

this proposed rule, when final, will be a major rule for the purpose of congressional review.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by 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 recordkeeping 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 would 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: Recordkeeping and Records Access Requirements for Food Facilities

Description: The Bioterrorism Act contains a provision authorizing the Secretary to develop regulations requiring food facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, animal food, or food ingredients. Records for nontransporters must include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and the way that it is packaged, and the receipt and shipping dates. Records for transporters must include similar information about the food or food packaging, sources, and recipients, identification of all modes of transportation, and responsible individuals, while the food or food packaging is in the custody of the transporter.

Description of Respondents: Facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food are required to establish and maintain records, including facilities in both interstate and intrastate commerce. Foreign manufacturers, processors, packers, and holders of food that would be required to register are required to maintain records if they ship food to the United States.

Burden: FDA estimates that the paperwork burden of this rule will be incurred by the number and types of firms and facilities listed in Table 43 of this document. FDA assumes that, approximately 841,000 facilities owned by approximately 646,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food, and the foreign facilities that manufacture, process, package, or hold food destined for consumption or use in the United States that would be required to register. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

TABLE 43.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Firm Estimate
Manufacturers	43,376	36,948
Wholesalers/Warehouses	95,745	76,952
Packaging ¹	36,907	34,633
Transporters/Packers	16,773	15,171
Retail Grocery and Specialty Food	207,657	153,277
Convenience Stores	128,985	68,866
Mixed-Type Facilities That Have Farms	30,497	24,397
Importers	18,902	15,122
Total Domestic	578,842	425,366
Final Holders	77,427	61,942
De minimus Processors/Packagers	22,600	18,080
Manufacturers	125,450	106,858
Other Facility Types		
Total Foreign	225,477	186,879

¹ Including outer packaging and food contact substances.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 includes learning about the regulation requirements, the redesign of records, and records maintenance including

information collection for these records. The burden for § 1.361 is associated with planning for and executing an FDA request for records. Because it is difficult to estimate with any degree of

precision the burden incurred from executing a records access request, we only compute the burden for firms to prepare for a potential records access request from FDA.