

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

0910-0502

SUPPORTING STATEMENT

Terms of Clearance:

September 14, 2012 - In accordance with the terms of 5 CFR 1320, the ICR is approved for a period of 6 months. Before resubmitting this collection for approval, FDA must develop an implementation plan for making this collection electronically fileable. *October 19, 2012* - Terms of the previous clearance remain in effect. The change is approved. In the next request for approval, the agency should ensure that the burden statement on their forms and in the system are consistent and reflect the burden accurately. We also ask that FDA submit or report on their progress in developing instructions for both the paper and electronic formats. We also will want to discuss whether the electronic pre-populates the forms for both updates and re-registration.

Response:

Electronic submission capability – Electronic submission of Food Facility Registration forms has been available and promoted as the best method of registering since October 2003, when the Registration Interim Final Rule was published.

Accuracy of burden statements – We have updated the burden statements on the draft pdf of Form FDA 3537 submitted with this request for approval to reflect the burden of the additional data elements required by FSMA. Form FDA 3537a was unchanged by FSMA. Previously, the public reporting burden of Form FDA 3537 was stated as: “The burden for this collection of information is estimated to average between 1 and 12 hours per response” This statement has been revised to read: “Public reporting burden for this collection of information is estimated to average 2.7 hours to register a domestic facility; 8.9 hours to register a foreign facility; 1.2 hours to submit an occasional update to an existing registration; and 0.5 hour to submit a biennial renewal of an existing registration” This same change will be made to the electronic system. Please also note that the expiration date on both pdf forms and the electronic system will be updated once it is received.

Instructions – Instructions for both the paper and electronic formats for Forms FDA 3537 and 3537a are available in the form of guidance documents, mouse-over help and a live help desk. The original pdf form and electronic system were approved by OMB in 2003 with these aids in lieu of having written instructions attached to or included as part of the form. FDA issued guidance with regard to food facility registration in 2003. The guidance is available on FDA’s website at: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>. FDA also offers mouse-over help on the electronic system. In addition, the FDA Industry System Help Desk is available by telephone at 1-800-216-7331 or 1-301-575-0156 from 7:30 a.m.-11:00 p.m. Eastern Time on U.S. Government business days (Monday to Friday, excluding U.S. government holidays) for technical assistance with online registration.

Electronic pre-population of updates and biennial renewal – When a respondent from a previously registered facility accesses the electronic system (see <http://access.fda.gov>) with its registration number and PIN, the electronic system will pre-populate the information needed for

both updates and registration renewal. The respondent must, however, complete any new information required by FSMA (if the facility has not previously submitted it) and will need to make any changes to previously entered information that are necessary to update the registration. The respondent will also need to complete the certifications/assurance statements associated with signing and submitting the electronic registration.

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.

FDA's regulations require that each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States register with FDA using Form FDA 3537 (§ 1.231). 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>. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit their preferred mailing address; type of activity conducted at the facility; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal.

In addition to registering, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to

manufacture/process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

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.¹ These amendments took effect October 1, 2012. To comply with this statutory deadline, FDA obtained OMB approval in September 2012 of the following additional collection of information requirements under the emergency processing provisions of the PRA:

- Modification of food facility registration forms to include the following mandatory fields: 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 as identified in the guidance document entitled, “Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories” (section 415(a)(2) of the FD&C Act 21 U.S.C. 350d(a)(2)) (the “Food Product Categories guidance”); and
- 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))).

FDA requests the extension of OMB approval of the information collection provisions in the Food Product Categories guidance and the following citations:

¹ FDA concludes 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.

Section 415(a)(2) and (3) of the FD&C Act -- Reporting

Requires registered facilities to submit registration renewals to FDA biennially and adds the following required elements to the registration submission: e-mail address for the contact person of a domestic facility, e-mail address for the U.S. agent for a foreign facility, an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act, and specific food product categories as identified in the Food Product Categories guidance document.

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 helps 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 uses 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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of January 22, 2013 (78 FR 4414). We received one comment after the close of the comment period. While we were not able to address the comment in the 30-day notice, we address it here. The comment supported food facility registration and suggested three changes: (1) requiring facilities to note if they intend to claim qualified facility status or believe they are eligible for the very-small on-farm exemption; (2) requiring facility profile information to be reported as part of the biennial registration process; and (3) requiring facilities to submit their food safety plans during registration. To the extent that the comment recommended changes to our food facility registration regulations that can only be accomplished by rulemaking, the comment is outside the scope of the Paperwork Reduction Act notice. We are, however, considering whether changes to our regulations are necessary due to the recent enactment of the FDA Food Safety Modernization Act, and, if we decide to revise the food facility registration requirements, suggestions concerning additional changes to those regulations can be made as part of any resulting rulemaking.

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 this collection of information as follows:

Table 1.-- Estimated Annual Reporting Burden¹

21 CFR Section and/or Section of FD&C Act	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
New Facilities						
<i>Domestic</i>						
21 CFR 1.230-1.233 and section 415 of the FD&C Act	FDA 3537 ²	11,080	1	11,080	2.7	29,916
<i>Foreign</i>						
21 CFR 1.230-1.233 and section 415 of the FD&C Act	FDA 3537	19,900	1	19,900	8.9	177,110
New Facility Registration Subtotal						207,026
Previously Registered Facilities						
Updates under 21 CFR 1.234 and section 415 of the FD&C Act	FDA 3537	118,530	1	118,530	1.2	142,236
Cancellations under 21 CFR 1.235	FDA 3537a	6,390	1	6,390	1	6,390
Biennial Renewal of Registration required by Section 415 of the FD&C Act	FDA 3537	224,930	1	224,930	0.50 (30 mins.)	112,465
Updates, Cancellations or Biennial Renewals Subtotal						261,091
Total Hours Annually						468,117

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

²The 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>.

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received via the Food Facility Registration Module or on paper Form FDA 3537 in the past 3 years. FDA received 12,011 new domestic facility registrations during 2010; 10,646 during 2011; and 10,584 during 2012. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 11,080. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 2.5 hours per average domestic facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 12 minutes (0.2 hour) per response for domestic facilities. The average domestic facility burden hour estimate of 2.7 hours takes into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new domestic facility registrations is estimated to be 29,916 hours (11,080 x 2.7 hours).

FDA received 20,598 new foreign facility registrations during 2010; 20,009 during 2011; and 19,092 during 2012. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 19,900. FDA estimates that listing the information required by the Bioterrorism Act and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 8.5 hours per average foreign facility registration. We estimate that the FSMA-required additional information for new facility registrations will require an additional 24 minutes (0.4 hour) per response for foreign facilities. The average foreign facility burden hour estimate of 8.9 hours includes an estimate of the additional burden on a foreign facility to obtain a U.S. agent, and takes into account that for some foreign facilities the respondent completing the registration may not be fluent in English and/or not have readily available Internet access. Thus, the total annual burden for new foreign facility registrations is estimated to be 177,110 hours (19,900 x 8.9 hours).

Based on its experience, FDA estimates that the average annual number of updates to facility registrations will remain unchanged at 118,530 updates annually over the next three years. FDA also estimates that updating a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. We estimate that the FSMA-required additional information for updates will require an additional 12 minutes (0.2 hour) per response. Thus, the total annual burden of submitting updates to facility registrations is estimated to be 142,236 hours (118,530 x 1.2 hours).

Based on its experience, FDA estimates that the average annual number of cancellations of facility registrations will remain unchanged at 6,390 cancellations annually over the next three years. FDA also estimates that cancelling a registration will, on average, require a burden of approximately 1 hour, taking into account fluency in English and Internet access. FSMA did not change the required information for cancellations. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

We estimate that the new biennial registration required by FSMA, 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 (0.5 hour) 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. Thus, the total annual burden for biennial registration is estimated to be 112,465 hours (224,930 x 0.5 hours).

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately \$33,592,075. FDA estimates that the registration process will involve an employee making an average wage similar that of a Federal government employee at the GS-12/Step-1 rate for the Washington-Baltimore locality pay area for the year 2013, which is \$35.88 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be \$71.76/hour. Thus, the annualized burden hour cost imposed by this collection of information is approximately \$33,592,075 (468,117 hours x \$71.76/hour).

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

The estimated annual cost to the Federal government is approximately \$8,709,000, to maintain a database and process paper submissions. FDA bases its estimate on the following:

FDA Costs	
Development/Modification/Enhancement	\$2,300,000
Maintenance/Steady State	\$4,300,000
Number of FTEs	2
Cost per FTE	\$97,000
Processing paper submissions	\$1,600,000
Mailing costs	\$35,000
FSMA-required changes to the paper form and the electronic submission system (design, software and network interface changes)	\$280,000
Total	\$8,709,000

15. Explanation for Program Changes or Adjustments

The time burden shown in the current inventory (505,696 hours) is higher than the requested burden of 468,117 hours. This adjustment is primarily the result of a reduction in the estimated number of new domestic and foreign registrations. Based on data from 2011 and 2012 registrations, new domestic registrations are estimated to decrease from 13,560 to 11,080 per year and new foreign registrations are estimated to decrease from 23,370 to 19,900 per year. Additionally, IC nos. 5, 6, and 8 were removed/deleted, as the burden for these previously new elements are now incorporated into the existing approved elements respectively.

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.