Recordkeeping and Records Access Requirements for Food Facilities

OMB Control No. 0910-0560

SUPPORTING STATEMENT

Terms of Clearance: None.

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) (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 the Food and Drug Administration's (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.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded FDA's access to records. Specifically, FSMA expanded FDA's access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA (we) reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, a FDA officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

On February 23, 2012, we issued an interim final rule in the *Federal Register* (77 FR 10658) (the 2012 IFR) amending § 1.361 to be consistent with the current statutory language in section 414(a) of the FD&C Act, as amended by section 101 of FSMA. In the 2012 IFR, we concluded that the information collection provisions of § 1.361 were exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities (77 FR at 10661). The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361 in Table 1.

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.

Our 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 must establish and maintain records. Respondents are from the private sector (for-profit businesses).

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 use whatever forms of information technology for retaining the appropriate records and making them available to regulatory officials. We estimate 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 FD&C 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

We estimate that ten percent (10%) of respondents are small businesses. The recordkeeping requirements of these regulations are mandated by section 414 of the FD&C Act, and there is no statutory exception for small businesses. However, we staggered the dates by which very small, small, and large sized firms must 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. We help small businesses comply with our requirements through our Regional Small Business Representatives and our scientific and administrative staffs. We have provided a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. Pursuant to the FD&C 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 FD&C Act. If the required records are not maintained, we 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 April 17, 2014 (79 FR 21767), we published a 60-day notice requesting public comment on the proposed collection of information. We received no comments in response to the notice.

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 our regulations at 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 must establish and maintain records. Respondents are from the private sector (for-profit businesses).

12 a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

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

21 CFR Section (Activity)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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 our 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, we estimate 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, we estimate 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, we estimate the number of new firms entering the affected businesses to be 5 percent of 379,493, or 18,975 firms. Thus, we estimate 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. We estimate that approximately the same number of firms (18,975) will exit the affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of Table 1. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to recordkeepers is approximately $168,557,152.20 per year. We estimate that the average hourly wage for the employee maintaining records would be equivalent to a GS-5/Step-1 level in the locality pay area of Washington-Baltimore in 2014, approximately $16.49/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to recordkeepers to be $32.98/hour. Thus, the overall estimated cost incurred by the recordkeepers is $168,557,152.20 (5,110,890 burden hours x $32.98/hr).

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

Our review of the retained records would occur as part of inspection activities. We would devote approximately 5 hours per inspection to the inspection of records. We estimate the annualized cost to the Federal government for the review of records retained by a firm to be $430.90 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be $43.09 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2014. Five hours multiplied by $43.09 per hour equals $215.45. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $430.90 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be $430,900 ($430.90 x 1,000).

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.