implementation services to Indian Tribes regarding the title IV–E program.

In order to plan for the review of Tribal title IV–E plans and technical assistance needs, the Administration for Children and Families (ACF) is requesting that all Federally recognized Indian Tribes, Tribal organizations or Tribal consortia (hereafter, ''Tribes'') that plan to operate a title IV–E program send a letter of intent to their ACF Regional Program Manager by December 31, 2008.

ACF will ask Tribes to include in the letter of intent the following information:

1. The Federal fiscal year (FY) in which the Tribe expects to begin operation of a title IV–E program. (According to the law, the earliest possible implementation period is FY 2010.)

2. Information on the intended Tribal service area for the Tribal title IV–E program.

Respondents: Indian Tribes, Tribal organizations and Tribal consortia.

ANNUAL BURDEN ESTIMATES

Information collection	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of Intent	562	1	1	562

Estimated Total Annual Burden Hours: 562.

Additional Information: ACF is requesting that OMB grant a 90-day approval for this information collection under procedures for emergency processing by November 28, 2008. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275 or e-mailing to *infocollection@acf.hhs.gov.*

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, (202) 395–7316.

Dated: November 13, 2008.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E8–27668 Filed 11–21–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0589]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mental Models Study of Health Care Providers' Understanding of Prescription Drug Effectiveness

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 Health Care Providers' Understanding of Prescription Drug Effectiveness. Together with other information being collected, the results from this study will be used to help inform FDA about how health care providers conceptualize the drug effectiveness portion of the risk/benefit tradeoff and how that conceptualization differs from how agency experts think about drug effectiveness. The information gathered in this study will be used to focus and strengthen future planned quantitative research. It will also contribute to FDA's ability to communicate drug effectiveness information to health care providers in labeling and other communications.

DATES: Submit written or electronic comments on the collection of information by January 23, 2009.

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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Mental Models Study of Health Care Providers' Understanding of Prescription Drug Effectiveness

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information.

Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that an advertisement that makes claims about a prescription drug include a ''air balance'' of information about the benefits and risks of the advertised product, in terms of both content and presentation (21 CFR 202.1(e)(5)(ii)). In past research, FDA has focused primarily on the risk component of the risk/benefit ratio. In the interest of thoroughly exploring the issue of fair balance, however, the presentation of effectiveness, or benefit, information is equally important. This component has received less scrutiny. The proposed information collection described here is the first step in a three-phase study designed to investigate the role of effectiveness information in prescription drug print advertising. Along the way, we plan to investigate how health care providers use labeling and other materials and experiences to reach conclusions about drug effectiveness. We will use this information to provide a benchmark with which to compare the information consumers receive from direct-to-consumer advertisements.

The information collection described here refers only to the qualitative portion of the study series, Phase I. The purpose of the proposed information collection is twofold. First, we plan to gather information in this phase that will help us to determine the proper concepts about which to inquire and the proper language to use when asking health care providers in the second phase about the effectiveness of certain drug products. Second, we will use the information gathered in this phase to identify gaps in the communication of effectiveness information in FDA sponsored materials, such as the physician labeling.

The proposed information collection described here (Phase I of a multi-phase project) will use ''mental modeling,'' a qualitative research method that compares a model of the decisionmaking processes of a group or groups to a model of the same decisionmaking processes developed from expert knowledge and experience. In this study, the decision models of certain health care providers concerning effectiveness decisions of various treatment options for individuals suffering from insomnia or rheumatoid arthritis will be compared to a decision model concerning drug effectiveness that was derived from the knowledge and experience of FDA reviewers responsible for product labeling, National Institutes of Health clinical experts in this field, and others involved in the training of medical professionals. FDA will use telephone interviews to determine from the health care providers the factors that shape their understanding and decisions about the effectiveness of various drug treatments for their patients. 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 designed by FDA and will provide information for designing the second (quantitative) phase of research with a national sample of health care providers.

Using a protocol derived from the research that resulted in the expert model, trained interviewers will conduct one-on-one telephone discussions with about 20 members of 2 categories of health care providers, general practitioners and rheumatologists, who provide direct patient care at least 50 percent of the time.

FDA has selected these two groups of physicians because the first group is reasonably likely to treat insomnia, whereas the second group treats rheumatoid arthritis. We selected these two medical conditions for focus in the next two phases of the research because prescription drug treatments for both are heavily advertised to consumers, drugs for these conditions are variable in their risk/benefit profiles, and yet they are each fairly complex in terms of risk/benefit profiles. Another function of the current information collection is to determine the feasibility of using these two medical conditions in the following quantitative phases.

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
40	1	1	0.75	30.0
Total				30.0

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

The study will involve about 40 respondents and take approximately 45 minutes each to complete. These estimates are based on the contractor's extensive experience with mental models research.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: November 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27801 Filed 11–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0474] (formerly Docket No. 2007N–0292)

George Kindness; 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 act) permanently debarring Mr. George Kindness from