manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(2) Establishing an ongoing drug-free awareness program to inform employees about—

(a) The dangers of drug abuse in the workplace;

(b) The grantee's policy of maintaining a drug-free workplace;

(c) Any available drug counseling, rehabilitation, and employee assistance programs; and

(d) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(3) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(4) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(a) Abide by the terms of the statement; and

(b) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(5) Notifying the agency in writing, within 10 calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(6) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted—

(a) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(b) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(1) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(2) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

[FR Doc. E9–7502 Filed 4–2–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0589]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 May 4, 2009.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Mental Models Study of Health Care Providers' Understanding of Prescription Drug Effectiveness.'' Also include the FDA 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: 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 Health Care Providers' Understanding of Prescription Drug Effectiveness

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks.[1] By its nature, the presentation of this risk information is likely to evoke active trade-offs by consumers and physicians, i.e., comparisons with the perceived risks of not taking a treatment, and comparisons with the perceived benefits of taking a treatment.[2] The FDA has an interest in fostering safe and proper use of prescription drugs, which is an activity that necessitates understanding of both risks and benefits. Thus, an indepth understanding of physicians' processing of this information, their thinking on relevant topics, and their informational needs are central to this regulatory task.

Under the act, FDA engages in a variety of 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

[1] For prescription drugs and biologics, the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)).

[2] See Swartz, L., Woloshin, S., Black, W., and Welch, H.G., ''The role of numeracy in understanding the benefit of screening mammography,''*Annals of Internal Medicine*, 127(11), 966–72, 1997.

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 proposed data collection will provide FDA with insight for evaluating and improving current communication procedures. It is designed to identify knowledge gaps for FDA to address, which would ultimately improve practitioner decisionmaking and hence the health outcomes of the affected patients. This new information collection uses ''Mental Modeling,'' which is a qualitative research method that compares a model of the decisionmaking processes of a group or groups to a model of the same process developed from expert knowledge and experience. In this study, the decision models of health care providers concerning their understanding of drug product efficacy and how they communicate their understanding to their patients will be compared to a model derived from the knowledge and experience of experts who review product labeling for the purpose of ensuring that prescribers get the information they need to make optimal prescribing decisions. FDA will use telephone interviews to determine from the health care providers the factors that influence their understanding of drug product efficacy and how they communicate their understanding to their patients. Comparing expert and health care provider responses will allow for a richer understanding of decisions determining drug product efficacy from labeling and other sources and how this understanding is communicated to their patients.

FDA regulations require that prescription drug advertisements that make (promotional) claims about a product also include risk information in a ''balanced'' manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. This balance applies to both the front display page of an advertisement and the brief summary page. However, beyond the ''balance'' requirement there is limited guidance and research to direct or encourage sponsors to present benefit claims that are informative, specific, and reflect clinical effectiveness data.

Research and guidance to sponsors on how to present benefit and efficacy information in prescription drug advertisements is limited. For example, ''benefit claims,'' broadly defined, appearing in advertisements are often presented in general language that does not inform patients of the likelihood of efficacy and are often simply variants of an ''intended use'' statement.[3] In a study involving a content analysis of direct-to-consumer (DTC) advertising, the researchers classified the ''promotional techniques'' used in the advertisements. Emotional appeals were observed in 67 percent of the ads while vague and qualitative benefit terminology was found in 87 percent of the ads. Only 9 percent contained data. However, for risk information, half the advertisements used data to describe side-effects, typically with lists of side-effects that generally occurred infrequently.

Additional research is necessary to uncover important information about how consumers understand effectiveness information about prescription drug products from DTC advertisements. This particular understanding is crucial to the risk-benefit tradeoff that patients must make with the consultation of a health care professional in order to achieve the best health outcomes. The qualitative information in this Mental Models phase of the research will provide a preliminary framework and help FDA craft subsequent quantitative studies.

Overview. The proposed information collection will use ''mental modeling,'' a qualitative research method wherein the decisionmaking processes of a group of physician respondents concerning the effectiveness of various prescription drug products are modeled and compared to a model based on expert labeling knowledge and clinical experience in drug effectiveness. The information will be collected by telephone interviews concerning the factors that influence perceptions and decisions related to drug effectiveness. This method will help identify physicians' beliefs, priorities, informational needs, visions and conceptualizations about how well particular drugs work. A comparison between expert and physician models based on the collected information may identify ''consequential knowledge gaps'' that can be redressed through labeling changes as well as helping FDA focus future quantitative research on the communication of drug benefit information. Thus, the information to be collected will be used by FDA to develop and strengthen research materials and design in future planned quantitative experiments.

The first step in the mental models process is to conduct background research to develop a model based on both experts' current knowledge and extant literature on drug effectiveness. The resulting ''simple expert model'' is a mapping of decisionmaking factors, relationships and influences, and is used to develop an interview protocol for a day-long workshop with experts, hereafter referred to as the ''expert elicitation.''

The expert elicitation was conducted November 28, 2007. It included nine experts from a variety of medical fields, including those versed in drug labeling issues and others with extensive clinical experience, particularly involving two medical conditions (insomnia, a medical condition frequently treated by general practitioners, and rheumatoid arthritis, a condition likely treated by specialists). Six experts were internal to FDA, two experts were from the National Institutes of Health, and one expert was external to the Federal Government, from the Association of Medical Colleges. The expert elicitation process does not solicit advice, opinions, or recommendations from the group, but instead tries to determine how each expert perceives the factors related to consumer decisionmaking, from their particular expert field. Results from the expert elicitation were used to develop the expert model, which generally includes adding new concepts and supporting details to the existing simple expert model. The new draft expert model was validated during a subsequent teleconference with the research team about a month following the initial elicitation. Following the validation, the project team finalized the expert model.

The expert model informs the development of the physician interview guide for physician telephone interviews. Mental models research is typically conducted with cohorts of respondents who represent categories of people whose mental models are to be compared, both individually with the expert model and between cohorts, identifying the potential for significant differences among cohorts. Interviews will be conducted with 40 health care providers to develop a mental model describing how each of 2 cohorts learns about drug product efficacy and how their understanding about efficacy is communicated to their patients. The cohorts are as follows:

(1) *Primary care providers*. This cohort includes office-based practitioners in primary care (general practice, family practice, and internal medicine) with at least 3 years of experience and who engage in patient care at least 50 percent of the time.

[3] Woloshin, S. and Schwartz, L., ''Direct to consumer advertisements for prescription drugs: what are Americans being told,'' *Lancet*, 358, 1141–46, 2001.

(2) *Specialists*. This cohort includes office-based practitioners in rheumatology with at least 3 years of experience and who engage in patient care at least 50 percent of the time.

Cohorts will be identified and recruited to represent a reasonable range of age, gender, and ethnicity.

Within each cohort, 20 practitioners will be interviewed by trained interviewers in one-on-one in-depth telephone interviews. A sample size of 40 (approximately 20 primary care providers and 20 rheumatologists) is sufficiently large for the qualitative findings to capture a wide depth and range of people's thinking. The interviews will take approximately 45 minutes. The health care provider interviews will be used to create a mental model of physician decisionmaking factors with respect to drug product effectiveness.

Potential physician participants will be randomly identified through a purchased list based on the American Medical Association's (AMA) Physician Masterfile. This list tracks all physicians, M.D. (doctor of medicine) and DO (doctor of osteopathic medicine), practicing in the United States, not only members of the AMA.

FDA intends this collection to be used as formative research. As with our focus group research (OMB control number 0910–0360), the results of this formative research will provide direction toward potential areas of focus. Further research is necessary, and planned, to test concepts obtained from these results. This research will be useful in designing survey questions for the next phases of this research project (which will be submitted for approval at a later date).

In the **Federal Register** of November 24, 2008 (73 FR 71006), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
21 U.S.C. 393(b)(2)(c) Questionnaire, Pretesting	4	1	4	.75	3
21 U.S.C. 393(b)(2)(c) Questionnaire, Study	40	1	40	.75	30
Total					33

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

Dated: March 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–7471 Filed 4–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0653]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 May 4, 2009.

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0184. 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.

Filing Objections and Requests for a Hearing on a Regulation or Order—(OMB Control Number 0910–0184)—Extension

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of January 14, 2009 (74 FR 2080), 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: