United States Food and Drug Administration

Third-Party Disclosure and Recordkeeping Requirements for Reportable Food

OMB Control No. 0910-0643

SUPPORTING STATEMENT

EXTENSION

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) implementation of section 417 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85), requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines "*reportable food*" as an "*article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals*." (See section 417(a)(2) of the FD&C Act). We believe that the most efficient and cost-effective means to implement the Registry is by utilizing our electronic Safety Reporting Portal. The information collection provisions associated with the submission of reportable food reports has been approved under OMB control number 0910-0291.

In conjunction with the reportable foods requirements, section 417 of the FD&C Act also establishes third-party disclosure and recordkeeping burdens. Specifically, we may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(6)(B)(i) to (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (i.e., the immediate previous source and/or immediate subsequent recipient) to notify their own immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(7)(C)(i) to (ii) of the FD&C Act).

Notification to the immediate previous source(s) and immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as email, fax, or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts, but we recommend that such notifications also be confirmed by one of the previous methods and/or documented in an appropriate manner. We may require that the notification include any or all of the following data elements: (1) the date on which the article of food was determined to be a reportable food; (2) a description of the article of food including the quantity or amount; (3) the extent and nature of the adulteration; (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known; (5) the disposition of the article of food, when known; (6) product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food; (7) contact information for the responsible party; (8) contact information for parties directly

linked in the supply chain and notified under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act, as applicable; (9) the information required by FDA to be included in the notification provided by the responsible party involved under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under section 417(d)(7)(A) of the FD&C Act; and (10) the unique number described in section 417(d)(4) of the FD&C Act (section 417(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (e) of the FD&C Act). We may also require that the notification provides information about the actions that the recipient of the notification will perform and/or any other information we may require (section 417(d)(6)(B)(iii)(II) and (III) and (d)(7)(C)(iii)(II) and (III) of the FD&C Act).

Section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods for a period of 2 years.

As required under section 1005(f) of FDAAA and to assist industry, we issued a guidance document entitled, "*Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007*," which is available at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug#reportable. The guidance contains questions and answers relating to the requirements under section 417 of the FD&C Act, including: (1) how, when and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 7.46 of FDA's regulations have been approved under OMB control number 0910-0249.

We therefore request extension of the OMB approval for the information collection provisions for third-party disclosure and recordkeeping set forth under section 417 of the FD&C Act regarding the Reportable Food Registry, and with the information collection associated with guidance.

2. Purpose and Use of the Information Collection

Section 417 of the FD&C Act establishes disclosure and recordkeeping burdens. Specifically, FDA may require a responsible party (as defined by statute) to notify the immediate previous source and/or immediate subsequent recipient of the reportable food (sections 417(d)(6)(B)(i) - (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (*i.e.*, the immediate previous source and/or immediate subsequent recipient) to notify its own immediate previous source and/or immediate subsequent recipient of the reportable food (sections 417(d)(7)(C)(i) - (ii) of the FD&C Act). Section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods for a period of two years.

The congressionally-identified purpose of the Registry is to provide a reliable mechanism to track patterns of adulteration in food which would support efforts by FDA to target limited inspection resources to protect the public health (see FDAAA, section 1005(a)(4)). The reporting and recordkeeping requirements described previously are designed to enable FDA to quickly identify and track an article of food (other than infant formula) for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals. We use the information collected under these authorities to help ensure that such products are quickly and efficiently removed from the market.

Description of Respondents: Mandatory respondents to this collection of information are owners, operators, or agents in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States ("responsible parties") who have information on a reportable food. Voluntary respondents to this collection of information are Federal, State, and local public health officials who have information on a reportable food.

3. Use of Improved Information Technology and Burden Reduction

Notification to the immediate previous source and immediate subsequent recipient of the article of food may be accomplished by electronic communication methods such as e-mail, fax or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts, but we recommend that such notifications also be confirmed by one of the above methods and/or documented in an appropriate manner.

Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. The FD&C Act 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.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

While the statutory requirements provide exceptions for small businesses, we believe the information collection imposes no undue burden. Also, we assist small businesses in complying with the requirements of the FD&C Act through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our Small Business Assistance webpage at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information is collected on an occasional, "*as needed*" basis. A "reportable food" is an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. (Section 417(a)(2) of the FD&C Act). We believe that prompt, mandatory reporting of reportable food is consistent with the congressional intent of FDAAA and important for public health reasons. Delayed or less frequent reporting of food events to FDA, or to the immediate previous source and immediate subsequent recipient of the article of food, would lessen the effectiveness of the reportable food registry as an early warning sign of possible safety problems with a particular food. Without reporting of all reportable food events, we would be unable to investigate and follow up promptly, which in turn could cause delays in alerting the public when safety problems are found.

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

This collection of information does not involve more than quarterly submission of information to the agency, submission of more than an original and 2 copies, retention of records for more than

three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation or require the disclosure of trade secrets or other confidential information.

Respondents are required to prepare a written response in less than 30 days. In the event of a reportable food event, we may require the responsible party to provide notification to the immediate previous source and/or immediate subsequent recipient of the article of food, as soon as practicable, but in no case later than the time specified by FDA.

With regard to the confidentiality of the information or the submission of trade secrets or proprietary information, the agency expects that it may inspect firm records containing confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act 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). To the extent 21 CFR 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

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 May 22, 2023 (88 FR 32775). 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 our Privacy Office to ensure appropriate handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via the electronic Safety Reporting Portal is name, email address, telephone number, and address. FDA determined that although PII is collected, 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, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden for this information collection as follows:

Table 1.--Estimated Annual Disclosure Burden[1]					
Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total					2,880

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

Although it is not mandatory under section 1005 of FDAAA that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden does not affect voluntary reporters of reportable food events.

Table 2.--Estimated Annual Recordkeeping Burden[1]					
Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Record	Total Hours
Maintenance of reportable food records under section 417(g) of the FD&C Act (mandatory reports)	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act (voluntary reports)	4	1	4	0.25 (15 minutes)	1
Total					301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For purposes of estimating number of records and hours per record, a "record" means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

The total burden for this information collection is 3,181 hours.

As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications for a period of 2 years. However, we do not expect that records will always be kept in relation to voluntary reportable food reports.

12b. Annualized Cost Burden Estimate

The total cost burden for this collection is estimated to be $403,566.86. For disclosures under section 417(d)(6), the annual hour cost burden to respondents is approximately $182,688 per year. This estimate is based upon the report being submitted by an employee making a salary equivalent to a GS-14-1 level in the locality pay area of Washington-Baltimore in 2023, which is $63.43/hour, increased 100% to $126.86 to account for overhead. We estimate that each disclosure to notify immediate previous source(s) and immediate subsequent recipient(s) of a reportable food event costs approximately $76.12 ($126.86 x 0.6 hours). Thus, the overall estimated cost incurred by the respondents is $182,688 (2,400 reports x $76.12/report).

For disclosures under section 417(d)(7), we estimate an hourly burden cost for notification by immediate previous source or immediate subsequent recipient to immediate previous source(s) and immediate subsequent recipient(s) to be $76.12 ($126.86 x 0.6 hours). This estimate is based upon the report being submitted by an employee making a salary equivalent to a GS-14-1 level in the locality pay area of Washington-Baltimore in 2023, which is $63.43/hour, increased 100% to $126.86 to account for overhead. Thus, the overall estimated reporting cost under section 417(d)(7) incurred by the respondents is $182,688 (2,400 reports x $76.12/report).

We estimate the recordkeeping hour burden costs to be about $31.72 ($126.86 x 0.25 hours) per record kept. This estimate is based upon the records being kept by an employee making a salary equivalent to a GS-14-1 level in the locality pay area of Washington-Baltimore in 2023, which is $63.43/hour, increased 100% to $126.86 to account for overhead. Thus, we estimate annual mandatory recordkeeping costs of $38,064 ($31.72/record x 1,200 records) and annual voluntary recordkeeping costs of $126.86 ($31.72/record x 4 records) for a total recordkeeping cost of $38,190.86.

Table 3.--Estimated Annual Cost Burden

Activity	Disclosures/Records	Hourly Costs	Total Respondent Costs
Disclosure under 417(d)(6)	2,400	$76.12	$182,688.00
Disclosure under 417(d)(7)	2,400	$76.12	$182,688.00
Mandatory Recordkeeping under 417(g)	1,200	$31.72	$38,064.00
Voluntary Recordkeeping under 417(g)	4	$31.72	$126.86
Total			$403,566.86

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 generally occurs as part of our response to a reportable food event. Assuming we devote 5 hours per inspection to the inspection of records, we estimate an annualized cost to the Federal government for the review of records retained by a firm to be $451.40 per review. In this calculation of cost, we estimate an hourly cost for review and evaluation using the wage rate for a GS-12, step 1 salary of $45.14 per hour for the locality pay area of Washington-Baltimore for 2023. We multiply the hourly rate by 5 ($225.70) and, to account for overhead, increased this cost by 100 percent, to arrive at $451.40 per review. We estimate that we conduct 694 reviews/inspections per year, thus bringing the cost to the Federal government to $313,271.60 (694 reviews x $451.40/review).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

We are not seeking approval to exempt the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.