Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 26, 1996 (61 FR 33232), FDA issued a final rule implementing the provisions of the Safe Medical Devices Act (the SMDA) regarding Humanitarian Use Devices (HUD's). The final rule contained information collection requirements subject to the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3507). In compliance with section 3507 of the PRA, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Title: Medical Devices; Humanitarian Use Devices.

Description: This regulation implements the provision of the SMDA regarding HUD's. A HUD is exempt from the effectiveness requirements of sections 514 and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d and 360e). In order to implement this exemption, FDA is amending the premarket approval regulations in 21 CFR part 814 by creating new subpart H. This final regulation prescribes the procedures for submitting Humanitarian Device Exemption (HDE) applications, amendments and supplements; procedures for obtaining an extension of the exemption; and the criteria for FDA review and approval of HDE's. This final rule will create a needed incentive for the development of devices for use in the treatment or diagnosis of diseases or conditions affecting a small number of individuals.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.102	20	1	20	40	800
814.104	15	1	15	320	4,800
814.106	10	1	10	120	1,200
814.108	12	1	12	80	960
814.110(a)	1	1	1	80	80
814.112(b)	1	1	1	8	8
814.116(b)	12	1	12	8	96
814.118(d)	1	1	1	8	8
814.120(b)	10	1	10	200	2,000
814.124(b)	2	1	2	2	4
814.126(b)(I)	2	1	2	120	240
Total					10,196

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(ii)	12	1	12	2	24
Total					24

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

Dated: October 24, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–27737 Filed 10–24–96; 3:21 pm]

BILLING CODE 4160–01–F

[Docket No. 96N–0325]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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.

DATES: Submit written comments on the collection of information by November 29, 1996.

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, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, rm. 16B–19, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (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—Reinstatement).

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'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 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, 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: (1) Document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); (2) 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), 108.35(d), and (e)); and (3) 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 low-acid 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:

ESTIMATED ANNUAL REPORTING BURDEN

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 2541c (Process Filing)	108.35(c)(2)	1,000	.50	500	.75	375
Total				7,300		2,591

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
108, 113, and 114	5,388	1	5,388	250	1,347,000

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

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. No burden has been estimated for the coding requirements in §§ 113.60(c) and 114.80(b) because coding is a usual and customary practice in the foods industry for liability purposes, inventory control, and process control in the event of a problem with the product. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy.

[FR Doc. 96–27746 Filed 10–28–96; 8:45 am]

BILLING CODE 4160–01–F