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

OMB Control No. 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) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which, among other things, 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.

FDA is amending its regulations governing food facility registration. We are proposing to codify the requirements of section 102 of FSMA that were self-implementing and effective upon enactment of FSMA. In addition, we are proposing to implement other requirements of section 102 of FSMA to include mandatory electronic registration submissions beginning in 2016, and amendments to the retail food establishment definition. The proposed rule also includes additional reporting requirements in order to improve the utility of the food facility registration database. FDA is therefore requesting OMB review and approval of the following revisions to the information collection provisions approved under OMB Control No. 0910-0502 as provided for under the FSMA amendments to section 415 of the FD&C Act, and as described and contained in the proposed rule entitled, "Amendments to Registration of Food Facilities," that published April 9, 2015 (80 FR 19159).

Reporting; 21 CFR 1.230 - 1.233

Requires a facility to register with FDA and sets forth additional information that the registration submission is required to contain, as well as requiring items of information that registrants were formerly encouraged to submit and the method of submitting the registration.

Reporting; 21 CFR 1.234

Requires a facility to submit timely updates within 30 days of a change to any required item of registration information.

Reporting; 21 CFR 1.245

Requires mandatory electronic registration submissions beginning in 2016, which would cause some food facilities to submit a request for a waiver from that requirement.
Requires verification procedures for registration submissions made by individuals other than the owner, operator, or agent in charge, as well as a verification procedure for U.S. Agents.

Reporting; 21 CFR 1.230 - 1.233

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. Form 3537 can no longer be submitted using CD-ROM for multiple registration submissions and updates.

2. Purpose and Use of the Information Collection

Registration is one of several tools implemented under the Bioterrorism Act that enables FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply or other food-related emergency by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. Further, in the event of an outbreak of foodborne illness, such information helps FDA determine the source and cause of the event. Also, registration information enables FDA to quickly notify food facilities that might be affected by an outbreak, terrorist attack, threat, or other emergency. The proposed amendments will further enhance FDA's capabilities with respect to responding to food safety issues, and in addition, provide FDA with information we can use to focus and better utilize our limited inspection resources. Implementation of the new collection provisions described above will further help 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.

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 or by mail. FDA estimates that nearly ninety-nine percent (99%) of the respondents will use electronic means to submit the required information. At the same time, if the rule is finalized as proposed, it would mandate the electronic submission of food facility registrations, while also allowing respondents to submit a request for waiver of the requirement to electronically submit their registration.

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: (1) LACF and infant formula registration are on a per-formulation or process basis; (2) there may be multiple registered products produced in a single facility or a single registered process or formulation may be produced in multiple facilities; (3) not all items of information required for Food Facility registration (especially relating to emergency contact) are required for LACF or infant formula registration at this time; and (4) these two registration programs do not cover all food types covered under Food Facility Registration.

Certain registration requirements also exist at the state and local level. However, such 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. FDA knows of no other registration systems that 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 under these laws. The same information is requested from large and small firms alike and is the minimal amount needed. However, FDA aids small businesses in complying with its requirements through its Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on its 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.

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. Also, all facilities that manufacture/process, pack or hold food for consumption in the U.S. are required to submit registration renewals to FDA biennially, and occasional updates within 30 days instead of 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 comply 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 proposed rule published in the *Federal Register* on April 9, 2015 (80 FR 19159).

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

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 for the information collection as follows:

Table 1.-- Estimated One time Reporting Burden[1]					
Activity/ 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
All facility registrations (1.230-1.233)	172,274	1	172,274	0.18 (11 mins)	31,584

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

To determine the number of facilities in the above table, we assume that some of the participants in the 2012 biennial registration renewal cycle were new registrants. We do not consider those new registrations in estimating the total burden associated with the FSMA requirements. FDA used the Small Business Administration's (SBA's) estimate that 12 percent of all businesses are new. Although SBA's estimate does not necessarily mean that 12 percent of all food facilities are new, we nevertheless find the SBA's estimate sufficiently relevant to apply to food facilities. We therefore estimate that 12 percent of currently-registered food facilities were not registered at the time of the 2012 registration renewal cycle. As such, we estimate that 88 percent of currently-registered food facilities, or 172,274 facilities, were registered in 2012.

Using our updated estimates for the time required to comply with the self-implementing FSMA provisions, we now estimate that the requirement for an email address for a domestic facility's contact person and a foreign facility's U.S. Agent will take 1 minute. We also now estimate that the assurance statement required by FSMA will take 5 minutes to provide, and that the post-FSMA changes to food product categories will not result in any additional burden for facilities.

We also estimate the one-time burden from the new data elements in the proposed rule. We estimate that the average burden per response would be increased by the new data elements in the proposed rule. FDA believes that the new information will be readily available to the firms. We estimate that entering the four additional pieces of information that are currently optional would require, on average, an additional minute for each new data element per response. The four additional pieces of information that are currently optional are: 1) Preferred mailing address, 2) e-mail address for the owner opperator or agent in charge, 3) type of activity or type of storage conducted at the facility, and 4) e-mail address of the emergency contact of a domestic facilitiy. In addition, we estimate that entering a D-U-N-S® Number, would require, on average, an additional minute per response. Thus, we estimate that these five proposed new data elements will require a total of five additional minutes. We estimate that the submission of the FSMA data elements and proposed new data elements would jointly increase the one-time burden from those activities by a total of eleven minutes (0.18 hour). The estimated one-time burden for currently-registered facilities is therefore 172,274 facilities x 0.18 hours = 31,584 hours.

Table 2.-- Estimated Annual Reporting Burden[1]					
Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total
New domestic facility registrations (1.230-1.233)	9,795	1	9,795	2.7	26,284
New foreign facility registrations (1.230-1.233)	13,697	1	13,697	8.7	118,993
Updates (1.234)	68,518	1	68,518	1.5	105,632
Cancellations (1.235)	6,390	1	6,390	1	6,390
Biennial renewals (1.235)	97,883	1	97,883	0.38	36,706
Waiver requests (1.245)	1,061	1	1,061	0.17	180
Third party registration verification procedure (proposed 1.232(a)(10))	41,256	1	97,883	0.25	10,314
U.S. Agent verification procedure (proposed 1.231(a)(5) and (b)(7))	57,070	1	57,070	0.5	28,535
Total Hours					332,971

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

The currently approved annual reporting burden for food facility registration under OMB Control No. 0910-0502 is 468,117 hours. The estimated reporting burden for food facility registration under the proposed rule is 332,971 hours, a decrease of 135,146 hours. This decrease is due to the recently reduced number of active registrations in the food facility registration database. Our estimates of the number of facilities that will submit new facility registrations are based on estimates by SBA that 12 percent of all businesses each year are new. As such, we estimate that 12 percent of registrations (or 23,500 registrations) are from new facilities entering the market. We are proposing to make additional changes to the currently-approved reporting burden as well. As discussed above, FDA obtained a 6-month emergency OMB approval of the self-implementing FSMA reporting burdens, and subsequently obtained a 3-year approval of these requirements. As described in the preliminary economic impact analysis, we estimate that 68,518 respondents will file updates, a decrease from the estimated number of 118,530 respondents reported in the 2013 request for extension, and we estimate that 97,883 respondents will file biennial renewals, a decrease from the estimated number of 224,930 respondents reported in the 2013 request for extension. These decreases are due to recent reductions in the number of active registrations in the food facility registration database.

Prior to FSMA, FDA estimated that the average burden associated with new domestic and foreign facility registrations was a respective 2.5 and 8.5 hours. (See 75 FR 30033.) We expect that the proposed rule would add an additional 11 minutes to that burden as a result of the proposed new data elements. Based on estimates by SBA that 12 percent of all businesses are new, we estimate that all new facilities each year will be equal to 12 percent of the total number

of registered facilities. Thus, we estimate that each year there will be 9,795 new domestic and 13,697 new foreign facility registrations, and that the average burden for those new registrations will be of 2.7 hours (2.5 hours plus 11 minutes) for new domestic facility registrations and 8.7 hours (8.5 hours plus 11 minutes) for new foreign facility registrations, as reported in table 2, rows 1 and 2.

The proposed rule would also shorten the time period for updates from 60 calendar days to 30 calendar days. The average burden per response for updates would increase from 1.2 hours to 1.54 hours (difference of 0.34 hours, or about 20 minutes), as reported in table 2 row 3. This proposed rule would also establish an abbreviated renewal process, which modifies our previous estimate that on average it would take 0.5 hours per renewal. With the option for an abbreviated renewal process, we estimate that half the facilities will take 15 minutes per renewal using the abbreviated renewal process and that half of facilities will take 30 minutes. This alters our previous estimate of 0.5 hours to submit a renewal to an average of 0.38 hours (23 minutes) to submit a renewal, as reported in table 2, row 5. This estimate takes into account that some registered firms would be able to take advantage of the abbreviated renewal process, while other firms would take more time to prepare and submit the renewal, as discussed in the preliminary economic impact analysis. We have not changed our estimate of the average burden per response for cancellations because the proposed rule does not add new data elements for cancellations.

If the rule is finalized as proposed, it would mandate the electronic submission of food facility registrations, while also allowing respondents to submit a request for waiver of the requirement to electronically submit their registration. As described in the preliminary economic impact analysis, we estimate that, on average, 1,061 facilities will seek a waiver each year. We also estimate that it would take a respondent ten minutes to prepare the proposed waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the total annual burden of submitting waiver requests is calculated to be 180 hours (1,061 x 0.17 hours), as reported in table 2, row 6.

If the rule is finalized as proposed, it would establish a verification procedure for registrations submitted by individuals other than the owner, operator, or agent in charge (third party registrations), as well as a verification procedure for U.S. Agents. To verify third-party registrations, FDA would send an e-mail to the owner, operator or agent in charge with a link allowing the owner, operator, or agent in charge to either confirm or deny that he or she authorized the registration submission on behalf of the facility. In connection with requiring his verification process, the proposed rule would add e-mail address to the list of required information identifying the individual who authorized submission of registrations submitted by individuals other than the owner, operator, or agent in charge. As described in the preliminary economic impact analysis, we estimate that it would take an owner, operator, or agent in charge fifteen minutes (0.25 hour) to participate in FDA's verification procedure. This estimate includes the time required to enter the e-mail address of the owner, operator, or agent in charge who authorized the submission. We further estimate that 82,513 registrations would be affected once every other year, or 41,257 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours (41,257 x 0.25 hour = 10,314 hours), as reported in table 2, row 7.

To verify the U.S. Agent, FDA would send an e-mail to the U.S. Agent at the e-mail address provided by the registrant. The e-mail address would include a link that would connect the U.S. Agent to FDA's food facility registration module, allowing the U.S. Agent to either accept or decline assignment with the facility. If the U.S. Agent accepts the assignment, FDA would also e-mail the facility of the U.S. Agent's acceptance. If, however, a U.S. Agent declines the assignment, the issuance of the registration number could be delayed. We estimate that the burden that will result from the verification procedure would be about 30 minutes (0.5 hours). We also estimate that 114,139 registrations would be affected once every two years, or 57,070 facility registrations annually. Thus, the total annual burden of these verifications is estimated to be 28,535 hours (57,070 x 0.5 hour = 28,535 hours), as reported in table 2, row 8.

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.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $9,698,111 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 $ 9,698,111 (135,147 burden hours x $71.76/hr = $9,698,111).

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 agency has revised its estimated annual burden for this information collection by an increase of 86,053 annual responses and by a decrease of 105,710 annual hours. This revised estimate is broken down as follows:

IC #	Annual Responses	Annual Hours
1	-1285	-3469
2	-6203	-57946
3	-50012	-39459
4 (No change)	0	0
5	-127047	-75269
6 (New IC)	172274	31584
7 (New IC)	41256	10314
8 (New IC)	57070	28535
Total	86053	-105710

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published or used for general statistical purposes.

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.