

measure the intended outcome? (5 points)

#### 5. Budget (Not Scored)

The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable.

#### 6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

### H. Other Requirements

#### Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Semiannual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirements
- AR-7 Executive Order 12372 Review
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. Sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

### J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Reneé Benyard, Grants Management Specialist, Acquisition and Assistance, Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: (770)488-2722, Fax number: (770)488-2777, email address: [bnb8@cdc.gov](mailto:bnb8@cdc.gov).

For program technical assistance, contact: Joanna Buffington, Program Management Official, Division of Viral Hepatitis, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop G-37, Atlanta, GA 30333, Telephone number: (404)371-5460, Fax number: (404) 371-5488, e-mail address: [jyb4@cdc.gov](mailto:jyb4@cdc.gov).

Dated: April 30, 2002.

**Sandra R. Manning,**

*CGFM, Director, Procurement and Grants Office, Center for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0123]

#### Agency Information Collection Activities; Proposed Collection; 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) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for firms that process acidified foods and thermally processed

low-acid foods in hermetically sealed containers.

**DATES:** Submit written or electronic comments on the collection of information by July 5, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers (OMB Control Number 0910-0037)—Extension**

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.

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)(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 (§§ 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 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)).

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for acidified foods and thermally processed low-acid foods in hermetically sealed containers as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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(c)(1) and 108.35(c)(1)	500	1	500	.17	85
Form FDA 2541a (Process Filing)	108.25(c)(2) and 108.35(c)(2)	1,000	7	7,000	.333	2,331
Form FDA 2541c (Process Filing)	108.35(c)(2)	275	2	550	.75	412
Total				8,050		2,828

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
108, 113, and 114	6,000	1	6,000	250	1,500,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant 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 §§ 108.25(g) and 108.35(h) have not

been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Dated: April 23, 2002.  
**Margaret M. Dotzel,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4734-N-17]

**Notice of Submission of Proposed Information Collection of OMB; Land Survey Report for Insured Multifamily Projects**

**AGENCY:** Office of the Chief Information Officer, HUD.