

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2013-N-1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or us) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 13, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers—21 CFR 108.25 and 108.35, and 21 CFR Parts 113 and 114*OMB Control Number 0910-0037—Extension*

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 that 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.

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)) (21 CFR 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 FDA 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 (21 CFR 113.87(a)).

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)); to 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 to 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 low-acid 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.

As described in FDA regulations, processors may obtain the paper version of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g at <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRRegistration/ucm2007436.htm>. Processors mail completed paper forms to us. However, processors who are subject to § 108.25 and/or § 108.35 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 will 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 pertains 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 paper-based form “mirror” 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).

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.

In the **Federal Register** of March 21, 2023 (88 FR 16990), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Form FDA No.	Number of respondents	Number 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 minutes)	207
108.25(c)(2); Food process filing for acidified method.	2541e	2,078	7	14,546	0.33 (20 minutes)	4,800
108.35(c)(2); Food process filing for low-acid retorted method.	2541d	842	7	5,894	0.33 (20 minutes)	1,945
108.35(c)(2); Food process filing for water activity/formulation control method.	2541f	111	4	444	0.33 (20 minutes)	147
108.35(c)(2); Food process filing for low-acid aseptic systems.	2541g	168	11	1,848	0.75 (45 minutes)	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	Number of recordkeepers	Number 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.

Since the publication of the 60-day notice we have adjusted our burden estimate. Our estimated burden for the information collection reflects an increase of 3,606 total burden hours and a corresponding increase of 10,141 total annual responses. This increase corresponds with data obtained from past submissions.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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