

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

This information collection supports Food and Drug Administration (FDA, us or we) regulations. 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), to require, 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 our regulations (21 CFR 1.230 - 1.235) set forth the requirements for the registration of food facilities. Information provided to us under these regulations helps us to quickly notify 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.

Advanced 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, 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.

To assist respondents of the information collection we developed the following forms. Each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States must register with FDA using Form FDA 3537 entitled "Food Facility Registration" (§ 1.231), unless exempt under 21 CFR 1.226 from the requirement to register. To cancel a registration, respondents must use Form FDA 3537a entitled "Cancellation of Food Facility Registration" (§ 1.235). 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 <https://www.access.fda.gov>. Registrations, updates, and cancellations are required to be submitted electronically. 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 outside the United States. However, if the further manufacturing/processing conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature, the former facility is required to register. In addition to the initial registration requirements, 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).

Accordingly, we are requesting extension of OMB approval of the information collection provisions in subpart H of our General Enforcement Regulations (21 CFR 1, subpart H) setting forth the requirements for the registration of food facilities, including Forms FDA 3537 entitled, “*Food Facility Registration*,” and 3537a entitled, “*Cancellation of Food Facility Registration*,” 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 us to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or other food-related emergency. Further, in the event of an outbreak of foodborne illness, the information provided helps us determine the source and cause of the event and enables us to quickly notify food facilities that might be affected by an outbreak, terrorist attack, threat, or other emergency. Finally, the registration requirements enable us 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, 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) of the FD&C Act 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).

## 5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ninety-nine (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. Assistance is also available for small businesses via the agency’s website at <https://www.fda.gov/industry/small-business-assistance>. In addition, the FDA Industry Systems Help Desk can answer computer system and technical questions related to the Food Facility Registration Module, as well as general questions about registration. 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 January 13, 2022 (87 FR 2159). No comments were received.

## 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

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via eForm (Food Facility Registration Module) is name, address, telephone number, email address, and fax number. The PII submitted via Form FDA 3537 (DHHS/FDA Food Facility Registration) is name, address, telephone number, email address, and fax number. The PII submitted via FDA Form 3537a (DHHS/FDA Cancellation of Food Facility Registration) is name, address, telephone number, email address, and fax number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

## 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 Cost

### 12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average 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
3 <sup>rd</sup> 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

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

### 12b. Annualized Cost Burden Estimate

The annual hourly cost burden to respondents is approximately \$23,963,123. 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 2022, which is approximately \$43.04/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be \$86.08/hour. Thus, the total estimated cost incurred by respondents for the information collection is approximately \$23,963,123 (278,382 burden hours x \$86.08/hr).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	278,382	\$86.08	\$23,963,123

## 13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 \$1,083,320 to maintain an electronic database and process paper submissions. We base our estimate on the following:

Table 3.--Estimated FDA Annual Cost

Modification/Enhancement/Maintenance/Steady State	\$500,000
Number of FTEs	2

Cost per FTE, (Fully loaded GS-8/Step 2, 2022 Cost @\$57,955/year)	\$115,910
Processing electronic and paper submissions	\$350,000
Mailing Costs	\$1,500
Total	\$1,083,320

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. However, burden costs were inadvertently entered into OMB's ROCIS automated system for this collection the last time this collection was approved by OMB, and those costs should be revised from \$22,248,289 to zero.

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 the 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.