Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

0910-0502

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the Food and Drug Administration (FDA). Sections 1.230 - 1.235 of FDA's regulations (21 CFR 1.230 - 1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations helps the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments. Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, FDA may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. Section 415(a)(2) of the FD&C Act, as amended by FSMA, also provides that, when determined necessary by FDA "through guidance," a food facility is required to submit to FDA information about the general food category of a food manufactured, processed, packed or held at such facility, as determined appropriate by FDA, including by guidance. FSMA also amended section 415 to provide FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that: (1) created, caused, or was otherwise responsible for such reasonable probability; or (2) knew of, or had reason to know of, such reasonable probability, and packed, received, or held such food. Under section 415(b)(2), FDA is required to provide a registrant subject to a suspension order with an opportunity to request an informal hearing on the actions required for reinstatement of registration and why the registration should be reinstated. Section 415(b)(3) provides that if FDA determines that a suspension of registration remains necessary, the registrant is required to

submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA.

FDA is therefore requesting emergency review of the following collections of information provided for under the FSMA amendments to section 415 of the FD&C Act, as well as approval of the collections of information contained in the draft guidance document entitled, "Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories":

- Modification of food facility registration forms to include the following mandatory fields based on section 415(a)(2) of the FD&C Act (21 U.S.C. 350d(a)(2)): the e-mail address for the contact person of a domestic facility and the e-mail address of the United States agent for a foreign facility, an assurance that FDA will be permitted to inspect the facility, and specific food categories;

- The requirement that registered facilities submit registration renewals to FDA biennially (section 415(a)(3) of the FD&C Act (21 U.S.C. 350d(a)(3));

- The food categories to be included in the food facility registration forms, as identified in the draft guidance document entitled, "Draft Guidance for Industry: Necessity of the Use of Food Product Categories in Registration of Food Facilities and Updates to Food Categories as Authorized by the FDA Food Safety Modernization Act" (section 415(a)(2) of the FD&C Act 21 U.S.C. 350d(a)(2)); and

- Collections of information found in section 415(b) of the FD&C Act for the suspension of a food facility's registration, including the submission of requests for informal hearings on the actions required for reinstatement of registrations and why such registrations should be reinstated, and, if FDA determines that certain suspensions of registration remains necessary, the submission of corrective action plans to demonstrate how registrants plan to correct the conditions found by FDA (section 415(b)(3)(A) of the FD&C Act (21 U.S.C. 350d(b)(3)(A)).[1]

These provisions are to be added to the existing information collections under this approval, specifically:

[1] FDA is characterizing the FSMA suspension of registration procedures as collection of information in Section 1 of this document for the purpose of informing OMB of this significant change to Registration as described in the previous ICR and requesting approval. However, FDA concludes in Section 12, below, that the suspension of registration collections of information in section 415(b) of the FD&C Act are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. If OMB disagrees with FDA's conclusion regarding the applicability of the exemption, FDA would like OMB to approve the FSMA suspension of registration procedures in response to this emergency request.

21 CFR 1.230 - 1.233 -- Reporting

Requires a facility to register with FDA and sets forth the information that the registration submission is required to contain, as well as items of information that registrants are encouraged, but are not required, to submit and the method of submitting the registration.

21 CFR 1.234 -- Reporting

Requires a facility to submit timely updates within 60 days of a change to any required item of registration information.

21 CFR 1.235 -- Reporting

Requires the registration for a facility to be cancelled when the facility ceases to operate, is sold to a new owner, or ceases to manufacture/process, pack, or hold food for consumption in the United States.

Form FDA 3537 and Form FDA 3537a

The terms "Form FDA 3537" and "Form FDA 3537a" refer to both the paper version of each form and the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov.

2. Purpose and Use of the Information Collection

Food Facility Registration, in conjunction with advance notice of imported food, helps FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Food Facility Registration provides FDA with information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information helps FDA and other authorities determine the source and cause of the event. In addition, the registration information enables FDA to notify more quickly the facilities that might be affected by the outbreak. See Interim Final Rule entitled, "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (68 FR 58894, at 58895; October 10, 2003).

Implementation of the new FSMA requirements described previously will help enable FDA to quickly identify and remove from commerce an article of food 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 will use the information collected under these provisions to help ensure that such food products are quickly and efficiently removed from the market.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food

for human or animal consumption in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The term "Form FDA 3537" refers to both the paper version of the form and the electronic submission system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov. Forms FDA 3537 and 3537a are available for download for registration by mail, fax, or CD-ROM. FDA estimates that ninety-four percent (94%) 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 requirements in Section 415 of the FD&C Act. FDA also requires registration of Low Acid Canned Foods (LACF) and infant formulas. However, these two registration programs are not a good substitute for the Food Facility Registration information collection for the following reasons. LACF and infant formula registration is on a per formulation or process basis; there may be multiple registered products produced in a single facility or a single registered process or formulation may be produced in multiple facilities; not all items of information required for Food Facility registration (especially relating to emergency contact) are required for LACF or infant formula registration; in addition, these two registration programs do not cover all food types covered under Food Facility Registration. Thus, LACF and infant formula registrations cannot satisfy the requirement of section 415(a)(5) of the FD&C Act that FDA compile and maintain an up-to-date list of registered facilities.

Certain registration requirements also exist at the state and local level. However, the registration requirements vary from jurisdiction to jurisdiction in terms of the information required, facilities covered, and form of reporting. FDA requires consistent reporting of information and coverage of facilities in order to comply with the requirement of section 415(a)(5) to compile and maintain an up-to-date list of registered food facilities. Finally, FDA is required to assign each food facility a unique registration number under section 415(a)(4) of the FD&C Act. None of these registration systems meet these requirements.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that approximately ninety-nine percent (99%) of the respondents are small businesses. The reporting requirements are those mandated by the Bioterrorism Act and FSMA and there is no statutory exception for small businesses in those acts. The same information is requested from large and small firms and is the minimal amount needed. However, 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/. In addition, the FDA Industry Systems Help Desk can answer computer system and technical questions, as well as general questions about Registration and will attempt to assist small businesses to register. The Help Desk is available Monday through

Friday from 7:00 a.m. to 11:00 p.m. Eastern Time. FDA strongly encourages electronic registration, but provides registration through postal mail, which can reduce the burden on small entities.

6. Consequences of Collecting the Information Less Frequently

A facility that begins to manufacture/process, pack, or hold food for consumption in the U.S. on or after December 12, 2003 is required to register before it begins such operations. In addition, all facilities that manufacture/process, pack or hold food for consumption in the U.S. are required to submit registration renewals to FDA biennially, occasional updates within 60 days of a change in a facility's required information, and cancellations when such facilities cease operations. If the collection is not conducted or is conducted less frequently, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States may not be in compliance with section 415 of the FD&C Act. If a facility is not registered or the registration for a facility is not updated when necessary, FDA may not be able to contact the facility in case of a known or potential threat to the food supply or other food-related emergency.

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

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 0910-0502 collection expires on August 31, 2013. Accordingly, FDA will soon begin the process of extending this collection and, in accordance with 5 CFR 1320.8(d), will publish a 60-day notice requesting public comment on the extension of OMB approval of this collection, including the FSMA-required changes.

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

Section 415(a)(5) of the FD&C Act provides that the list of facilities and any registration documents submitted pursuant to section 415(a) of the FD&C Act shall not be subject to disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 552), and information derived from such list or registration document shall not be subject to disclosure under FOIA to the extent that it discloses the identity or location of a specific registered person. 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).

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 complying with the information collection provisions of the FSMA changes to section 415 of the FD&C Act as follows:

Table 1.--Estimated Annual Reporting Burden Imposed by FSMA Provisions[1]

Activity - Citation	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Domestic New Facility Registration - Submission of additional data elements required by section 415 of the FD&C Act, as amended by FSMA	FDA 3537[2]	13,560	1	13,560	0.20 (12 mins.)	2,712
Foreign New Facility Registration – Submission of additional data elements required by section 415 of the FD&C Act, as amended by FSMA	FDA 3537	23,370	1	23,370	0.40 (24 mins.)	9,348
Biennial Renewal of Registration - Submission of additional data elements required by Section 415 of FD&C Act, as amended by FSMA	FDA 3537	224,930	1	224,930	0.50 (30 mins.)	112,465
Occasional Facility Update - Updates to additional data elements required by section 415 of the FD&C Act, as amended by FSMA	FDA 3537	118,530	1	118,530	0.20 (12 mins.)	23,706
Total Hours						**148,231**

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov._

The estimate of the number of facilities that will submit new facility registrations, biennial renewals of registration, updates to registration or cancellations of registration is based on the FDA's experience over the past 3 years, and the estimates submitted with the last request for

extension of OMB approval of this collection. The estimate of the number of hours that it will take a firm to gather the information needed is based on FDA's experience with firms submitting similar information. FDA believes that the information to be submitted will be readily available to the firms.

We estimate that the hours per response are affected by the new data elements required by FSMA. We estimate that the FSMA-required additional information for new facility registrations will require an additional 12 minutes per response for domestic facilities and an additional 24 minutes per response for foreign facilities, as reported in Table 1. We also estimate that the new biennial registration, which will require the submission of certain new data elements and the verification and possible updating of other information rather than re-entering all information, will require 30 minutes per response, including time for the new FSMA-required information. FDA estimates that, on an annualized basis, the number of biennial registrations submitted over the next three years will be 224,930. This estimate is based on the number of currently registered firms (449,860) divided by two. In addition, FDA expects that, each year, some firms will need to submit an occasional update of registration. We estimate that the FSMA-required additional information for occasional registration updates will require an additional 12 minutes per response, as reported in Table 1.

Although FDA's authority to suspend registration under section 415(b) of the FD&C Act became effective on July 3, 2011, FDA is required by section 415(b) to promulgate regulations to implement the suspension of registration provisions. Such regulations may more fully explain components of the suspension of registration provisions. Registered facilities are subject to the suspension of registration requirements in section 415(b) of the FD&C Act regardless of the status of the regulations implementing section 415(b). FDA will provide a registrant subject to a suspension order with an opportunity for an informal hearing. FDA will reinstate a registration if it determines that adequate grounds do not exist to continue the suspension of the registration (section 415(b)(3) of the FD&C Act). If FDA determines that a suspension of registration remains necessary after providing opportunity for an informal hearing, FDA will require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA (section 415(b)(3)(A) of the FD&C Act).

As noted, FDA expects to conduct a future rulemaking to implement the suspension of registration provisions. During the rulemaking, FDA will estimate the information collection burdens, if any. At this time, however, we conclude that the collections of information in section 415(b) of the FD&C Act are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulation in 5 CFR 1320.4(c) provides that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file or the equivalent would be opened with respect to a particular food facility as part of an investigation regarding suspending the registration of such a food facility. Thus, we have not included the burden of the FDA procedures associated with suspension of registration, including the registrant's opportunity to request an informal hearing related to the suspension of the registrant's registration, and, if

FDA determines that a suspension of registration remains necessary, the requirement that a registrant submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by FDA.

Finally, the estimated burden for the new registration data elements required by the new FSMA legislation and as discussed above are in addition to the currently approved information collection provisions. The currently approved provisions are as follows:

Table 2. Estimated Annual Reporting Burden for Currently Approved IC Provisions for Food Facility Registration

21 CFR Section	FDA Form No.	Number of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Facilities						
Domestic						
1.230-1.233	FDA 3537[1]	13,560	1	13,560	2.5	33,900
Foreign						
1.230-1.233	FDA 3537	23,370	1	23,370	8.5	198,645
					New Facility Registration Subtotal	**232,545**
Previously Registered Facilities- Updates (Form 3537) and Cancellations (Form 3537a)						
1.234	FDA 3537	118,530	1	118,530	1	118,530
1.235	FDA 3537a	6,390	1	6,390	1	6,390
					Updates or Cancellations to Existing Registration Subtotal	124,920
Total Hours Annually						**357,465**

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

Thus, the total estimated reporting burden for the information collection is 505,696.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $10,637,057 per year for the new information collections required under FSMA. 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 for the new information collections required under FSMA is $ 10,637,057 (148,231 burden hours x $71.76/hr = $10,637,057).

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 both the paper version of Form FDA 3537 and the electronic system known as the Food Facility Registration Module include changes to the design, to the software and to the network interface. FDA estimates that these costs will total $280,000. When added to the cost for the currently approved information collections, the total cost to government is $8,709,000.

15. Explanation for Program Changes or Adjustments

The reporting burden hours are caused by FSMA, which amended section 415 of the FD&C Act to require FDA to collect additional information in the agency's Food Facility Registrations. The burden reported in table 2 reflects only the FSMA-required changes to registration (new data elements, but primarily the new biennial registration requirement). The burden of 148,231 hours will be added to the burden currently approved under OMB Control Number 0910-0502 (357,465).

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.