through (f)(4) and is shown in row 8 of table 53 of this document.

C. Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we assume that the 3,097 responsible parties without Internet access (4 percent of the 77,427 importers) will have to purchase the appropriate computer equipment and gain Internet access to transmit the information. Assuming computer equipment costs each firm \$2,000 and yearly Internet access costs each firm \$240 (\$20 per month for 12 months), this results in a one-time computer cost for these facilities of \$6,194,000 and a recurring Internet access cost of \$743,000. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 1 of table 53 of this document.

For the 7,743 new firms that enter the import market each year, we expect 310 of them to need to purchase computer equipment and obtain Internet access. On an annual basis we expect new importers to spend \$620,000 on computers and \$74,400 on Internet access to be able to submit their prior notice information. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 2 of table 53 of this document.

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