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 these topics: (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.

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910–0325—Extension)

Under part 530 (21 CFR Part 530), a veterinarian is permitted to prescribe the extralabel use of approved new animal drugs. Section 530.22 (b) of the implementing regulations permits FDA, if it finds there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to: (1) Establish a safe level for a residue from the extralabel use of the drug, and (2) require the development of an analytical method for the detection of residues above that established safe level. To date, FDA has not established a safe level for a residue from the extralabel use of any new animal drug and therefore has not required the development of analytical methodology. However, the agency believes that there may be instances when analytical methodology will be required. Thus, FDA is estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. The agency believes that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal government, or individuals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12302 Filed 6–2–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0129]

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) 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: Fax written comments on the collection of information by July 3, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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—(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 (§ 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 108.35(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)).

In the **Federal Register** of March 4, 2008 (73 FR 11649), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
113 and 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 of this document, 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 §§ 108.25(d) and 108.35(d) and 108.35(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 §§ 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: May 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12337 Filed 6–2–08; 8:45 am]

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