FOOD CANNING ESTABLISHMENT REGISTRATION, PROCESS FILING AND RECORD KEEPING FOR ACIDIFIED FOODS AND THERMALLY PROCESSED FOODS IN HERMETICALLY SEALED CONTAINERS

OMB No. 0910-0037

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is authorized to prevent the interstate distribution of food products that may be injurious to health or that are otherwise adulterated, as defined in section 402 of the act (21 U.S.C. 342). Under the authority granted to FDA by section 404 of the act (21 U.S.C. 344), FDA 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 FDA 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 must 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.

We are requesting OMB's approval of the following specific citations:

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) - Record keeping

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) - Record keeping

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) - Record keeping

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) - Record keeping

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) - Record keeping

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)- Disclosure (Language approval only)

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 - Record keeping

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

21 CFR 113.87(a) - Record keeping/Disclosure

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 - Record keeping

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 - Record keeping

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

21 CFR 114.80(b) - Disclosure (Language approval only)

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

21 CFR 114.89 - Record keeping

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) - Record keeping

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

We are also requesting OMB approval of the following forms:

Form FDA 2541, Food Canning Establishment Registration (21 CFR 108.25(c)(1) and 108.35(c)(1)). (Attachment C)

Form FDA 2541a, Food Canning Establishment Process Filing Form For All Methods Except Aseptic (21 CFR 108.25(c)(2) and 108.35(c)(2)). (Attachment D)

Form FDA 2541c, Food Process Filing For Low-Acid Aseptic Systems (21 CFR 108.35(c)(2)). (Attachment E)

2. Purpose and Use of the Information Collection

To protect the public health, FDA 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 FDA using Form FDA 2541 (Sections 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 Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (Sections 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 (Section 113.87(a) (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 are also required to document corrective actions when process controls and procedures do not fall within specified limits (Sections 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 (Sections 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 (Sections 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 (Sections 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 field investigators and Center personnel to verify fulfillment of the requirements in 21 CFR 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.

3. Use of Improved Information Technology and Burden Reduction

FDA has developed an electronic system to permit registration and filing over the Internet. The electronic submission capability of the Low Acid Canned Food (LACF) Program titled *eLACF* is the second major registration application to be supported by and integrated under the new FDA Unified Registration and Listing System (FURLs). This meets a major milestone in the Agency's plan to provide one place (FURLS) for industry to access multiple registration systems.

The information recorded on processing records, by industry, is the primary means whereby the safety and freedom from adulteration of acidified foods and thermally processed low-acid foods in hermetically sealed containers may be assured. The recorded information is specific to each commercial processor and can only be generated by that establishment. It is not of a general nature and is not available in libraries and academia. Any use of improved technology appropriate to satisfy the requirements is acceptable to FDA.

4. Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, no other federal government agency is engaged in the collection of this information. There can be no duplicative collection of this information because the information maintained in fulfilling the statutory requirements under section 404 of the act is unique to each establishment.

5. Impact on Small Businesses or Other Small Entities

The information collected is of a regulatory nature and the requirements are the same for small or large food processing establishments. However, FDA has Small Business Representatives who help small businesses whose products are regulated by FDA.

6. Consequences of Collecting the Information Less Frequently

The information cannot be collected less frequently. Commercial processors engaging 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 on Form FDA 2541 within 10 days of so engaging, and to file scheduled processes on Forms FDA 2541a, or 2541c, within 60 days of registration and prior to the packing of a new product. This timing for reporting assures against improperly or inadequately processed or packed acidified foods or thermally processed low-acid foods in hermetically sealed containers being introduced into interstate commerce and becoming a public health threat to the nation.

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

The collection fully complies with 5 CFR 1320.5(d)(2).

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 March 4, 2008 (73 FR 11649). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts 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 Forms FDA 2541a and FDA 2541c 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. These materials are kept confidential in accordance with 21 U.S.C. 331(j). 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).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

The total annual estimated burden imposed by this collection of information is 1,868,352 hours annually (4,852 + 1,863,500 = 1,868,352).

Table 1.-Estimated Annual Reporting Burden[1]

Form No.	CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2541 (Registration)	108.25 and 108.35	515	1	515	.17	88
Form FDA 2541a (Process Filing)	108.25 and 108.35	1,489	8.62	12,835	.333	4,274
Form FDA 2541c	108.35	84	7.77	653	.75	490

Table 1.-Estimated Annual Reporting Burden[1]						
(Process Filing)						
Total						4,852

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

Table 2.-Estimated Annual Recordkeeping Burden[1]					
CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record keeper	Total Hours
21 CFR Parts 113, 114	7,454	1	7,454	250	1,863,500

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

FDA based its estimate on registrations and process filings received over the past 3 years. FDA has changed its estimate of the number of recordkeepers in Table 2, reducing the figure from 8,950 to 7,454. The agency reexamined the figure and excluded firms that were inactive or out of business, yet still registered. Thus, the lower figure is a more accurate estimate of the number of recordkeepers. The reporting burden for Sections 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. To avoid double-counting, estimates for Sections 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the average hourly wage of the recordkeepers is $27.50 per hour. The estimated annualized cost to respondents for the hour burden for this collection of information is 1,868,352 total annual burden hours x $27.50/hour = $51,379,680.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

The annualized costs to the Federal government are $895,820. Approximately 2.5 person years (PY) are expended by food technologists for technical review of the process filing forms (FDA 2541a and 2541c). 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 annual burden for on-site review of the manufacturers records is approximately 2 hours at $71.26 an hour, or $142.52, for each on-site records inspection. On average, a total of 400 inspections are performed each year for a total cost of $57,008. The burden for the review of records which have been copied and forwarded to CFSAN because of potential problems is approximately 6 hours at $71.26 an hour, or $427.56per event. On average, records for 35 inspections each year are reviewed by CFSAN for a total cost of $14,964. Thus, the total cost for FDA inspection and review is $71,972.

One person year (PY) for a fully supported FDA employee equals 2080 hours at a cost of $148,212. The estimated costs incurred by the Government are listed below:

o Contract (annual expense)	$230,000
o Food Technologists - 1.5 PY	$222,318
o Technicians - 2.5 PY	$370,530
o Printing	$ 1,000
o On-site Inspections	$ 57,008
o Records Inspections	$ 14,964
Total	$895,820

15. Explanation for Program Changes or Adjustments

The decrease in burden hours is due primarily to a reduction in the number of recordkeepers, but there was also a reduction in the number of respondents (fewer new registrations and new process filings).

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

No exceptions requested.