Supporting Statement for

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

OMB No. 0910-0502

A Justification

1. Need and Legal Basis

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 to be registered with the 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. Domestic facilities are required to be registered whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to be registered 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 be registered.

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.

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. Information Users

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 in a registration 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 the initial submission, the registration for a facility is required to be updated within 60 days of a change to any item of required registration information, using Form FDA 3537 (§ 1.234), and to be cancelled, using Form FDA 3537a, 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, (§ 1.235).

3. Improved Information Technology

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 for both FDA and the registrant. In addition, registration updates and cancellations may be accomplished electronically. The system the agency has developed can accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week, 365 days a year. The individual registering a facility will receive confirmation of electronic registration and the facility's registration number instantaneously once all the required fields on the registration screen are completed. However, FDA will accept paper registrations. 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.

4. Duplication 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. 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. FDA is attempting to assist small businesses to comply with the registration requirements through the CFSAN small business office. 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. Less Frequent Collection

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

There are no special circumstances associated with this information collection.

8. *Federal Register* Notice/Outside Consultation

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of June 2, 2006 (71 FR 32104), FDA published a 60-day notice requesting public comment on the information collection provisions. We received no comments.

9. Payment/ Gift to Respondent

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

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. Sensitive Questions

There are no questions that would be considered of a sensitive nature.

12. Burden Estimate (Total Hours and Wages)

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[1]

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[2]	13,650	1	13,650	2.5	34,125
Foreign						
1.230-1.233	FDA 3537	29,200	1	29,200	8.5	248,200
					New Facility Registration Subtotal	**282,325**

Previously Registered Facilities- Updates (Form 3537) and Cancellations (Form 3537a)						
1.234	FDA 3537	92,850	1	92,850	1	92,850
1.235	FDA 3537a	1,300	1	1,300	1	1,300
					Updates or Cancellations to Existing Registration Subtotal	94,150
					Total Hours Annually	**376,475**

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

[2]The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at http://www.access.fda.gov.

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 82,485 new domestic facility registrations during 2003; 32,099 during 2004; and 13,652 during 2005. Based on this experience, FDA estimates the annual number of new domestic facility registrations will be 13,650. 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 34,125 hours (13,650 x 2.5 hours).

FDA received 89,990 new foreign facility registrations during 2003; 49,574 during 2004; and 29,193 during 2005. Based on this experience, FDA estimates the annual number of new foreign facility registrations will be 29,200. 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 248,200 hours (29,200 x 8.5 hours).

FDA received 131,354 updates to facility registrations during 2003; 137,384 during 2004; and 92,835 during 2005. Based on this experience, FDA estimates that it will receive 92,850 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 92,850 hours.

FDA received 12,556 cancellations of facility registrations during 2003; 7,467 during 2004; and 1,280 during 2005. Based on this experience, FDA estimates the annual number of cancellations will be 1,300. 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 1,300 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).

Wages

FDA estimates that the cost of an administrative worker's time is $25.10 per hour, including overhead; a manager's time was valued at $56.74 per hour, including overhead.

13. Capital costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

FDA costs are to set up and maintain a database and process paper submissions.

FDA Costs	Year one	Year two	Year three	Year four	Year 5
Development/ Modification/ Enhancement	$8,200,000	$3,000,000	$3,300,000	$2,300,000	$2,300,000
Maintenance/Steady State	$1,560,000	$3,500,000	$4,300,000	$4,300,000	$4,300,000
Number of FTEs	4	4	4	2	2
Cost per FTE	$97,000	$97,000	$97,000	$97,000	$97,000
Processing paper submissions	$2,900,000	$1,600,000	$1,600,000	$1,600,000	$1,600,000
Mailing costs	$180,000	$35,000	$35,000	$35,000	$35,000
New hardware	$0	$0	$0	$650,000	$0
Total	**$13,228,000**	**$8,523,000**	**$9,623,000**	**$9,079,000**	**$8,429,000**
Total discounted at 7%	**$13,228,000**	**$7,965,000**	**$8,405,000**	**$7,411,000**	**$6,430,000**
Total discounted at 3%	**$13,228,000**	**$8,275,000**	**$9,071,000**	**$8,309,000**	**$7,489,000**

15. Program or Burden Changes

The decrease in burden is due to a reduction in the number of new registrations. All firms in business when the registration interim final rule published on October 10, 2003 should have registered with FDA before December 12, 2003.

16. Publication and Tabulation Dates

The information from this collection will not be published.

17. Display of OMB Approval Date

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"

FDA has not identified any exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I.