United States Food and Drug Administration

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

OMB Control No. 0910-0037

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, our, or we) regulations, programs, and forms. Section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance which may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

The statutory requirements discussed above are codified in FDA regulations found at 21 CFR parts 108, 113, and 114, where individual provisions are discussed more fully below. To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(1)). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Forms FDA 2541d, FDA 2541e, and 2541f for all methods except aseptic processing, or Form FDA 2541g for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (§ 113.87(a)).

As described in our regulations, processors may obtain the paper versions of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g by contacting us at a particular address or at https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm. Processors may mail completed paper forms to us. However, processors who are subject to §§ 108.25, 108.35, or both have an option to submit Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g electronically.

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are offering the public the opportunity to use four forms, each of which pertain to a specific type of commercial processing and is available both on the electronic submission system and as a paper-based form. The electronic submission system and the paper-based form "mirrors" each other to the extent practicable.

The four process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method);
- Form FDA 2541e (Food Process Filing for Acidified Method);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems).

Accordingly, we therefore request extension of OMB approval for the paper and electronic versions of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g and the reporting and recordkeeping provisions contained in the applicable regulations for food canning provisions found in 21 CFR parts 108, 113, and 114 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

As more fully described in Item 1, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us and provide data on the processes used to produce these foods.

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

We permit electronic registration of food canning establishments (FCE) on the Internet via the FCE online registration system. The agency estimates that about ninety-five percent (95%) of the registrations will be submitted electronically in the next three years. We permit electronic process filing on the Internet via the Low-Acid Canned Food (LACF) Program. Food canning establishments can communicate with the LACF Program by sending an email to lacf@fda.hhs.gov. The agency estimates that about ninety-eight percent (98%) of the process filings will be submitted electronically in the next three years. Both applications are available through the FDA Unified Registration and Listing System (FURLS).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that ten percent (10%) of respondents are small businesses. The information collected is of a regulatory nature and the requirements are the same for small or large food processing establishments. We aid small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. We also provide assistance via our Small Business Assistance webpage at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally and is consistent with statutory requirements. The information cannot be collected less frequently. Commercial processors engaged in the manufacture, processing, or packing of acidified foods or thermally processed low-acid foods in hermetically sealed containers are required to register with FDA within 10 days of so engaging, and to file scheduled processes within 60 days of registration and prior to the packing of a new product.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The collection fully complies with 5 CFR 1320.5(d)(2). 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), we published a 60-day notice for public comment in the *Federal Register* of March 21, 2023 (88 FR 16990). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

All production records and inspection reports collected from establishments by FDA during inspections are maintained in FDA District Compliance files which have limited access. The food processing information contained on the process filing forms submitted to FDA is privileged and

confidential. The process filing information is safeguarded at the Center for Food Safety and Applied Nutrition (CFSAN), FDA, and is accessible only to properly authorized FDA and contractor personnel. Any records that the agency may copy or take possession of would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). The information also is safeguarded by section 301(j) of the FD&C Act (21 U.S.C. 331(j)).

Privacy Act

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 Form FDA 2541 (Food Canning Establishment Registration) includes point of contact name, business address, business telephone number, business fax number, business email address, and signature. The PII submitted via Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method), Form FDA 2541e (Food Process Filing for Acidified Method), Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method), and Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems) includes point of contact name, signature, and business telephone 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, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under FOIA, 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 information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
108.25(c)(1) and 108.35(c)(2); Food canning establishment registration	2541	1,218	1	1,218	0.17 (10 mins.)	207
108.25(c)(2); Food process filing for acidified method	2541e	2,078	7	14,546	0.33 (20 mins.)	4,800

108.35(c)(2); Food process filing for low-acid retorted method	2541d	842	7	5,894	0.33 (20 mins.)	1,945
108.35(c)(2); Food process filing for water activity/formulation control method	2541f	111	4	444	0.33 (20 mins.)	147
108.35(c)(2); Food process filing for low-acid aseptic systems	2541g	168	11	1,848	0.75 (45 mins.)	1,386
108.25(d), 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce	N/A	1	1	1	4	4
Total						8,489

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

We base our estimates in Table 1 on registrations, process filings, and reports received. The estimates for hours per response are based on our experience with similar programs and information received from industry.

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
113.100 and 114.100	10,392	1	10,392	250	2,598,000

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

Our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $196,320,751.48 per year. We estimate that the average hourly wage for the employee preparing and submitting the registrations and process filings would be equivalent to a GS-11/Step-1 level in the locality pay area of Washington-Baltimore in 2023, $37.66/hour. Doubling this wage to account for

overhead costs, we estimate the average hourly cost to respondents to be $75.32/hour. Thus, the overall estimated cost incurred by the respondents is $196,320,751.48 (2,606,489 burden hours x $75.32/hr).

Table 3.--Estimates of Annualized Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparing and submitting registrations and process filings	2,606,489	$75.32	$196,320,751.48

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 annualized cost to the Federal government is $1,062,412. Approximately 2.5 full-time equivalents (FTE) are allocated for technical review by food technologists of the process filing forms (FDA 2541d, FDA 2541e, FDA 2541f and 2541g). In addition, approximately 1.5 FTEs are needed for administration, coordination, and computer programming. A contractor provides new system development, computer data entry, and administrative support (filing, mail handling) for the project. The cost of the contract is $248,400 per year. The estimated annual cost of printing forms and instructions is $1,100.

We estimate that on-site review of manufacturers' records would be done by an employee at the GS-11/Step-6 level in the locality pay area of Washington-Baltimore in 2023, $43.93/hour. Doubling this wage to account for overhead costs, we estimate the average hourly cost to the Federal government to be $87.86/hour. The annualized cost for on-site review of the manufacturers records is approximately 2 hours at $87.86/hour or $175.72, for each on-site records inspection. On average, a total of 400 inspections are performed each year for a total cost of $70,288. The burden for the review of records, which have been copied and forwarded to CFSAN because of potential problems is approximately 6 hours at $87.86 an hour or $527.16 per event. On average, records for 35 inspections each year are reviewed by CFSAN for a total cost of $18,450.60, rounded to $18,451. Thus, the total cost for FDA inspection and review is $88,739 ($70,288 + $18,451).

The resources needed for a fully supported FTE equals 2,080 hours at a cost of $181,043. The estimated costs incurred by the Federal government are listed below:

• Contract (annual expense)	$248,400
• Food Technologists - 1.5 FTE	$271,565
• Technicians - 2.5 FTE	$452,608
• Printing	$1,100
• On-site Inspections	$70,288
• Records Inspections	$18,451
Total	$1,062,412

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate as an adjustment. Based on our experience with the program and actual submissions, we expect the number of responses to increase by 10,141 (34,343 – 24,202)

and the number of burden hours to increase by 3,606 (2,606,489 – 2,602,883). The adjustment is limited to the reporting burden, and we retain the estimates for recordkeeping. The information for the adjustment became available after the publication of the 60-day notice in the *Federal Register* of March 21, 2023 (88 FR 16990).

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from this data collection will not be published or tabulated.

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.