United States Food and Drug Administration

Registration of Food Facilities

OMB Control No. 0910-0502

SUPPORTING STATEMENT – **Part 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 or we). 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.

On July 14, 2016, we amended our regulations governing food facility registration in our final rule entitled "Amendments to Registration of Food Facilities," (81 FR 45912). The codified requirements of section 102 of the Food Safety Modernization Act (FSMA) were self-implementing and effective upon enactment of FSMA. The regulations also implement 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 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, 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.

We therefore request extension of OMB approval for the information collection provisions in subpart H of our General Enforcement Regulations setting forth

the requirements for the registration of food facilities, and the associated electronic and paper-based forms, as discussed in this supporting statement.

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 regulations 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 collection provisions described above assist 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 regulations mandate 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

While certain registration requirements may exist at state and local levels, requirements vary from jurisdiction to jurisdiction in terms of the information required, facilities covered, and form of reporting. We require consistent reporting of information and coverage of facilities to comply with the requirement of section 415(a)(5) to compile and maintain an up-to-date list of registered food facilities. Also, we are required to assign each food facility a unique registration number under section 415(a)(4) of the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ninety-nine percent (99%) of respondents are small businesses and 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 7:30 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. If a facility is not registered or the registration for a facility is not updated when necessary, we 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.

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 April 19, 2019 (84 FR 16519). One comment was received offering general support for the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents of the information collection.

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. This ICR does not request any personally identifiable information and includes a form that does not require a Privacy Act Statement.

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

We estimate the burden for the information collection as follows:

Table 1 – 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	1.2	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.

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 for a total of 26,447 and 119,164 burden hours, as reflected in table 1, rows 1 and 2.

The regulations do not shorten the time period for updates and we estimate that the number of respondents is 53,836 per year (55% of facilities). The average burden per response for updates is 1.2 hours for total estimated burden of 64,603 hours, as reflected in table 1 row 3.

In the regulations, we have not changed our estimate of the average burden per response for cancellations because these regulations do not add new data elements for cancellations. The burden remains at 6,390 hours, as reflected in table 1, row 4.

The regulations also established an abbreviated renewal process, in which we estimate that half the facilities take 15 minutes per renewal using the abbreviated renewal process and of facilities take 30 minutes, for an estimate of 0.38 hours (23 minutes) to submit a renewal for a total of 37,196 burden hours, as reported in table 1, row 5. This estimate takes into account that some registered firms take advantage of the abbreviated renewal process, while other firms take more time to prepare and submit the renewal.

The regulations 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. In connection with requiring his verification process, these regulations add e-mail addresses 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. We estimate that it takes fifteen minutes (0.25 hour) to participate in FDA's verification procedure and 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 1, row 6.

For the U.S. agent verification process, we estimate 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 regulations also provide 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). 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 allows 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.

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 1, row 7.

12b. Annualized Cost Burden Estimate

The annual hourly cost burden to respondents is approximately $22,248,289. We estimate 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 2019 which is approximately $39.96/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $79.92/hour. Thus, the total estimated cost incurred by respondents for the information collection is $ 22,248,289 (278,382 burden hours x $79.92/hr = $22,248,289).

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	278,382	$79.92	$22,248,289

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 $1,066,716 to maintain an electronic database and process paper submissions. We base our estimate on the following:

FDA Costs	
Modification/Enhancement/Maintenance/Steady State	$500,000
Number of FTEs	2
Cost per FTE, (Fully loaded GS-8/Step 2, 2019 Cost)	$107,608
Processing electronic and paper submissions	$350,000
Mailing Costs	1,500
Total	**$1,066,716**

15. Explanation for Program Changes or Adjustments

This information reflects adjustments. We have decreased the number of respondents completing one-time registrations and waiver requests, thus realizing previous one-time estimates. This results in an overall decrease by 174,395 responses (from 454,322 to 279,927), and by 31,370 hours (from 309,752 to 278,382). We have also uploaded reported cost information to be reflected at www.reginfo.gov.

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. FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.