Recordkeeping and Records Access Requirements for Food Facilities

OMB No. 0910-0560

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 FD&C Act or 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 of FDA's regulations (21 CFR 1.326 through 1.363) 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.

We request the extension of OMB approval for the following collection of information requirements:

21 CFR 1.337 -- Recordkeeping

Requires respondents to establish and maintain records to identify the immediate previous sources of food.

21 CFR 1.345 -- Recordkeeping

Requires respondents to establish and maintain records to identify the immediate subsequent recipients of food.

21 CFR 1.352 -- Recordkeeping

Requires respondents to establish and maintain records for each food they transport in the United States.

2. Purpose and Use of the Information Collection

Information maintained under these regulations will help FDA to identify and locate quickly food that might be affected by deliberate or accidental contamination and to inform the appropriate individuals and food facilities of specific terrorist threats.

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.

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.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies may opt to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. The agency estimates that about twenty-five percent (25%) of the recordkeeping will be accomplished electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, no other federal government agency is engaged in the collection of this information. There can be no duplicative collection of this information because the information maintained in fulfilling the statutory requirements for recordkeeping under section 414 of the act is unique to each firm and its customers and suppliers. Moreover, the regulation states that,

> The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released. (21 CFR 1.330)

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. The recordkeeping requirements of these regulations are mandated by section 414 of the act and there is no statutory exception for small businesses. However, FDA staggered the dates by which very small, small, and large sized firms were required to comply with the rule. Very small firms were given 24 months to comply, small firms were given 18 months, while large firms were given 12 months. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Pursuant to the act and the implementing regulations, a record is established for each transaction involving food at the time the transaction occurs. The information cannot be collected less frequently. If the collection is not conducted or is conducted less frequently, persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States would not be in compliance with section 414 of the act. If the required records are not maintained, FDA may not be able to identify and locate quickly food that might be affected by deliberate or accidental contamination or to inform the appropriate individuals and food facilities of specific terrorist threats.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of January 13, 2011 (76 FR 2396), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter containing multiple comments in response to the notice.

(Comment 1) One comment was generally supportive of the necessity of the information collection and its practical utility.

(Response) FDA agrees. As discussed previously in this document, 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.

(Comment 2) Another comment stated that accurate recordkeeping is integral to the effective and timely tracing of food products through the supply chain and, to support effective product tracing, suggested that industry should determine the Critical Tracking Events (CTEs) and the Key Data Elements (KDEs) necessary for product tracing; FDA should encourage the adoption of standard ways to express this information as well as the adoption of electronic recordkeeping and electronic submission of data to the agency; and, review of product tracing procedures should be part of standard audits.

(Response) FDA agrees that recordkeeping is key to effective product tracing. However, to the extent that the comments suggest changes to the requirements of the recordkeeping regulations in sections 1.326 through 1.363, such requests are outside the scope of the four collection of information topics on which the notice solicits comments. Such changes to the current recordkeeping requirements can only be accomplished by notice and comment rulemaking.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The regulation does not specify confidentiality. However, all confidential information received by FDA is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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.

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours) [2]	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.

[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

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 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.

12 b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage of the recordkeepers is $15 per hour. The overall estimated cost incurred is $76,663,350 (5,110,890 burden hours X $15/hr = $76,663,350).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/ Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would occur as part of inspection activities. FDA would devote approximately 5 hours per inspection to the inspection of records. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $426.60 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation to be $42.66 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010. Five hours multiplied by $42.66 per hour equals $213.30. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $426.60 per review. If FDA inspected 1,000 firms annually, FDA estimates that the total annual cost to the Federal Government would be $426,600 ($426.60 x 1,000 = $426,600).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.