Reporting and Recordkeeping Requirements for Reportable Food

0910-NEW

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 currently under development within the agency: the MedWatch^{Plus} Portal. The agency expects the system to be operational on September 8, 2009.

In addition, Section 1005(f) of FDAAA required FDA to issue guidance to industry about submitting reports through the electronic portal of instances of reportable food and providing notifications to other persons in the supply chain of such article of food. FDA is issuing 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.

FDA is requesting emergency OMB approval of the information collection provisions in the guidance titled, "Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007," and the following sections of the act:

Sections 417(d)(6)(B)(i) and 417(d)(6)(B)(ii) of the act – Third Party Disclosure

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 – Third Party Disclosure

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.

In accordance with the 5 CFR 1320.13, the use of normal clearance procedures will cause the agency's guidance document to not be finalized in time for the launch of the portal on September 8, 2009, which will cause a statutory deadline to be missed. FDA is requesting OMB approval by August 17, 2009

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.

This is a new collection of information. 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 June 16, 2009 (74 FR 28498), FDA published a 30-day notice requesting public comment on the proposed information collection. In addition, FDA published the Notice of Availability of the draft guidance in the Federal Register of June 11, 2009 (74 FR 27803). FDA received fifteen letters in response to the notices, each containing one or more comments responsive to the comment request on the four specified aspects of the collection of information. Summaries of the comments and the agency's responses are provided in the following paragraphs.

(Comment) FDA should clarify whether or not it will accept reports voluntarily submitted by any parties other than the "responsible party" or public health officials. FDA should prevent the filing of "nuisance" reports through the RFR electronic portal.

(Response) FDA will not be accepting voluntary reports other than from Federal, State, or local public health officials. The portal provides a screening question asking the reporter if they are reporting under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register, of if they are submitting as a public health official. FDA is encouraging all users to provide contact information in all reports which both verifies the source of the report and allows FDA to conduct any needed follow-up.

In addition, we have a system requirement that addresses our abilities to assess and link duplicate reports to minimize the problem of duplicate reporting. In addition, the Web portal will allow follow-up information as well as attachments to be entered and linked to a previously submitted report. This capability will assist the agency in identifying possible nuisance reports.

(Comment) The guidance should be clarified to indicate when the 24 hour reporting window starts, for example: when a presumptive positive is found, or when a positive is confirmed.

(Response) FDA modified the guidance to clarify that, if a presumptive positive result provides 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, the responsible person is required to submit a report to FDA through the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after receiving the presumptive positive result.

(Comment) Information collected through the registry is publicly available via a Freedom of Information Act (FOIA) request. Exemption 4 under the Freedom of Information Act protects Trade Secret and Confidential Business Information that is collected by FDA and this information should be treated appropriately and not inadvertently disclosed under a FOIA request.

(Response) 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, 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.

(Comment) FDA should develop procedures by which erroneous filings and inaccurate information can be purged from the system before someone is harmed. The purging of inaccurate or erroneous reports should be done by FDA automatically where FDA detects the errors or upon request of a responsible party when FDA verifies the error.

(Response) FDA does not intend to "purge" any records, even those found to be in error. The record will be marked and annotated, but not "purged". 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. With regard to allowing a responsible party to correct an inaccurate or erroneous

report, the Web portal will allow follow-up information as well as attachments to be entered and linked to a previously submitted report.

(Comment) The portal should allow for the submission of data in a variety of forms and formats. FDA needs to allow the system to accept information in the form of a Word document, a PDF file, an Excel spreadsheet, a text delimited file as well as other formats.

(Response) The MedWatch Plus portal will allow submission of attachments to reports in commonly-used file formats, such as Microsoft Word, Excel and Adobe. The agency intends to publish guidance that will provide a list of acceptable file types. In the event that a user would like to submit an attachment that is in an unacceptable file type, the agency intends to communicate with the user via a message providing instructions for file types we will accept and contact information for a help desk providing IT support and additional assistance to the public.

The rational questionnaire will facilitate the collection of consistent, complete, accurate information and produce a structured report utilizing the HL7-ICSR data exchange message. The agency will continue to support the submission of 'batched' adverse event reports through the FDA electronic submission gateway. The FDA is moving toward the use of the HL7-ICSR message exchange; however, acceptable, alternative data exchange message formats (e.g., E2BM, E2BR) will be supported for a period of time that has not been yet been determined.

(Comment) FDA should share information and coordinate regulatory efforts with USDA and promptly provide to USDA reports it receives about foods that fall within USDA's jurisdiction.

(Response) When the MedWatch Plus portal is operational, reporters will be able to use the animal adverse event view of the rational questionnaire to report adverse events associated with devices used in animals and adverse reactions associated with compounded drugs for animals. Furthermore, adverse event reports submitted through the portal will be forwarded to the U.S. Department of Agriculture.

(Comment) The FDA, instead of the firm, should notify the FDA district office so as to not result in duplicative operations by the district office and the agency's headquarters.

(Response) The firm is the appropriate party to notify the FDA district office. Under §7.46 of FDA's regulations (21 CFR 7.46), firms that voluntarily remove or correct a distributed product (foods and drugs (animal or human), cosmetics, medical devices and biologicals) are asked to immediately notify the appropriate FDA district office of such actions.

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

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in question 28 of the guidance have been approved under OMB control no. 0910–0249.

FDA estimates the burden for this information collection as follows:

Hour Burden Estimate

Table 1. -- Estimated Annual Third Party Disclosure 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 also estimates that approximately 1,200 reportable food events with mandatory reporters will occur annually. The agency originally estimated that it would receive 1,200 reportable food reports in the burden estimates 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 (60-day notice available at 73 FR 63153 (October 23, 2008); 30-day notice available at 74 FR 23721(May 20, 2009)). We provided the following analysis:

> FDAAA, Section 1005, the Reportable Food Registry, established new electronic mandatory and voluntary reporting requirements for instances of "reportable" food, meaning 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 received 625 voluntary food complaints leading to adverse events from January 1, 2008, to June 30, 2008, and there were 206 and 182 Class 1 Recalls for human food in Fiscal Years 2006 and 2007, respectively. Based on these experiences, FDA estimates that FDA 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 will utilize the upper-bound estimate of 1,200 for these calculations.

(73 FR 63153 at 63157; 74 FR 23721, at 23727)

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

This is a new collection. 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.

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.