United States Food and Drug Administration

Third Party Disclosure and Recordkeeping
Requirements for Reportable Food

OMB Control No. 0910-0643

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (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*." (Section 417(a)(2) of the FD&C Act). Section 417 of the FD&C Act requires FDA to establish an electronic portal (the Reportable Food electronic portal) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. FDA believes 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 0910–0643.

As required under section 1005(f) of FDAAA and to assist industry, FDA issued 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 online at *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm180761.htm*. 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 questions D5 and D6 of the guidance have been approved under OMB control number 0910–0249.

FDA is therefore requesting OMB approval of the information collection provisions referenced in the guidance document and found in section 417 of the FD&C Act:

Sections 417(d)(6)(B)(i) and 417(d)(6)(B)(ii) of the FD&C Act – Reporting

These sections of the FD&C Act allow FDA to require the responsible party that registers a food facility that manufactures, processes, packs, or holds an article of food to notify the immediate previous source(s) and immediate subsequent recipient(s) of a reportable food.

Sections 417(d)(7)(C)(i) and 417(d)(7)(C)(ii) of the FD&C Act – Reporting

These sections of the FD&C Act allow FDA to require the responsible party that is notified, i.e., the immediate previous source(s) and immediate subsequent recipient(s), to notify their immediate previous source(s) and immediate subsequent recipient(s) of the reportable food.

Section 417(g) of the FD&C Act – Recordkeeping

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

2. Purpose and Use of the Information Collection

Section 417 of the FD&C Act establishes third party disclosure and recordkeeping burdens. Specifically, FDA may require the responsible party 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, FDA 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 the Food and Drug Administration to target limited inspection resources to protect the public health" (Pub. L. 110-085, 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. FDA uses the information collected under these laws 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 the 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

Respondents may report instances of reportable food to the Registry via the electronic Safety Reporting Portal. The Safety Reporting Portal is an electronic system that accepts, among other data, information concerning instances of reportable food. FDA estimates that one-hundred percent (100%) of the respondents will use electronic means to submit the required information.

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 FDA recommends 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. FDA is required by statute to established a reportable food registry.

5. Impact on Small Businesses or Other Small Entities

While FDAAA provides no statutory exception for small businesses, we believe the information collection imposes equivalent burden for small and large firms alike. However, FDA aids small businesses in dealing with the requirements of the FD&C Act 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

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). FDA believes 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, FDA 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, FDA 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, FDA 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), FDA published a 60 day notice for public comment in the Federal Register of June 7, 2017 (82 FR 26489). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA provides no assurance of confidentiality to responsible persons who voluntarily decide to, or are required to, submit a reportable food report to FDA, or notify an immediate previous source and immediate subsequent recipient of the article of reportable food, or maintain records related to reportable foods. Under section 417(h) of the FD&C Act, a record in the Reportable Food Registry is subject to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552), except that FDA registration numbers are protected from disclosure as provided by section 415(a)(4) of the FD&C Act. In addition, as discussed above, confidential commercial information is protected from disclosure under 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). To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

When a responsible party submits data and supporting information through the secure portal that entry and supporting data is not publicly available through the portal to anyone but the reporting entity and FDA. In other words, there is no public access to the portal or repository of data submitted under this section. Even when a subsequent recipient or previous supplier enters information to the portal pertinent to a report filed by a responsible party, the original information is not available to the recipient or supplier directly through the portal.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1. -- Estimated Annual Third Party Disclosure Burden[1]					
Activity/FD&C Act	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 mins.)	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 mins.)	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 mins.)	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 mins.)	720
Total					2,880

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

Third-Party Disclosure Burden

FDA estimates that approximately 1,200 reportable food events with mandatory reporters will occur annually. Based on its experience, FDA estimates that it could receive 200 to 1,200 "reportable" food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. FDA utilized the upper-bound estimate of 1,200 for these calculations.

FDA estimates that notifying the immediate previous source(s) will take 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) will take 0.6 hours per reportable food. FDA also estimates that it will take 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their immediate previous source(s) and immediate subsequent recipient(s). The agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under FDAAA Section 1005 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 will not affect voluntary reporters of reportable food events. Therefore, FDA estimates that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under sections 417(d)(6)(B)(i) and B(ii) and 417(d)(7)(C)(i) and (C)(ii) of the

FD&C Act for 1,200 reportable foods will be 2,880 hours annually ((1,200 x 0.6 hours) + (1,200 x 0.6 hours) + (1,200 x 0.6 hours) + (1,200 x 0.6 hours)). This annual burden is shown in Table 1.

Table 2. -- Estimated Annual Recordkeeping Burden[1]					
Activity/FD&C Act	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 mins.)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act -- Voluntary reports	4	1	4	0.25 (15 mins.)	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.

Recordkeeping Burden

The agency has determined that there will be recordkeeping burdens associated with FDAAA. Section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods for a period of 2 years. Based on our experience, we estimate that each mandatory food report will require 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory food reports is thus estimated to be 300 hours (1,200 records x 0.25 hours). We do not expect that records will always be kept in relation to voluntary reportable food reports.

Therefore, FDA estimates that records will be kept for four of the 1,200 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour (4 x 0.25 hours). The estimated total annual recordkeeping burden is estimated to be 301 hours.

12b. Annualized Cost Burden Estimate

The total burden for this collection is estimated to be $341,531.36.

For reporting under section 417(d)(6), the annual hour cost burden to respondents is approximately $154,608 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 2017, which is $53.68/hour, increased 100% to $107.36 to account for overhead. FDA estimates that each report to notify immediate previous source(s) and immediate subsequent recipient(s) of a reportable food event costs $64.42

($107.36 x 0.6 hours). Thus, the overall estimated cost incurred by the respondents is $154,608 (2,400 reports x $64.42/report).

FDA also estimates the hour burden costs for notification by immediate previous source or immediate subsequent recipient to immediate previous source(s) and immediate subsequent recipient(s) to be $64.42 ($107.36 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 2017, which is $53.68/hour, increased 100% to $107.36 to account for overhead. Thus, the overall estimated reporting cost under section 417(d)(7) incurred by the respondents is $154,608 (2,400 reports x $64.42/report).

FDA estimates the recordkeeping hour burden costs to be about $26.84 ($107.36 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 2017, which is $53.68/hour, increased 100% to $107.36 to account for overhead. Thus, we estimate annual mandatory recordkeeping costs of $32,208 ($26.84/record x 1,200 records) and annual voluntary recordkeeping costs of $107.36 ($26.84/record x 4 records).

Table 3 – Annualized Cost Burden			
Activity	Total Burden per 3rd Party Report of Record	Hourly Wage Rate	Total Respondent Costs
Reporting under 417(d)(6)	2,400	$64.42	$154,608
Reporting under 417(d)(7)	2,400	$64.42	$154,608
Mandatory Recordkeeping under 417(g)	1,200	$26.84	$32,208
Voluntary Recordkeeping under 417(g)	4	$26.84	$107.36
Total			$341,531.36

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

FDA's review of the retained records would generally occur as part of its response to a reportable food event. 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 $382.00 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation at a base GS-12, step 1 salary of $38.20 per hour for the locality pay area of Washington-Baltimore-Northern Virginia for 2017. Five hours multiplied by $38.20 equals $191.00. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $382.00 per review.

15. Explanation for Program Changes or Adjustments

The information collection reflects agency adjustments. Specifically we have decreased our recordkeeping estimate by 149 hours, with a corresponding [decrease in responses by 596 responses]. Because we expect fewer records to be maintained, we have adjusted our estimate accordingly. Also, in ROCIS, we have consolidated the third-party disclosure ICs into one element from four in this collection while we have listed the recordkeeping elements individually (i.e., we consolidated the total number for ICs from six to three). Therefore, for this submission of extension, this ICR now has three ICs in ROCIS, but the information collection activities and the burden associated with each IC remain broken down into six ICs in Item 12 of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish data from this information collection.

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.