DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0056] (formerly Docket No. 2007N–0444)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0560. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352 (OMB Control Number 0910–0560)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 (21 CFR 1.326 through 1.363) of FDA's regulations set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA's regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and packaging, and the receipt and shipping dates §§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

In the **Federal Register** of November 19, 2007 (72 FR 65033), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the agency estimates the number of new firms entering the affected businesses to be 5 percent (5%) of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: January 30, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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