

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2007N-0460]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Reports of Corrections and Removals****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 information collection requirements for reports of corrections and removal.

**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> or <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, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from 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.

**Reports of Corrections and Removals—21 CFR Part 806; (OMB Control Number 0910-0359)—Extension**

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105-115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

Respondents to this collection of information are manufacturers and importers of medical devices.

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

**TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>**

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	488	1	488	10	4,880
TOTAL					4,880

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
806.20	132	1	132	10	1,320
TOTAL					1,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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.*

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## 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-