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) added section 415 to the Federal Food, Drug, and Cosmetic Act (the 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 register with 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 will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply.

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.

We request the extension of OMB approval for the following collection of information requirements and forms:

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

As noted above, information provided to FDA under these regulations will help 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 will be used to support FDA enforcement activities and to screen imported food shipments. 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).

Information FDA requires on the registration form includes, among other things, the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3 (21 CFR 170.3), unless "most/all" human food categories "or none of the above mandatory categories" is selected as a response; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit other items of information, including their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; 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).

Description of Respondents: Respondents to this collection of information include 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 include the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

As noted above, 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 agency strongly encourages electronic registration because it is faster and more convenient. The system the agency has developed can accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. However, paper registrations will be accepted. Form FDA 3537 is available for download for registration by mail, fax, or CD-ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail

system and the number of paper registrations that FDA will have to enter manually. Form FDA 3537a is also available for download.

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 also requires registration of Low Acid Canned Foods (LACF) and infant formulas. However, these two registration programs are not a good substitute for the 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 BT 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. Thus, LACF and infant formula registrations cannot satisfy the Bioterrorism Act's statutory mandate to compile and maintain an up-to-date list of registered facilities.

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 mandate in section 415(a)(4) to compile and maintain an up-to-date list of registered food facilities. Finally, FDA is required to assign each facility a unique registration number that is not subject to the Freedom of Information 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 of this regulation are those mandated by the Bioterrorism Act and there is no statutory exception for small businesses in that act. However, FDA aids small businesses in dealing with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. 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

Respondents will submit the required information on an occasional basis, as required by section 415 of the act. 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 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), in the FEDERAL REGISTER of March 16, 2010 (75 FR 12547), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received one letter, containing multiple comments, in response to the notice.

(Comment)
One comment contended that it was unnecessary for companies to have to register their facilities with FDA.

(Response)
FDA disagrees. In the Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule (*see* 68 FR 5378 at 5387 to 5413) FDA asserted that requiring registration of manufacturers/ processors, packers, and holders of food would aid in deterring and limiting the effects of foodborne outbreaks in four ways. One, by requiring registration, persons who might intentionally contaminate the food supply would be deterred from entering the food production chain. Two, if FDA is aware of a specific food threat, a registration database would make FDA better able to inform the facilities potentially affected by the threat. Three, FDA would be able to deploy more efficiently its domestic compliance and regulatory resources. Four, FDA inspectors, using prior notice and registration, would be better able to identify shipments offered for import for inspection.

Registering with FDA creates a paper trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the false registrant. Persons who might attempt to intentionally contaminate the U.S. food supply would be deterred, by the creation of additional evidence that might be used against them, from starting a business in the food supply chain. Persons who might intentionally contaminate the food supply but refuse to register would be subject to criminal and civil sanctions and, if foreign, would risk having their product held at a U.S. port. With emergency contact information and product categories, FDA can quickly call or e-mail the emergency contact at both domestic and foreign facilities that may be targeted by a specific food threat. If FDA suspects a particular product is at risk, the agency can quickly identify which facilities to contact. This rapid communication ability will allow facilities to respond quickly to a threat and possibly limit the effect of a deliberate strike on the food supply, as well as public health emergencies due to accidental contamination of food.

(Comment)
One comment stated that facilities that hold food should not be required to register.

(Response)
FDA disagrees with the suggested change to its regulations. The agency's regulations implement the food facility registration requirements in section 305 of the Bioterrorism Act, 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 FDA.

(Comment)
One comment stated that, to lessen the burden of the regulation, FDA should not require firms to update their registration information, but only to cancel their registration when the facility stops holding food.

(Response)
FDA disagrees with the suggested change to its regulations. Requiring registrants to update the registration information for their facilities will directly enhance FDA's ability to satisfy the agency's obligation to maintain an up-to-date list of registered facilities, as required by section 415(a)(4) of the act, 21 U.S.C. 350d(a)(4). FDA has balanced the greater efficiency of the agency's having specific information regarding food manufactured/processed, packed, or held at each facility against the burden on facilities to submit initially and update this information as circumstances change. Without updated emergency contact information and product categories, the agency's ability to quickly call or e-mail the emergency contact at facilities that may be targeted by a specific food threat would be negatively impacted.

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 of the act provides that the list of facilities and any registration documents submitted pursuant to that subsection shall not be subject to disclosure under the Freedom of Information Act (5 U.S.C. § 552). In addition, all information received by FDA is subject to the agency's regulations concerning confidentiality in 21 CFR 20.61.

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 agency's regulations for food facility registration as follows:

Table 1- Estimated Annual Reporting Burden

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]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.

This estimate is based on FDA's experience and the average number of new facility registrations, updates and cancellations received in the past 3 years. FDA received 12,681 new domestic facility registrations during 2006; 14,629 during 2007; and 13,378 during 2008. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 13,560. 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. The average domestic facility burden hour estimate of 2.5 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 33,900 hours (13,560 x 2.5 hours).

FDA received 25,513 new foreign facility registrations during 2006; 23,302 during 2007; and 21,281 during 2008. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 23,370. 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. The average foreign facility burden hour estimate of 8.5 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 198,645 hours (23,370 x 8.5 hours).

FDA received 114,199 updates to facility registrations during 2006; 128,070 during 2007; and 113,318 during 2008. Based on this experience, FDA estimates that it will receive 118,530 updates annually. 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. Thus, the total annual burden for updating all registrations is estimated to be 118,530 hours.

FDA received 5,703 cancellations of facility registrations during 2006; 5,578 during 2007; and 7,888 during 2008. Based on this experience, FDA estimates the annual number of cancellations will be 6,390. 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. Thus, the total annual burden for cancelling registrations is estimated to be 6,390 hours.

Additionally, importers of food from foreign facilities that are not registered and are required by FDA to move their food shipment to secure storage must notify FDA of the location of that secure storage. This paperwork burden is already estimated in the Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (OMB Control Number 0910-0520).

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $21,397,854.90. FDA estimates that the registration process will involve an employee making an average wage similar that of a Federal government employee at the GS-11/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010, which is $29.93 per hour. To account for overhead, this cost is increased by 100 percent, which is $59.86 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $21,397,854.90 (357,465 hours x $59.86 per 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 $8,429,000, 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
Total	**$8,429,000**

15. Explanation for Program Changes or Adjustments

The decrease in burden is due primarily to a reduction in the number of new registrations (both domestic and foreign).

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.