

UNITED STATES FOOD AND DRUG ADMINISTRATION

Recordkeeping and Records Access Requirements for Food Facilities

OMB Control No. 0910-0560

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection request supports Food and Drug Administration (FDA, agency, or we) regulations. 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 our ability to respond to and 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. FDA may access records relating to specific suspect articles of food; records relating to any article of food that is reasonably believed likely to be affected in such a manner; or if we believe that there is a reasonable probability that the use of or exposure to an article of food 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. Because we believe the information collection provisions under § 1.361 are 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 associated with these regulations.

Accordingly, we request extension of OMB approval for the information collection provisions found in §§ 1.337, 1.345, and 1.352 as discussed in this supporting statement.

## 2. Purpose and Use of the Information Collection

Information in the records maintained under these regulations will assist FDA to quickly identify and locate 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&C Act, 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 we have provided Small Business assistance on the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

## 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), we published a 60-day notice for public comment in the *Federal Register* of April 7, 2020 (85 FR 19489). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. The information collection 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.

*Privacy Act*

This ICR collects personally identifiable information (PII) or information of a personal nature. The PII collected is for business contact purposes only and includes business name, business address, business telephone numbers. The business contact information is maintained and stored at the vendor facility.

We further determined that although PII is collected and stored at the vendor facility, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected. We also minimized the PII to be collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

## 12. Estimates of Annualized Burden Hours and Cost

### 12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Recordkeeping Burden<sup>1</sup>

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	6.61	2,508,449
1.337, 1.345, and 1.352; Learning for new firms	18,975	1	18,975	4.50	85,388
Total					2,593,837

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to our burden estimate to account for advances in information and communication technology (ICT) that have occurred in the last decade. Because the transition from paper-based to electronic records systems is widespread, we estimate that the average burden per recordkeeping has decreased about 50 percent. With regards to records maintenance, we estimate that approximately 379,493 facilities each spend about half the amount of time from the 13.228 hours previously reported to 6.61 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 2,508,449 hours annually.

In addition, we estimate that new firms entering the affected businesses 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 is 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities each spends on average 4.5 hours learning about the recordkeeping and records access requirements, for a total of 85,388 hours annually. This estimate reflects a reduction from 4.79 to 4.5 average hours per facility to account for the increase in facilities using internet, which increased from 71 to 99 percent. We estimate that approximately the same number of firms (18,975) exits 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 2,593,837 hours.

### 12b. *Annualized Cost Burden Estimate*

The annual hour cost burden to recordkeepers is \$97,683,901.42 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 2020, approximately \$18.83/hour. Doubling this wage to account for overhead costs, we double our estimate of the average hourly cost to recordkeepers to be \$37.66/hour. Thus, the overall estimated cost incurred by the recordkeepers is \$97,683,901.42 (2,593,837 burden hours x \$37.66/hr).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Records Maintenance	2,508,449	\$37.66	\$94,468,189.34
Learning for New Firms	85,388	\$37.66	\$3,215,712.08
Total			\$97,683,901.42

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 \$491.90 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be \$49.19 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020. Five hours multiplied by \$49.19 per hour equals \$245.95. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government \$491.90 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be \$491,900 (\$491.90 x 1,000).

15. Explanation for Program Changes or Adjustments

We have adjusted our estimate of burden for the information collection to reflect current recordkeeping practices. As more respondents transition from paper-based to electronic records systems, we believe greater recordkeeping efficiencies are achieved and we have therefore decreased our estimate of the hourly recordkeeping burden by 50%, resulting in 2,517,053 fewer hours since last OMB approval.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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.