Dated: February 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4741 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–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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Screener	10,000	1	10,000	0.0055	55
Pretest	150	1	150	0.42	63
Experiment	5,000	1	5,000	0.25	1,250
Total					1,368

[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. 2011–4740 Filed 3–2–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0344]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Testing Communications on Medical Devices and Radiation-Emitting Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2010 (75 FR 63838), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0678. The approval expires on January 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4738 Filed 3–2–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–N–0238] (formerly 2006N–0062)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Expanded Access to Investigational Drugs for Treatment Use" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of December 14, 2006 (71 FR 75147), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0653. The approval expires on December 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–4739 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–0478]

Albert Poet: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Albert Poet, MD from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Poet was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Poet was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Poet failed to respond. Dr. Poet's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 3, 2011.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory