Recovery and Reinvestment Act of 2009 (ARRA). For ease of reference, the APOE will be exclusively referred to by its new name in the remainder of this notice, even if it is referring to past activities.

The charter will terminate on January 21, 2013, unless renewed by appropriate action. The APOE was chartered under 42 U.S.C. 222 of the PHSA, as amended. The APOE is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Pursuant to the amended charter, the APOE will advise the Secretary of Health and Human Services and the CMS Administrator concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in or eligible for Medicare, Medicaid, and CHIP.
- Enhancing the Federal government's effectiveness in informing the Medicare, Medicaid and CHIP consumers, providers and stakeholders pursuant to education and outreach programs of issues regarding these and other health coverage programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, and CHIP education programs.
- Assembling and sharing an information base of "best practices" for helping consumers evaluate health plan options.
- Building and leveraging existing community infrastructures for information, counseling and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under health care reform.

B. Requests for Nominations

The APOE shall consist of no more than 20 members. The Chair shall either be appointed from among the 20 members, or a Federal official will be designated to serve as the Chair. The charter requires that meetings shall be held approximately four times per year. Members will be expected to attend all meetings. The members and the Chair shall be selected from authorities knowledgeable in one or more of the following fields:

- Senior citizen advocacy.
- Outreach to minority communities.
- Health communications.
- Disease-related advocacy.
- Disability policy and access.
- Health economics research.
- Health insurers and plans.
- Health IT.
- Direct patient care.
- Matters of labor and retirement.

Representatives of the general public may also serve on the APOE.

This notice also announces that as of January 2011, there are 12 expired terms of membership. This notice is an invitation to interested organizations or individuals to submit their nominations for membership on the APOE. The CMS Administrator will appoint new members to the APOE from among those candidates determined to have the expertise required to meet specific agency needs, and in a manner to ensure an appropriate balance of membership. We have an interest in ensuring that the interests of both women and men, members of all racial and ethnic groups, and physically challenged individuals are adequately represented on the APOE. Therefore, we encourage nominations of qualified candidates who can represent these interests. Any interested person may nominate one or more qualified persons.

Current members whose terms expired in 2010 or 2011 may be considered for reappointment, subject to committee service guidelines.

Each nomination must state that the nominee has expressed a willingness to serve as a Panel member and must be accompanied by a curricula vitae and a brief biographical summary of the nominee's experience.

While we are looking for experts in a number of fields, our most critical needs are for experts in health disparities, State Health Insurance Assistance Programs (SHIPs), health insurance plans, aging, Web health education, e-prescribing, retirement/financial planning, health research, public health and prevention, caregiving, CHIP, health insurance exchanges, and minority health education.

We are requesting that all curricula vitae include the following:

- Date of birth.
- Place of birth.
- Title and current position.
- Professional affiliation.
- Home and business address.
- Telephone and fax numbers.
- E-mail address.
- List of areas of expertise.

Phone interviews of nominees may also be requested after review of the nominations.

In order to permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

Members are invited to serve for 2-year terms, contingent upon the renewal of the APOE by appropriate action prior to its termination. A member may serve after the expiration of that member's term until a successor takes office. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term.

III. Copies of the Charter

The Secretary's Charter for the APOE is available on the CMS Web site at: *http://www.cms.gov/FACA/04_APOE.asp,* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 25, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–4754 Filed 2–28–11; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0265] (formerly Docket 2007N–0026)

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 (the PRA).

DATES: Fax written comments on the collection of information by April 4, 2011.

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: 202–395–7285, or e-mailed to *oira_submission@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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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)—Revision

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.

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)).

These collection of information provisions are currently approved under OMB control number 0910–0037 (expires August 31, 2011). 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).

Elsewhere in this issue of the **Federal Register**, FDA is publishing 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. Because OMB approval for the collections of information in the regulations the final rule amends is set to expire on August 31, 2011, FDA is also submitting those collections (as revised by the final rule) for OMB review, along with the others currently approved under OMB control number 0910–0037.

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.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form No.	21 CFR section	Number 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 × 1 annual response × 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 × 8.62 annual responses × 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 × 7.77 annual responses × 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.

FDA permits electronic registration and filing on the Internet. The electronic submission capability of the Low Acid Canned Food (LACF) Program entitled *e*LACF was the second major registration 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 e-mail to *lacf@fda.hhs.gov.*

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR part/section	Number 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 $\times$ 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., 1×10 seconds and 4×15 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 $\times$ 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 $\times$ 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.

Dated: February 23, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–4474 Filed 3–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

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 April 4, 2011.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

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.

Radioactive Drug Research Committees—(OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research