

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0780]

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Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

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: In compliance with section 3507 of the PRA (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 (21 CFR 108.25(c)(1) and (c)(2), (d), (e), (g); 108.35(c)(1), (c)(2), (d), (e), (f), (h); 113.60(c); 113.83; 113.87; 113.89; 113.100; 114.80(b); 114.89; 114.100(a) through (d)) (OMB Control Number 0910-0037—Extension)

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

In the **Federal Register** of April 30, 1999 (64 FR 23334), the agency requested comments on the proposed collections of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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)	300	1	300	.17	51
Form FDA 2541a (Process Filing)	108.25(c)(2) and 108.35(c)(2)	1,000	6.5	6,500	.333	2,165
Form FDA 2541(c) (Process Filing)	108.35(c)(2)	1,000	.50	500	.75	375
Total						2,591

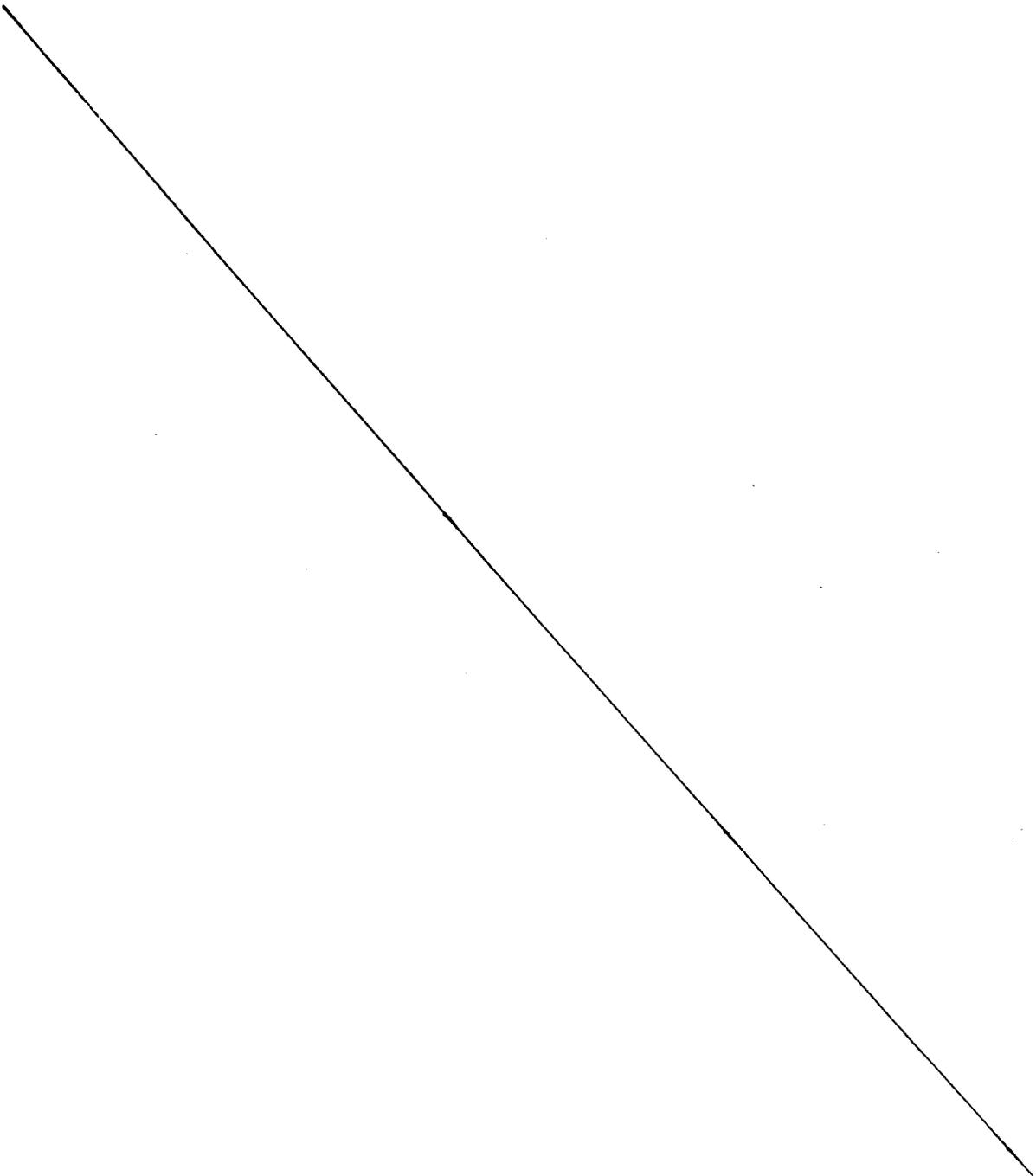
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
108, 113, and 114	5,865	1	5,865	250	1,466,250

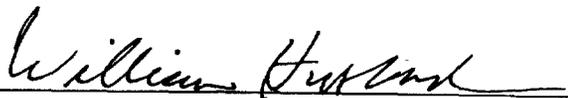
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

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: July 19, 1999



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

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