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

0910-0037

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under the Federal Food, Drug, and Cosmetic Act (the FD&C 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 FD&C Act (21 U.S.C. 342). Under the authority granted to FDA by section 404 of the FD&C 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.

In the *Federal Register* of March 14, 2007 (72 FR 11990), FDA published a proposed rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the proposed rule). This document proposed to revise FDA's regulations for thermally processed low-acid foods in part 113 to, among other things, provide for the use of temperature-indicating devices other than mercury-in-glass thermometers during processing, require that temperature-indicating devices be tested for accuracy against a calibrated reference device, and to establish recordkeeping requirements for temperature-indicating devices and reference devices maintained by the processor. In compliance with the PRA (44 U.S.C. 3506(c)(2)(B)), the Agency requested public comment on the information collection provisions of the proposed rule (72 FR 11990 at 12004).

On March 3, 2011 (76 FR 11892), FDA published a final rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the final rule). The final rule revises the information collection currently approved under OMB control number 0910-0037 by adding recordkeeping requirements in new § 113.100(c) and (d). The information to be recorded under these regulations is related to accuracy tests of temperature-indicating devices and reference devices maintained by processors of low-acid canned foods. These tests must be performed to ensure the accuracy of the devices during the processing of these foods. If these devices are not accurate, the processor cannot ensure that the low-acid canned foods it produces are safe to eat, and consumers may be harmed. The recordkeeping requirements of the final rule are necessary to document that appropriate accuracy tests have been performed with the appropriate frequencies for each temperature-indicating device and each reference device maintained by the processor. Records of accuracy tests for these devices also help processors

determine how frequently the devices should be tested for accuracy. Much of the information is currently generated for accuracy tests performed under current regulations. However, the information may not be recorded as required under the final rule.

Current low-acid canned food regulations recommend, but do not require, that processors keep records of accuracy tests for mercury-in-glass thermometers, including test date, standard used, method used, and person performing the test. The final rule requires processors to keep records documenting the accuracy of temperature-indicating devices (including but not limited to mercury-in-glass thermometers) and of reference devices that are maintained by the processor. These records include the identifier of the device being tested, such as its tag or seal; the name of the manufacturer of the device; the identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the device or, if an outside facility conducts the accuracy test, documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology or other national metrology institute standard; the identity of the person or facility that performed the accuracy test and adjusted or calibrated the device; the date and results of each accuracy test, including the amount of adjustment; and the date on or before which the next accuracy test must be performed.

In addition to requesting public comment on the new recordkeeping provisions, the proposed rule also stated that FDA had submitted the recordkeeping provisions to OMB for review (72 FR 11990 at 12005). However, due to an administrative error, the Agency did not actually do so, and, therefore, FDA is submitting them to OMB now.

We request OMB approval of the paper and/or electronic versions of Forms FDA 2541, FDA 2541a, and FDA 2541c and the reporting and recordkeeping burdens contained in the following 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) - 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

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 (§§ 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 Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c 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 (§§ 108.25(c)(2) and 108.35(c)(2)). For processors of thermally processed low-acid foods in hermetically sealed containers, operating processes and procedures must be posted near the processing equipment or made available to the operator (§ 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 (§§ 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 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.

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 process filing on the Internet. The electronic submission capability of the Low Acid Canned Food (LACF) Program entitled *eLACF* was the second major application to be supported by and integrated under the FDA Unified Registration and Listing System (FURLs). Food canning establishments can request an electronic account 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.

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 FD&C Act is unique to each establishment.

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. 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). 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 the *Federal Register* of March 14, 2007 (72 FR 11990), FDA published a proposed rule entitled "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (the proposed rule). In compliance with the PRA (44 U.S.C. 3506(c)(2)(B)), the Agency requested public comment on the information collection provisions of the proposed rule (72 FR 11990 at 12004). FDA received six letters, each containing one or more comments on the proposed rule. Although the Agency did not identify any comments referring specifically to the PRA, several comments discussed the proposed recordkeeping provisions. FDA has summarized and responded to these comments in section II of the final rule (Comments 1, 4, 11 through 13, and 18).

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments 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. 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

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.

The total annual estimated burden imposed by this collection of information is 2,380,467 hours annually (4,852 + 2,375,615 = 2,380,467).

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this information collection as follows:

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

Form No.	21 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 (Process Filing)	108.35	84	7.77	653	.75	490
Total						4,852

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

FDA bases its estimates of the number of respondents and the hours per response on its experience with registration and process filing and on information from industry. FDA estimates the total burden of registration under §§ 108.25 and 108.35 to be 88 hours (515 respondents x 1 annual response x 0.17 hours = 87.55 hours, rounded to 88 hours). FDA estimates the total burden of process filing on Form FDA 2541a under §§ 108.25 and 108.35 to be 4,274 hours (1,489 respondents x 8.62 annual responses x 0.333 hours = 4,274.12 hours, rounded to 4,274 hours). FDA estimates the total burden of process filing on Form FDA 2541c under § 108.35 to be 490 hours (84 respondents x 7.77 annual responses x 0.75 hours = 489.51 hours, rounded to 490 hours). 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 per 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 §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

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

21 CFR Part/Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
21 CFR Parts 113 and 114	9,500	1	9,500	250	2,375,000
Burden added by new § 113.100(c) and (d)	4,225	15	63,375	0.0097	615
Total					2,375,615

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

FDA received six letters, each containing one or more comments on the proposed rule. Although the Agency did not identify any comments referring specifically to the PRA, several comments discussed the proposed recordkeeping provisions. FDA has summarized and responded to these comments in section II of the final rule (Comments 1, 4, 11 through 13, and 18). None of the comments on the proposed rule suggested that we modify our burden estimates for the new information collection provisions. Thus, we have not changed our estimates of the annual frequency per recordkeeping or the hours per record. We have, however, increased the estimated number of recordkeepers to reflect growth in the low-acid canned food processing industry since the 2007 proposed rule.

Currently, there are 9,491 active firms in the LACF database, which encompasses processors of low-acid canned food, processors of acidified food, and processors of both types of food. Thus, we estimate the number of processors keeping records under parts 113 and 114 to be 9,500, as shown in table 2, row 1 of this document. In the final rule, we estimated that there are approximately 8,450 foreign and domestic low-acid canned food processing establishments. This estimate, which does not encompass establishments that process only acidified foods (because such processors are not affected by the final rule), was based on data in the LACF database as of September 2009. As discussed in the explanation of the recordkeeping estimate for the final rule in the following paragraphs, our estimate assumes that half of the LACF industry currently does not record all of the device accuracy testing information that the final rule requires. Thus, as shown in table 2, row 2 of this document, we estimate that 4,225 low-acid canned food manufacturers that are not currently keeping the records that are required under the final rule will begin to keep such records to comply with the final rule when it becomes effective.

FDA bases its estimates of the number of recordkeepers and the hours per record on its experience and on information from industry. FDA estimates that it takes 250 hours per respondent to comply with the recordkeeping requirements in parts 113 and 114. In table 2, row 1 of this document, FDA estimates the total burden of recordkeeping under parts 113 and 114 before the effective date of the final rule to be 2,375,000 hours (9,500 respondents x 250 hours = 2,375,000 hours). Table 2, row 2 reports the average annual recordkeeping burden of the final rule. The burden of the recordkeeping requirement of the final rule consists of the set-up time required to design and establish a form for recording the required information, and the additional hours of labor needed to record the information. The set-up time required for designing a new recordkeeping form is assumed to be minimal because we estimate that only a few data elements required in the final rule are currently unreported by some processors and that only small modifications to a processor's recordkeeping form would be required to accommodate the additional data elements.

We estimate that the amount of time needed to comply with the recordkeeping requirements of the final rule will be small because current industry practice is to keep track of most, if not all, of this information. Because current incentives to track accuracy of mercury-in-glass thermometers may vary across the industry, however, some information that is currently generated during accuracy tests may not be recorded as required under the final rule. Thus, we assume there will be a burden incurred from the final rule to record information that is currently generated, but not recorded.

We assume that half of the industry currently does not record all of the device accuracy testing information that the final rule requires. We further assume that current practice by these firms is to leave unrecorded 1 to 4 separate pieces of information required under the final rule, and that each piece of information takes between 10 and 15 seconds to record. Consequently, we estimate that half of all low-acid canned food manufacturers will spend between 10 seconds and 1 minute (i.e., 1 x 10 seconds and 4 x 15 seconds) per device to record information required in the final rule.

Based on a survey conducted by FDA between 1992 and 1993 of mercury-in-glass thermometer calibration in the low-acid canned food industry, we estimate that low-acid food firms use an average of 10 temperature-indicating devices, including reference devices. We estimate that 4,225 low-acid canned food manufacturers (half of the industry) currently do not fully record the accuracy test results required by the final rule. Because the regulations specify that each device must be tested upon installation and at least once per year thereafter, or more frequently if necessary to ensure accuracy, we estimate that each device requires 1 to 2 tests per year (midpoint of 1.5 tests per year). We therefore estimate the annual frequency per recordkeeping to be 15 (i.e., 10 devices x 1.5 tests per year). We estimate the burden for recording the additional information to be between 10 and 60 seconds per device (midpoint of 35 seconds or 0.0097 hours per device). Therefore, the estimated total annual burden in hours for the recordkeeping requirements of the final rule is approximately 615 hours (63,375 x 0.0097 = 614.7 hours, rounded to 615 hours). Thus, the final rule increases the total burden of this information collection by approximately 0.3 percent, from 2,375,000 hours to 2,375,615 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $142,494,755 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 2011, approximately $29.93/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $59.86/hour. Thus, the overall estimated cost incurred by the respondents is $142,494,755 (2,380,467 burden hours x $71.76/hr = $142,494,755).

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 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 $427.56 per 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

This is a revision request in which the burden hours for the final rule "Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" are being added to the information collection currently approved under OMB control number 0910-0037. We estimate that the recordkeeping requirements in new § 113.100(c) and (d) add 615 hours. Due to the rulemaking, we are characterizing this revision as a program change due to agency discretion.

In addition, parts 113 and 144 reflect an increase in the total burden hours from 1,863,500 hours to 2,375,000, an increase of 511,500 hours. This increase is due to a large increase in the estimated number of recordkeepers, as compared with three years ago. Thus, the total increase in the estimated recordkeeping burden is 512,115 hours (615 + 511,500 = 512,115).

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.