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 × 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 × 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 × 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

study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application (IND) under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

In the **Federal Register** of November 30, 2010 (75 FR 74059), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Forms	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
361.1(c)(3) and (4)	FDA 2914	80	1	80	1	80
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1,190
361.1(d)(8)		50	6.8	340	0.1	34
Total						1,304

[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 section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per records	Total hours
361.1(c)(2)	80	4	320	10	3,200
361.1(d)(5)	50	6.8	340	0.75	255
Total					3,455

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

Dated: February 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4741 Filed 3–2–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0098]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Label Statements Experimental Study

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled "Infant Formula Label Statements Experimental Study."

DATES: Submit either electronic or written comments on the collection of information by May 2, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 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.

Infant Formula Label Statements Experimental Study—(OMB Control Number 0910–NEW)

FDA is planning to conduct an experimental study about certain types of label statements on infant formula, such as those that are either structure function claims or similar to such claims. An example of the type of statements that are of interest is: "Supports brain and eye development." The Infant Formula Label Statements Experimental Study will collect information from four groups: Pregnant women, mothers of infants less than 12 months old, mothers of children older than 1 year but younger than 5 years old, and women of childbearing age who do not have a child younger than 5 years. The purpose of the study is to assess women's understanding of and response to various statements on infant formula labels. The study results will be used to help the Agency to understand the role that certain types of statements on infant formula labels have in influencing formula choice.

The data will be collected over the Internet from a sample of 5,000 adult women selected from an online consumer panel. Participants will be randomly assigned to an experimental condition. The study will show participants one of five explanations of the regulatory, scientific, or marketing context (or none of these) of infant formula marketing in the United States and will ask them to compare two sets of two experimental infant formula labels. One label will always be a control label with no statement similar to a structure function claim. The other label will include one of the statements of interest to the study. The study will focus on purchase choice, perceived similarity of the formula to breast milk, and perceived likelihood that the formula has certain health benefits. In addition, information about certain covariates will be collected, depending on the group the participant is in. Covariate information will include, as appropriate, month of pregnancy, plans for feeding the infant, number of children, age of youngest child, whether the youngest child was fed infant formula, whether the youngest child was ever breast fed, whether the mother bought infant formula for her youngest child, priorities used to select the formula purchased, and attitudes about the differences between breast milk and formula. Participation in the study is voluntary.

Approximately 10,000 women will be screened. We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 55 hours. A pretest will be conducted with 150 participants. We estimate that it will take a respondent 15 minutes (0.25 hours) to complete the experiment and 10 minutes (0.167 hours) to complete debriefing questions for the pretest, for a total of 25 minutes (0.42 hours) per respondent and a total of 63 hours for the pretest. Five thousand (5,000) adult women will complete the experiment. We estimate that it will take a respondent 15 minutes (0.25 hours) to complete the entire experiment, for a total of 1,250 hours. Thus, the total estimated burden is 1,368 hours. FDA's burden estimate is based on prior experience with consumer experiments that are similar to this proposed experiment.

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