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

OMB Control No. 0910-0502
RIN 0910-AG69

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 through its final rule entitled "*Amendments to Registration of Food Facilities*." The rulemaking codifies the requirements of section 102 of the Food Safety Modernization Act (FSMA) that were self-implementing and effective upon enactment of FSMA. The final rule also implements other requirements of section 102 of FSMA to include mandatory electronic registration submissions beginning 2020; amendments to the retail food establishment definition; and additional reporting requirements in order to improve the utility of the food facility registration database.

Accordingly, we are requesting approval of the information collection provisions associated with OMB control no. 0910-0502, as identified below and revised by the final rule, including Forms FDA 3537 entitled, "*Food Facility Registration*," and 3537a entitled, "*Cancellation of Food Facility Registration*."

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.

21 CFR 1.230 - 1.233; describes initial facility registration as well as registration renewal and sets forth required information that the registration submission must contain, as well as method of submission.

21 CFR 1.234; describes requirements for updating a facility's registration.

21 CFR 1.235; describes the requirements for notifying FDA of registration cancellation.

21 CFR 1.245; describes the submission of waiver requests from the requirement under §§ 1.231(a)(2) and (b), 1.234(d), and 1.235(d) that initial registration, renewals, updates, and cancellations be submitted electronically.

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. These 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

FDA estimates that nearly ninety-nine percent (99%) of the respondents will use electronic means to submit the required information. At the same time, the final rule mandates the electronic submission of food facility registrations by 2020, 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 collecting this information. While certain registration requirements also exist at the state and local level, these 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. Also, FDA is required to assign each food facility a unique registration number under section 415(a)(4) of the FD&C Act. We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

While we estimate that approximately ninety-nine percent (99%) of respondents are small businesses, we assist small businesses in complying with our regulatory requirements through Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our 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

The information collection schedule is consistent with statutory requirements. Less frequent collection may result in increased potential threats to the food supply or other food related emergencies.

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 the Federal Register of April 9, 2015 (80 FR 19159), FDA published a proposed rule to revise its regulations regarding the registration of food facilities. While we received many comments regarding requirements of the rule, none of the comments specifically addressed the four information collection topics solicited under the PRA. Comments in response to the rulemaking may be found under docket no. FDA-2002-N-0323 and are discussed in the final rule found at 81 FR 45,912. As finalized, we believe the rulemaking imposes minimal burden on respondents as necessary to comply with regulatory requirements for food facility registration.

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 in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by 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

12a. 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	Form FDA	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
All facility registrations; 1.230-1.233	3537	172,274	1	172,274	0.18 (11 mins)	31,009
Waiver requests; 1.245	3537	2,121	1	2,121	0.17 (10 mins)	361
TOTAL						31,370

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 already 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 this final rule. We estimate an increase in the average burden per response due to the new data elements required by this final 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 will 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 operator 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 facility. As explained in the preamble to the final rule, we revised the final rule and no longer require facilities to use D-U-N-S® numbers. Instead, the final rule requires the use of a unique facility identifier (UFI) recognized as acceptable by FDA. We are also postponing the requirement to submit a UFI until the registration renewal period beginning October 1, 2020. We estimate that entering a unique facility identifier requires, on average, an additional minute per response. Thus, we estimate that entering these five new data elements will require a total of five additional minutes. We estimate that the submission of the FSMA data elements and new data elements will jointly increase the one-time burden from those activities by a total of eleven minutes (0.18 hour). The estimated onetime burden for currently-registered facilities is 172,274 facilities x 0.18 hours = 31,584 hours. According to 2014 registration data, 2,121 registrations were from facilities that submitted paper registrations. We believe these same facilities are more likely to request a waiver from the requirement to electronically submit their registration. We estimate that it will take a respondent ten minutes to prepare the waiver request submission and attach it to their paper Form FDA 3537 registration submission. Thus, the onetime burden of submitting waiver requests is estimated to be 361 hours (2,121 x 0.17 hours). The estimated total one-time burden for currently-registered facilities is therefore 31,370 hours.

FDA estimates the annual burden of the proposed rule's revision of this information collection as follows:

Table 2 – Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total
New domestic facility registration; 1.230-1.233)	9,795	1	9,795	2.7	26,447
New foreign facility registration; 1.230-1.233	13,697	1	13,697	8.7	119,164
Updates; 1.234	53,836	1	53,836	1.5	64,603
Cancellations; 1.235	6,390	1	6,390	1	6,390
Biennial renewals; 1.235	97,883	1	97,883	0.38	37,196
3rd party registration verification	41,256	1	41,256	0.25	10,314
U.S. Agent verification	57,070	1	57,070	0.25	14,268
TOTAL			279,927		278,382

[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 this final rule is 278,382 hours, a decrease of 189,735 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. As described in our Preliminary Regulatory Impact Analysis (PRIA), we estimate that on an annualized basis 97,833 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 and we have retained these estimates for the final rule.

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 final rule will add an additional 11 minutes to that burden as a result of the required 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 reflected in table 2, rows 1 and 2.

The final rule does not shorten the time period for updates from 60 calendar days to 30 calendar days as originally proposed. In the PRA analysis for the proposed rule, in which we estimated the burden for the proposed 30-day update requirement, we estimated that 68,518 respondents (70% of facilities) would submit updates each year. For a 60-day update requirement, we estimated that the number of respondents was 53,836 per year (55% of facilities). The average burden per response for updates remains unchanged as 1.2 hours, as reflected in table 2 row 3. In the proposed rule, we also proposed to shorten the time period to submit cancellations from 60 calendar days to 30 calendar days. Although we are not finalizing that proposal, we have not changed our estimate of the average burden per response for cancellations because this final rule does not add new data elements for cancellations.

The final rule also establishes an abbreviated renewal process, which modifies our previous estimate that on average it will 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 will be able to take advantage of the abbreviated renewal process, while other firms will take more time to prepare and submit the renewal, as discussed in the PRIA.

Furthermore, the final rule establishes 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. In connection with requiring his verification process, this final rule adds 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 PRIA, we estimate that it takes fifteen minutes (0.25 hour) to participate in FDA's verification procedure. We have retained this estimate. We

further estimate that 82,513 registrations will be affected once every other year, or 41,256 annually. Thus, the total annual burden of these verifications is estimated to be 10,314 hours (41,256 x 0.25 hour = 10,314 hours), as reflected in table 2, row 6.

For the U.S. agent verification process, in the PRIA we estimated a resulting burden from the verification procedure to be about 30 minutes (0.5 hours) by 114,139 affected registrations once every two years, or 57,070 facility registrations annually. However, the final rule also provides for the creation of a U.S. agent voluntary information system (VIS), which we estimate will reduce the time for verification procedures for U.S. agents by half (from 30 minutes to 15 minutes). As currently envisioned, the system is designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. Specifically, the system will allow a U.S. agent to directly provide their contact information (that is, the same contact information required for foreign food facility registration) and the name of the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. agent contact information through foreign food facility registrations, many of which are created and updated by the facility, rather than the U.S. agent for the facility. We expect that the system will allow agents to provide their name, full mailing address, phone number, email address, and an emergency contact phone number, as well as the name of the facility or facilities for which the agent agrees to serve. After a U.S. agent provides this information, FDA will provide the agent with an identification number that the agent could provide to foreign facilities it has agreed to represent as a U.S. agent. If a foreign facility uses a U.S. agent identified in the system, the facility will have the option of providing the name and identification number for the U.S. agent in its registration rather than the specific U.S. agent's contact information required for food facility registrations (e.g., address, email address, phone number). After using the identification number, and if the foreign facility name matches a facility name the U.S. agent identified in the system, the U.S. agent contact information in the system will then be linked and automatically populated in the foreign facility registration. When the confirmation copy of a foreign facility registration is sent to the U.S. agent, it will be sent to the contact information provided by the U.S. agent to ensure that the U.S. agent is aware of the connection with each foreign facility registration.

We expect that when a foreign facility uses an identification number for a registered U.S. agent and the name of the facility matches the facility name the agent has identified, that we will consider the use of that identification a verification of U.S. agent information for purposes of the U.S. agent verification step. Thus, we estimate the total annual burden of the foreign facility U.S. agent verifications to be 14,268 hours (57,070 x 0.25 hour = 14,268), as reflected in table 2, row 7.

12b. Annualized Cost Burden Estimate

The annual hourly cost burden to respondents is approximately $13,615,384. FDA estimates that the average hourly wage for the employee preparing and submitting the request for certification to 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 total estimated

cost incurred by respondents for the information collection is $ 13,615,384 (189,735 burden hours x $71.76/hr = $13,615,384).

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 information collection has been revised to reflect new regulatory requirements. This results in an overall increase of 73,492 responses and a decrease of 158,365 burden hours. These totals include annual and one-time burdens. Specific adjustements are as follows:

IC #	Annual Responses	Annual Hours
1	-1,285	-3,469
2	-6,203	-57,946
3	-64,964	-77,633
4 (No change)	0	0
5	-127,047	-75,269
6 (New IC)	+41,256	+10,314
7 (New IC)	+57,070	+14,268
One time burdens	+174,395	+31,370

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

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.