TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total	118	2.39	142	160	10,915

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

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19626 Filed 8–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0087] (formerly Docket No. 2007N–0461)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 September 24, 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–NEW and title, ''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.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

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 an ''expert 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 an expert 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 24 to 30 members of each of 2 categories of health care providers (described in the following paragraph) who provide health care services to pregnant and 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 primary care practitioners.

(2) Selected specialties of healthcare providers who directly care for women of reproductive age who have chronic health conditions (allergists, psychiatrists, neurologists, and cardiologists).

In the **Federal Register** of December 11, 2007 (72 FR 70328), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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
60	1	1	1.0	60.0

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

The study will involve about 60 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 six health care providers. These resulted in the current protocol.

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19653 Filed 8–22–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0453]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of FDA's regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit written or electronic comments on the collection of information by October 24, 2008.

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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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, including each proposed extension of an existing 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.

Regulations Under the Federal Import Milk Act—21 CFR Part 1210 (OMB Control Number 0910–0212)—Extension

Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50° F (21 U.S.C. 142).

FDA's regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.