Changes to Reportable Food Registry Reports
Under the FDA Food Safety Modernization Act

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085) (FDAAA) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). 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). The Secretary has delegated to the Commissioner of the Food and Drug Administration (FDA) the responsibility for administering the FD&C Act, including section 417. To further the development of the RFR, section 417 of the FD&C Act required FDA to establish an electronic portal by which instances of reportable food ("RFR reports") must be submitted to FDA by responsible parties and may be submitted by public health officials. The portal was established in 2009. RFR reports are submitted electronically using the FDA Safety Reporting Portal (approved under OMB control number 0910-0645).

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (P.L. 111-353) (the legislation or FSMA). Section 211 of the legislation amended section 417 of the FD&C Act to require the Food and Drug Administration (FDA) to collect additional information in the agency's RFR reports:

> (1) a description of the article of food;
> (2) affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food;
> (3) contact information for the responsible party; and
> (4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.

FDA is requesting emergency OMB approval of the information collection provisions in the following sections of the act:

Section 417 of the FD&C Act - Reporting

Section 417 of the FD&C Act sets forth information that the respondent is required to submit in the agency's RFR reports. We have uploaded screenshots of this registry.

In accordance with the 5 CFR 1320.13, the use of normal clearance procedures will cause the agency's revisions to RFR reports not to be finalized and also cause the agency to be unable to generate one page notices by June 4, 2012, which will cause a statutory deadline to be missed. More importantly, however, FDA believes that public harm will occur if normal PRA clearance procedures are followed. In the six months or more it can take to obtain a full PRA clearance to authorize the new data elements, a significant number of consumers could be exposed to serious adverse health consequences or death. FDA believes that these circumstances can be mitigated or prevented through prompt reporting of these adulterated foods. FDA can then use this information to post warnings on its website for consumers. If consumers are not notified that the grocery store has sold a reportable food, they will be at risk of consuming hazardous food products that pose a risk of **serious adverse health consequences or death**. The Agency will be at risk of not fulfilling its FSMA mandate and public harm is reasonably likely to occur. FDA is requesting OMB approval by May 14, 2012.

2. Purpose and Use of the Information Collection

The Congressionally-identified purpose of the RFR 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" (121 Stat. 965). The new FSMA required reporting and third-party disclosure requirements described previously are designed to enable FDA to quickly identify, track and remove from commerce 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 to prevent foodborne illnesses. These actions will further enhance FDA's ability to quickly identify and remove adulterated food/feed from commerce and to help protect the nation's food supply against terrorist acts and other public health emergencies.

Description of Respondents: 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 who have information on a reportable food. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

As noted above, RFR reports are submitted electronically using the FDA Safety Reporting Portal Thus, FDA estimates that one hundred percent (100%) of the respondents will use electronic means to submit the required information.

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

FDA estimates that seventy-five percent (75 %) of respondents are small businesses. The reporting requirements of section 417 of the FD&C Act are applicable to all businesses including small businesses. Section 211 of FSMA 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. FDA aids small businesses in complying with its requirements 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

Data collection occurs occasionally. 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 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), FDA will publish an advance notice of proposed rulemaking requesting public comment on the FSMA changes to the RFR and the new one-page notices FSMA requires FDA to post on www.fda.gov beginning June 4, 2012.

As described above, RFR reports are submitted electronically using the FDA Safety Reporting Portal (approved under OMB control number 0910-0645). The 0910-0645 collection expires on September 30, 2012. FDA is in the process of extending this collection and will publish a 60-day notice requesting public comment on the changes to the data elements of the RFR reports.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide 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, or are required, to submit a RFR report to FDA. 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.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of additional data elements required by section 417 of the FD&C Act	1,877	1	1,877	0.20 (12 minutes)	375

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

This estimate is based on FDA's experience with the RFR and the average number of RFR reports submitted in Years 1 and 2 of the RFR. In Year 1 of the RFR, 2,600 total submissions were received, of which 2,240 were determined to be reportable after review by the FDA Risk Control Review Team and entered into the Reportable Food Registry (the Registry). In Year 2 of the RFR, a total of 1,153 submissions were received, of which 882 were determined to be reportable. (See Reportable Food Registry Second Annual Report available at: http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm241681.htm). Based on this, FDA estimates that, on average, it will receive approximately 1,877 submissions annually (2,600 + 1,153 = 3,753; 3,753/2 = 1,876.5, rounded to 1,877).

The agency estimates that all of the FSMA changes to the RFR data elements will, in total, require 12 additional minutes per submission (0.2 hour). FDA bases its estimate on its experience with similar information collections. The annual reporting burden for the FSMA changes to the RFR reports is thus estimated to be 375 hours (1,877 x 0.2 hour = 375.4 hours, rounded to 375 hours).

FDA notes, however, that the submission of RFR reports is approved under OMB Control Number 0910-0645. In that collection, the reporting burden estimate associated with RFR report submissions is an average, based on a broad range of RFR report submissions. FDA further notes that not all of the FSMA required changes in the data elements are likely to be utilized in any one submission. Thus, FDA estimates that the FSMA required changes in the data elements will not change the average reporting burden estimated for the 0910-0645 collection, where FDA has estimated the maximum reporting burden for a mandatory report to be 1 hour.

As described above, section 417 of the FD&C Act requires FDA to generate one-page notices from RFR reports to post on www.fda.gov for grocery stores to display to consumers when a reportable food has been sold. The third-party disclosure burden in section 417 is the requirement for grocery stores to display the one-page notice to consumers when a reportable food has been sold. No burden has been estimated for the third party disclosure required by section 417 of the FD&C Act because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information

originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $26,910 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the request for certification would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2012, approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $71.76/hour. Thus, the overall estimated cost incurred by the respondents is $26,910 (375 burden hours x $71.76/hr = $26,910).

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 collection.

14. Annualized Cost to the Federal Government

FDA's costs to add the data elements to the existing RFR reports include changes to the design, software and to the network interface. FDA estimates that these costs will total $900,000.

15. Explanation for Program Changes or Adjustments

This is a new collection of information. The reporting burden hours are caused by section 211 of FSMA, which amended section 417 of the FD&C Act to require FDA to collect additional information in the agency's RFR reports.

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

There are no exceptions to the certification.