In preparing the previous clearances for approval of the information collection requirements under §§ 806.10 and 806.20, FDA reviewed the reports of corrections and removals submitted for the previous 3 years under part 7 (21 CFR part 7), the agency's recall provisions. FDA has determined that estimates of the reporting burden in § 806.10 should be revised to reflect a 1.2 percent increase for reports and records submitted under 21 CFR part 7 due to a decrease in class I and class II recall actions. FDA also estimates the reporting burden in § 806.20 should be revised to reflect a reduction of 8 percent for reports and records submitted under 21 CFR part 7 due to a decrease in class III recall actions. The time needed to collect information has not been changed.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23962 Filed 12–10–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0461]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Communicating With Health Care Providers About the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women With Chronic Conditions

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 the information collection provisions of the Mental Models Study of Communicating With Health Care Providers About the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women With Chronic Conditions. Together with other information being collected, the results from this study will be used to help inform FDA about how health care providers use prescription drug labeling and other available information in making treatment decisions and how that use differs from how agency experts believe such information is used. It will also contribute to FDA's ability to plan internal and external communications activities that address any misperceptions and gaps in understanding about prescription drug labeling.

DATES: Submit written or electronic comments on the collection of information by February 11, 2008.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Jonna Capezutto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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: (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.

Mental Models Study of Communicating With Health Care Providers About the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women With Chronic Conditions

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The proposed information collection will help FDA advance public health by identifying misperceptions and knowledge gaps about how health care providers use information to make decisions about the use of prescription drugs for the targeted patient groups. Knowledge of these misperceptions and gaps provides opportunities for FDA to target its communications more precisely to such gaps and areas of misperception in health care providers' mental models regarding treatment decisions.

FDA engages in various communication activities to ensure that patients and health care providers have the information they need to make informed decisions about treatment options, including the use of prescription drugs. FDA regulations (21 CFR § 201.57) describe the content of required product labeling, and FDA reviewers ensure that labeling contains accurate and complete information about the known risks and benefits of each drug. This data collection and analysis is designed to identify knowledge gaps that FDA could then address, which would ultimately improve decision making and potentially improve health outcomes.

The project will use ''mental modeling,'' a qualitative research method that compares a model of the decision-making processes of a group or groups to a model of the same decision-

making processes developed from expert knowledge and experience. In this study, the decision models of certain health care providers concerning treatment options for pregnant and nursing women will be compared to a decision model concerning such treatment options that was derived from the knowledge and experience of FDA reviewers responsible for product labeling. FDA will use telephone interviews to determine from the health care providers the factors that influence their treatment decisions for pregnant and nursing women with chronic conditions. A comparison between expert and health care provider models based on the collected information may identify consequential knowledge gaps that can be redressed through messages or information campaigns designed by FDA.

Using a protocol derived from the research that resulted in the ''expert model,'' trained interviewers will conduct one-on-one telephone discussions with about 25 members of 2 categories of health care providers (described below) who provide health care services to pregnant or nursing women.

The two categories of health care providers are:

(1) Those who directly care for pregnant and nursing women, including obstetricians, OB/GYNs (obstetrician/gynecologists), nurse midwives, and general practitioners.

(2) Those who directly care for women of reproductive age with significant chronic health conditions (e.g., allergists, psychiatrists, or cardiologists).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
54	1	1	1.0	54.0
TOTAL				54.0

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

The study will involve about 54 respondents and take approximately 1 hour each to complete. These estimates are based on the contractor's extensive experience with mental models research. FDA conducted pretests of the mental models protocol with three health care providers. These resulted in the current protocol.

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23976 Filed 12–10–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0337]

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 January 10, 2008.

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: 202–395–6974, or e-mailed to *baguilar@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: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

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