Third Party Disclosure and Recordkeeping Requirements for Reportable Food

OMB Control No. 0910-0643

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), among other things. Section 417 of the act requires the Secretary of Health and Human Services (the Secretary) to establish within the Food and Drug Administration (FDA) a Reportable Food Registry (the Registry). The Secretary has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the act, including section 417.

Section 417 of the act 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 act). Section 417 of the 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 made the decision that the most efficient and cost effective means to implement the requirements of section 417 of the act relating to the Registry was to utilize the business enterprise system within the agency: the MedWatch^{Plus} Portal.

Section 1005(f) of FDAAA also required FDA to issue a guidance for industry on submitting reports through the electronic portal, (1) Of instances of reportable food and (2) providing notifications to other persons in the supply chain of such article of food. FDA has issued a guidance containing questions and answers relating to the requirements under section 417 of the 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.

This collection of information was initially approved under the emergency processing provisions of the PRA for 180 days. FDA is following up this initial emergency clearance with a request for a 3 year extension of approval for this collection of information. Listed below, are the following sections (requirements) for which FDA is seeking OMB approval

Sections 417(d)(6)(B)(i) and 417(d)(6)(B)(ii) of the act – Reporting

These sections of the 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 act -- Reporting

These sections of the 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 act -- Recordkeeping

Section 417(g) of the 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

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 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 their own immediate previous source and/or immediate subsequent recipient of the reportable food (Sections 417(d)(7)(C)(i) - (ii) of the act). Section 417(g) of the 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 regulations to help ensure that such products are quickly and efficiently removed from the market.

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 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 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

FDA is the only Federal agency that collects this information as a result of the mandatory reporting and recordkeeping requirements in Section 417 of the act. No duplication can occur as each "responsible party" (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 who have information on a reportable food) is responsible for his own shipping and receiving records. Each reportable food event is unique. The information needed to track the scope and breadth of adulteration in food is the exact shipping and distribution patterns for a specific lot or group of lots of a particular product. The information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDAAA contains no statutory exception for small businesses from its provisions. The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by these information collection provisions. The reporting and recordkeeping provisions discussed in the guidance are applicable to all businesses including small businesses. However, FDA aids small businesses in dealing with the requirements of the act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

6. Consequences of Collecting the Information Less Frequently

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 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, the 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), in the Federal Register of October 20, 2009 (74 FR 53746), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two letters in response to the notice before the close of the comment period, each containing one or more comments.

(Comment 1) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it underestimated the potential number of such sources and recipients that may require notification. The comment stated that there could be more than 12,500 different sources for the grain portion of a single shipment of finished feed, and more than 80 different immediate previous sources for the other feed ingredients present. Similarly, another comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it assumed only one previous source and one subsequent recipient.

(Response) FDA appreciates the data provided in the comment. However, the agency notes that the comment did not provide any proposed change to the burden hours set forth. Thus, FDA has not changed the burden hour estimate in table 1 of this document. Please note that we expect to be able to obtain relevant data from the electronic reporting system that we can use to better estimate the burden of this reporting. We also note that this burden is imposed by the law itself. The reporting to immediate previous source(s) and immediate subsequent recipient(s) of a reportable food is authorized by sections 417(d)(6)(B)(i), 417(d)(6)(B)(ii), 417(d)(7)(C)(i), and 417(d)(7)(C)(ii) of the act. FDA has no way of knowing how long each supply chain is or how many ingredients will be involved with each reportable event. However, we did attempt to account for this reporting. We estimated burdens assuming two immediate previous sources and two

immediate subsequent recipients for each of the 1,200 estimated annual reportable food events.

(Comment 2) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food, arguing that the 0.6 hours estimated by the agency does not adequately allow for recall notification writing, editing, review and approval by the notifying entity and FDA. The comment estimated that it would take a minimum of four hours to prepare an FDA-approved Class I recall notification. The comment further argued that recall follow-up activities and communications between the affected entity(ies) and the FDA will take additional time.

(Response) FDA disagrees and notes that the comment references the Class I recall procedures governed by part 7 of FDA's regulations (21 CFR part 7). We did not estimate a burden for this process because the procedures and the associated burden estimates have already been approved under OMB control number 0910-0249 (FDA Recall Regulations, 21 CFR part 7).

(Comment 3) One comment argued that FDA underestimated the burden of notifying the immediate previous source(s) and the immediate subsequent recipient(s) of the article of food because it assumed that one form of notification, noting that multiple methods of notification are typically necessary: e-mail, facsimile and postal mail.

(Response) FDA disagrees. With regard to the method of notification for the purposes of this information collection, as described elsewhere in this document, notification 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 notifications also be confirmed or documented in an appropriate manner. Multiple forms of notifications are not required and, therefore, were not included in the burden estimate.

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 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 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, the 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 though the secure portal that entry and supporting data is not publicly available through the portal to anyone but the reporting entity and the FDA. In other words, there is not public access to the portal and 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

FDA estimates the burden for this information collection as follows:

Hour Burden Estimate

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

Activity	No. of Respondents	Annual Frequency per Response	Total annual Responses	Hours Per Response	Total Hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the act (mandatory reporters only)	1,200	1	1,200	0.6	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the act (mandatory reporters only)	1,200	1	1,200	0.6	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the act (mandatory reporters only)	1,200	1	1,200	0.6	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the act (mandatory reporters only)	1,200	1	1,200	0.6	720

Total	2,880

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

Reporting Burden

FDA estimates that notifying the immediate previous recipient will take 0.6 hours per reportable food and notifying the immediate subsequent recipient will take 0.6 hours per reportable food. FDA also estimates that it will take 0.6 hours for the immediate previous source or the immediate subsequent recipient to also notify their immediate previous source and immediate subsequent recipient. The agency bases its estimate on its experience with mandatory and voluntary reports recently submitted to FDA that would be considered "reportable food" reports in the future. (73 FR 63153 at 63157; October 23, 2008). These burden estimates have been submitted to OMB in the proposed collection of information entitled, "Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire," which is currently under review (74 FR 23721, May 20, 2009).

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 and immediate subsequent recipient under sections 417(d)(6)(B)(i) and B(ii) and 417(d)(7)(C)(i) and (C)(ii) of the 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).

Reporting Cost Burden Estimate

FDA estimates the hour burden costs to notify their immediate previous source and immediate subsequent recipient of a reportable food event is $44 ($73.83 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 2009, $49.22/hour, increased to $73.83 to account for overhead. Thus, $44 per report x 2,400 reports = $105,600.

FDA also estimates the hour burden costs for the immediate previous source or the immediate subsequent recipient to also notify their immediate previous source and immediate subsequent recipient to be about $44 ($73.83 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 2009, $49.22/hour, increased to $73.83 to account for overhead. Thus, $44 per report x 2,400 reports = $105,600.

Table 2. -- Estimated Annual Recordkeeping Burden[1]

Activity	No of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records[2]	Hours per Record	Total Hours
Maintenance of reportable food records under section 417(g) of the act -- Mandatory reports	1,200	1	1,200	0.25	300
Maintenance of reportable food records under section 417(g) of the act -- Voluntary reports	600	1	600	0.25	150
Total					450

Recordkeeping

The agency has determined that there will be recordkeeping burdens associated with FDAAA. Section 417(g) of the act requires that responsible persons maintain records related to reportable foods for a period of two years. 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. FDA bases its estimate on its experience with recordkeeping for food and cosmetics derived from cattle materials (71 FR 59653 at 59667). The annual recordkeeping burden for mandatory food reports is thus estimated to be 300 hours (1,200 x 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reporting. Therefore FDA estimates that records will be kept for 600 of the 1,200 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 150 hours annually (600 x 0.25 hours). The estimated total annual recordkeeping burden is shown in Table 2.

Recordkeeping Cost Burden Estimate

FDA estimates the recordkeeping hour burden costs to be about $18 ($73.83 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 2009, $49.22/hour, increased to $73.83 to account for overhead. Thus we estimate $18 per record x 1,200 records = $21,600 for annual mandatory recordkeeping costs; $18 per record x 600 records = $10,800 for annual voluntary recordkeeping costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this 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 $350.30 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 $35.03 per hour for the locality pay area of Washington-Baltimore-Northern Virginia for 2009. Five hours multiplied by $35.03 per hour equals $175.15. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $350.30 per review.

15. Explanation for Program Changes or Adjustments

The increase in reporting and recordkeeping burdens reflect our estimate of the number of reportable food events that FDA would require the immediate previous source and immediate subsequent recipient of a reportable food to be notified and that they also notify *their* immediate previous source and immediate subsequent recipient; this burden includes any mandatory notification and the associated mandatory (and some voluntary) recordkeeping regarding the event. As noted in Table 2, FDA has added the maintenance of reportable food records under section 417(g) of the act for "voluntary reports" to the recordkeeping burden estimate, since the emergency approval. FDA estimates that records will be kept for 600 of the 1200 voluntary reports expected to be received annually. Thus, the recordkeeping burden (additional program change / increase) is estimated to be 150 hours annually (600 x 0.25 hours).

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.