

B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. The analysis below, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

1. Number of Establishments Affected

FDA finds that this proposed rule would affect the 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small businesses according to the definitions of the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A above are regulatory relief options.

2. Costs Per Entity

Small businesses will be affected by this proposed rule in a couple of ways. First, this proposed rule requires importers to notify FDA of incoming products electronically before the food arrives at the U.S. border. The annual cost of doing so is about \$770 per importer (see tables 1, 2, and 17 of this document). As discussed above and shown in tables 1 and 2, about 3,100 U.S. importers do not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about \$2,000 per importer) and Internet access (at a cost of about \$240 annually) in order to comply with this proposed rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, as paper notices could not be submitted and processed in the proposed prior notice timeframe and would therefore actually be more burdensome to importers because paper notices would need to be submitted earlier.

Second, this proposed rule will potentially cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before crossing the U.S. border. The costs of lost product value vary with the required notice timeframe. We discuss the various costs associated with this possibility in the options previously outlined. FDA requests comments on

the effect of this proposed rule on small entities.

3. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act established a deadline for beginning prior notice that applies to all FDA-regulated imported food. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the prior notice provision contains no such language. Thus, it appears that Congress intended for all entities to be subject to the effective date established in the Bioterrorism Act. Nonetheless, the agency recognizes that the prior notice requirement will cause an economic burden on small businesses; therefore, we are seeking comment on whether it would be consistent with section 307 for the agency to set staggered effective dates that would give small businesses more time to comply. FDA also seeks comment on how FDA could effectively distinguish between large and small businesses if it considered staggered effective dates.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$112 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act. See table 17 for the total costs.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching

existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prior Notice of Imported Food

Description: Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 381(m)) requires prior notification to the Secretary of Health and Human Services of an article of food that is being imported or offered for import into the United States. The purpose of this notification is to enable the food to be inspected at ports of entry into the United States.

Section 801(m) of the Act states that the Secretary shall by regulation identify the parties responsible for providing the notice and explain the information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 801(m)(1) of the Act states that the Secretary shall require submission of notice providing the identity of each of the following: the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. Section 801(m)(2)(A) of the Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. FDA's prior notification of imported food shipments proposed regulation would implement these statutory provisions.

FDA estimates the burden for this information collection as follows: