U.S. 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

**Terms of Clearance:** None.

**A. Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) regulations. Specifically, section 402 of the Federal Food, Drug, and Cosmetic Act (the 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 codifed 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)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). 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 (21 CFR 113.87(a)).

*Description of proposed revisions to forms and electronic submission system:*
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/aboutfda/reportsmanualsforms/forms/default.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 (see 76 FR 11783 at 11785, March 3, 2011).

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 pertain to a specific type of commercial processing and will be available both on the electronic submission system and as a paper-based form. The electronic submission system and the paper-based form will "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).

Some of the data entry fields and headings on the four process filing forms have been revised to increase the efficiency of our review of the process filings and clarify the forms to help respondents who submit food process filings. These revisions are editorial only and do not change the burden estimate.

Revisions to Forms FDA 2541d, FDA 2541e, and FDA 2541f include modifying headings to clarify instructions to the user, adding text to checkbox fields to direct the user to other parts of the form, and adding "not applicable" checkboxes to existing fields. Some number fields were also lengthened. We believe these revisions will assist respondents in providing more accurate and timely information to the agency.

Revisions to Form FDA 2541d, section F.1 restricts a user's choice by allowing selection of either "Agitating" or "Still" mode, but not both. Section G.6 increases the field size from 3 positions before the decimal to 5 positions before the decimal.

Revisions to Form FDA 2541e, section B.2 adds text in the "Voluntary" section to clarify the determination that the product is not an acidified food. Section C.2 adds

text next to the "No" checkbox to direct the user to the next spot on the form if checked. Sections C.3.d, C.4.d, and C.6.h offers an option of checking "Not Applicable" instead of providing a measurement. Section C.5 replaces the text "10 pounds or more of the product" with "Industrial Size." Section E.1 specifies the product and section G.11 adds the text "(Steam or Water)" to clarify the type of bath. Section I, columns 3 and 4 adds the option of checking "Lowest Hold Temp" for clarity and increases the numbered field size to 4 positions before the decimal.

Revisions to Form FDA 2541f, section C.2.c adds text next to the "No" checkbox to direct the user where to go next on the form if checked. Sections C.3.d, C.4.d, and C.6.h allows checking "Not Applicable" instead of providing a measurement. Section C.5 replaces the text "10 pounds or more of the product" with "Industrial Size." Section G.10 adds the text "(Steam or Water)" to clarify the type of bath, and section I, column 3 adds the option of checking "Lowest Hold Temp" for clarification.

Revisions to Form FDA 2541g, section H, columns 4 and 9, increase the size of the fields from 3 to 5 positions before the decimal.

We request OMB approval of the paper and/or 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:

**21 CFR 108.25(c)(1) - Reporting (Establishment Registration)**

Commercial processors file information on each establishment engaged in processing acidified foods not later than 10 days from start-up.

**21 CFR 108.25(c)(2) - Reporting (Process Filing)**

Provide information on the scheduled processes before packing any new acidified food product not later than 60 days after registration.

**21 CFR 108.25(d) - Reporting**

Requires packers to report any instance of potential health endangering significance wherein the food has entered distribution in interstate commerce.

**21 CFR 108.25 (e) - Recordkeeping**

Requires processors of acidified foods to develop and keep on file plans for recalling products that may endanger the public health.

**21 CFR 108.25(g) - Recordkeeping**

Requires packers to prepare, review, and retain all production records for 3 years from date of manufacture.

**21 CFR 108.35(c)(1) - Reporting (Establishment registration)**

Commercial processors file information on each establishment engaged in processing low-acid foods not later than 10 days from start-up.

**21 CFR 108.35(c)(2) - Reporting (Process Filing)**

Provide information on the scheduled processes for low-acid foods prior to packing any new product.

**21 CFR 108.35(c)(2)(ii) - Reporting (Process Filing)**

Intentionally modified process shall be substantiated as to its adequacy and recorded in writing in the packer's files prior to its use and to report process changes to FDA within 30 days after first use.

**21 CFR 108.35(c)(2)(ii) - Recordkeeping**

Requires packer to record and file full information on any change of a previously filed scheduled process.

**21 CFR 108.35(d) - Reporting**

Requires packers to report any instance of spoilage or process deviation the nature of which indicates potential health significance wherein the food has entered distribution.

**21 CFR 108.35(e) - Reporting**

Requires packer to report any instance wherein such food, which may be injurious to health because of microbial contamination, has entered distribution.

**21 CFR 108.35(f) - Recordkeeping**

Requires processors of thermally processed low-acid foods sealed in hermetically sealed containers develop and keep on file plans for recalling products that may endanger the public health.

**21 CFR 108.35(h) - Recordkeeping**

Requires a commercial processor to prepare, review, and retain all records of processing, processing deviations, container closure inspections, and other records for a period of 3 years.

**21 CFR 113.60(c)- Recordkeeping**

Requires thermally processed low-acid foods in hermetically sealed containers be marked with an identifying code to permit lots to be traced after distribution.

**21 CFR 113.83 - Recordkeeping**

Requires preparation and permanent retention of complete records covering process establishment by the person or organization establishing the process.

**21 CFR 113.87(a) - Recordkeeping**

Requires that 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 113.89 - Recordkeeping**

Requires a record of evaluation procedures used for process deviation evaluations for thermally processed low-acid foods; a separate file or log identifying process deviations, and the actions taken.

**21 CFR 113.100 - Recordkeeping**

Specifies processing and production information to be observed and recorded by retort or processing operator.

**21 CFR 114.80(b) – Recordkeeping**

Requires acidified foods be marked with an identifying code to permit lots to be traced after distribution.

**21 CFR 114.89 - Recordkeeping**

Retention of records of procedures and results of evaluating acidified finished food products for potential hazard to public health.

**21 CFR 114.100(a) through (d) - Recordkeeping**

Specifies three year retention of records and reports dealing with production processes and controls.

2. Purpose and Use of the Information Collection

As more fully described in section 1, above, 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 21 CFR 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

FDA permits electronic registration of food canning establishments (FCE) on the Internet via the FCE online registration system. The agency estimates that about eighty percent (80%) of the registrations will be submitted electronically in the next three years. FDA permits 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 eighty percent (80%) 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. FDA is exclusively charged with implementing and enforcing the statutory requirements under section 404 of the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

FDA estimates 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. FDA aids 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. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

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), FDA published a 60 day notice for public comment in the Federal Register of June 20, 2017 (82 FR 28069). While no comments were submitted to the docket, it was noted that the notice included an inadvertent reference to outdated forms. We regret this oversight and made appropriate corrections to our 30 day notice, noting also that we are continuously open to suggestions on how the collection instruments might be improved.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

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 in locked files at the Center for Food Safety and Applied Nutrition, FDA, and are 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 act (21 U.S.C. 331(j)).

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

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this information collection as follows:

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

| 21 CFR Section | FDA Form No. | No. of Respondents | No. of Responses per Responden | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|---|
| 108.25(c)(1) and 108.35(c)(2); Food canning | 2541 | 645 | 1 | 645 | 0.17 (10 mins.) | 110 |
| 108.25(c)(2); Food process filing for acidified method | 2541e | 726 | 11 | 7,986 | 0.33 (20 mins.) | 2,659 |
| 108.35(c)(2); Food process filing for low-acid retorted method | 2541d | 336 | 12 | 4,032 | 0.33 (20 mins.) | 1,343 |
| 108.35(c)(2); Food process filing for water activity/formulation control method | 2541f | 37 | 6 | 222 | 0.33 (20 mins.) | 74 |
| 108.35(c)(2); Food process filing for low-acid aseptic systems | 2541g | 42 | 22 | 924 | 0.75 (45 mins.) | 693 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 108.25(d); 108.35(d) and (e); Report of any instance of potential health-endangering spoilage, process deviation, or contamination | N/A | 1 | 1 | 1 | 4 | 4 |
| Total | | | | | | 4,883 |

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

FDA bases its estimate of the number of respondents in table 1 on registrations, process filings, and reports received over the past 3 years. The average burden per response estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

We have not modified our average burden per response estimates.

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.

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double- counting, we have not included estimates for § 108.25(e), (g), and (h) because they merely cross- reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b) (21 CFR 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the third party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. 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 $165,907,762.40 per year. FDA estimates 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 2017, approximately $31.87/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $60.46/hour. Thus, the overall estimated cost incurred by the respondents is $157,370,306.18 (2,602,883 burden hours x $63.74/hr = $165,907,762.40).

Table 3 - Estimates of Annualized Cost Burden

| Activity | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Preparing and submitting registrations and process filings | 2,602,883 | $63.74 | $165,907,762.40 |
| Total | | | $165,907.762.40 |

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 annualized cost to the Federal Government is $920,647. Approximately 2.5 person years (PY) 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 PY are expended 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 $230,000 per year. The estimated annual cost of printing forms and instructions is $1,000.00.

The annualized cost for on-site review of the manufacturers records is approximately 2 hours at $73.66 an hour, or $153.32, for each on-site records inspection. On average, a total of 400 inspections are performed each year for a total cost of $61,328. The burden for the review of records which have been copied and forwarded to CFSAN because of potential problems is approximately 6 hours at $73.66 an hour, or $441.96 per event. On average, records for 35 inspections each year are reviewed by CFSAN for a total cost of $15,468. Thus, the total cost for FDA inspection and review is $76,796.

One person year (PY) for a fully supported FDA employee equals 2080 hours at a cost of $153,212. The estimated costs incurred by the Government are listed below:

| | |
|---|---|
| o Contract (annual expense) | $230,000 |
| o Food Technologists - 1.5 PY | $229,819 |
| o Technicians - 2.5 PY | $383,032 |
| o Printing | $ 1,000 |
| o On-site Inspections | $ 61,328 |
| o Records Inspections | $ 15,468 |
| Total | $920,647 |

15. Explanation for Program Changes or Adjustments

The burden estimate has not changed from our previous estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

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

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.