United States Food and Drug Administration

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

This information collection request supports Food and Drug Administration (FDA, agency, or we) regulations. Specifically, 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) 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. These requirements are codified under 21 CFR sections 1.326 through 1.363.

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. The 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 the required information and are retained for the required time period.

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.

Finally, because we believe the information collection provisions under 21 CFR § 1.361 to be exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) (see FDA's interim final rule of February 23, 2012 (77 FR 10658)), we have not included an estimate of burden hours associated with the regulation in Table 1.

Accordingly, we request OMB approval of the information collection provisions found in the following regulations:

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 contaminated or potentially contaminated 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 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 information collection 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

   We are unaware of duplicative information collection. Under section 414 of the FD&CAct, FDA is specifically charged with the safety of United States food supply. We believe the information collection requirements found in the applicable regulations do not duplicate those associated with other food safety requirements.

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. 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.

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 accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of June 14, 2017 (82 FR 27263). FDA received one comment. The comment was supportive of the information collection but requested that FDA coordinate with the U.S. Department of Agriculture. FDA addresses issues regarding duplication of information collection in question 4 of this supporting statement.

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

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.

This estimate is based our experience and on our initial 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.

12b. 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 2017, approximately $17.38/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to recordkeepers to be $34.76/hour. Thus, the overall estimated cost incurred by the recordkeepers is $177,654,536.40 (5,110,890 burden hours x $34.76/hr).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Records Maintenance	5,020,000	$34.76	$174,495,200.00
Learning for New Firms	90,890	$34.76	$3,159,336.40
Total			$177,654,536.40

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 information collection.

14. Annualized Cost to the Federal Government

    Our review of the retained records occurs as part of inspection activities. We devote approximately 5 hours per inspection to the inspection of records. We estimate the cost to the Federal government for the review of records retained by a firm to be $454.20 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be $45.42 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2017. Five hours multiplied by $45.42 per hour equals $227.10. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $454.20 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be $454,200 ($454.20 x 1,000).

15. Explanation for Program Changes or Adjustments

    The burden estimate has not changed from our previous estimate.

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.