Dated: December 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31381 Filed 12–14–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0418]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

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 14, 2011.

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:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0130. 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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850,. 301–796–3792.
Elizabeth.Berbakos@fda.hhs.gov.

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.

Institutional Review Boards—OMB Control Number 0910–0130—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

In the **Federal Register** of August 17, 2010 (75 FR 50766), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received regarding the information collection.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per recordkeeper	Total hours
56.115	2,500	14.6	36,500	100	3,650,000
Total					3,650,000

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

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 2,500 IRBs. The IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

Dated: December 8, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

[FR Doc. 2010–31389 Filed 12–14–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0184]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Patient Information Prototypes

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 14, 2011.

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:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–new and title "Experimental Study of Patient Information Prototypes." 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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–792–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

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.

Experimental Study of Patient Information Prototypes—(OMB Control Number 0910–New)

In order to make informed decisions about health care and to use their medications correctly, consumers need easy access to up-to-date and accurate information about the risks, benefits and safe use of their prescription drugs. Consumers currently receive multiple pieces of paper with their prescription drugs from the pharmacy, containing information that is developed and distributed through various sources. Written prescription drug information is provided through a voluntary effort (Consumer Medication Information) [1] as well as through FDA mandated use of Medication Guides [2] and Patient Package Inserts (PPI).[3] Patients describe a wide range of experiences and varying degrees of satisfaction with information currently provided at the time medicines are received at the pharmacy. In some cases, the written documents are difficult to read and understand, duplicative and overlapping, incomplete or contradictory. FDA has held multiple public meetings to solicit feedback on providing balanced, comprehensive, and up-to-date prescription drug information to consumers.

Since 1968, FDA regulations have required that PPIs written specifically for patients be distributed when certain prescription drugs or classes of prescription drugs are dispensed. PPIs are required for estrogens and oral contraceptives, are considered part of the product labeling, and are to be dispensed to the patient with the product. In the 1970s, FDA began evaluating the general usefulness of patient labeling for prescription drugs resulting in a series of regulatory steps to help ensure the availability of useful written consumer information. Other PPIs are submitted to FDA voluntarily by manufacturers and approved by FDA, but their distribution is not mandated by regulation. In the **Federal Register** of July 6, 1979 (44 FR 40016), FDA proposed regulations that would have required written patient information for all prescription drugs, and in the **Federal Register** of September 12, 1980 (45 FR 60754), FDA finalized those regulations. In the **Federal Register** of September 7, 1982 (47 FR 39147), the regulations were revoked based, in part, on assurances that the effort could be handled more efficiently within the private sector.

In the **Federal Register** of August 24, 1995 (60 FR 44182), FDA proposed the "Prescription Drug Product Labeling: Medication Guide Requirements," designed to set specific distribution and quality goals and timeframes for distributing written information to patients. In the **Federal Register** of December 1, 1998 (63 FR 66378), the Agency published a final rule that established a program under which Medication Guides would be required for a small number of drugs considered to pose a serious and significant public health concern (21 CFR 208.20).

Evidence suggests that both the content (*e.g.,* organization) and format (*e.g.,* white space) of a document will impact the comprehension of patient information. Research on reading behavior and document simplification suggests that the use of less complex terminology presented in shorter sentences with a more organized, or chunked, structure should improve consumer processing for at least three reasons. First, it should decrease the cognitive load engendered by the current physician-directed format. Second, a more structured and organized patient information document should present a less imposing processing demand, increasing consumers' willingness and self-perceived ability to read and understand the presented material. Research with the format of over-the-counter (OTC) drug labels,[4] the nutrition facts label,[5] and other information formats [6] demonstrates that information presented with section headings, graphics (such as bullets), and other design elements is more easily read than information presented in paragraph format. Consumers are more likely to engage in behavior they believe they can successfully complete.[7] Third, a patient information document that provides readers with clearer "signals" regarding the most important information should help readers prioritize the importance of the presented information. This should increase the probability that the set of information identified as important is subjected to more complete mental processing, thereby increasing the communication of that information.[8]

As part of FDA's efforts to improve the patient information received with prescription drugs, a Risk Communications Advisory Committee meeting was held on February 26 and 27, 2009. At this meeting, committee members discussed issues such as the ones described previously in this document and listened to stakeholder problems regarding the design and distribution of patient information. Following the advisory committee meeting, the working group created four prototypes to aid discussion at a public workshop to be held later in the year.

This public workshop was held on September 24 and 25, 2009. During the workshop stakeholders from industry, consumer advocacy, and academia converged to discuss desirable features for a single-document patient leaflet, if that were to be developed, consumer tested, and distributed. Participants were divided into six groups to address the pros and cons of the four prototypes with the goal of deciding which features participants appreciated and did not appreciate. For additional information on the September 24 and 25, 2009, public workshop, go to *http://www.fda.gov/Drugs/NewsEvents/ucm168106.htm*.

Given the information obtained from workshop participants, the working

[1] Public Law 104–180, August 6, 1996, Title VI, Effective Medication Guides.

[2] Part 208 (21 CFR part 208).

[3] 21 CFR 310.501 and 310.515.

[4] Aikin, K.J., "Consumer Comprehension and Preference for Variations in the Proposed Over-The-Counter Drug Labeling Format, Final Report," 1998; Vigilante, W.J., M.S. Wogalter, "The Preferred Order of Over-the-Counter (OTC) Pharmaceutical Label Components," *Drug Information Journal,* 31, 973–988, 1997.

[5] Levy, A.S., S.B. Fein, R.E. Schucker, "More Effective Nutrition Label Formats Are Not Necessarily More Preferred," *Journal of the American Dietetic Association,* 92(10), 1230–1234, 1992.

[6] Lorch, R., E. Lorch, "Effects of Organizational Signals on Text-Processing Strategies," *Journal of Educational Psychology,* 87(4), 537–544, 1995; Lorch, R., E. Lorch, "Effects of Organizational Signals on Free Recall of Expository Text," *Journal of Educational Psychology,* 88(1), 38–48, 1996; Lorch, R., E. Lorch, W. Inman, "Effects of Signaling Topic Structure on Text Recall," *Journal of Educational Psychology,* 85(2), 281–290, 1993.

[7] Wood, R., A. Bandura, "Impact of Conceptions of Ability on Self-Regulatory Mechanisms and Complex Decision Making," *Journal of Personality and Social Psychology,* 56(3), 407–415, 1989.

[8] Lorch, R., E. Lorch, "Effects of Organizational Signals on Text-Processing Strategies," *Journal of Educational Psychology,* 87(4), 537–544, 1995; Lorch, R., E. Lorch, "Effects of Organizational Signals on Free Recall of Expository Text," *Journal of Educational Psychology,* 88(1), 38–48, 1996; Lorch, R., E. Lorch, W. Inman, "Effects of Signaling Topic Structure on Text Recall," *Journal of Educational Psychology,* 85(2), 281–290, 1993.

group refined several prototypes and designed a study to investigate the usefulness of three possible patient information formats from a user perspective. The results of this study will inform FDA as to the usefulness and parameters of various format options for the patient information documents.

Description of the Project

This project is designed to test different ways of presenting information about prescription drugs to patients who have obtained a prescription. The information used will be based on a fictitious medication for the treatment of rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis. Data collection will occur via computer at training and testing facilities with orientation and debriefing conducted by interviewers. Participants will include adults who have been diagnosed with one of the conditions the fictitious drug treats. Participants will be prescreened to obtain a reasonable representation of health literacy, including those who score at the lower end of the scale. Questionnaire measures will include open- and closed-ended questions. Extensive pretesting of materials and stimuli will be conducted to refine the experimental stimuli and dependent measures and to ensure the stimuli meet minimum communication requirements and are delivering expected messages.

Proposed Study Design and Protocol

The study is experimental and will have two independent variables in a 3x2 design. The independent variables are Format (3 levels: Drug Facts, Minimal Column, and Column Plus) and Order (2 levels: Warning first and Indication first).

FORMAT

Order	Drug facts	Minimal column	Column plus
Warning first.			
Indication first.			

The Order manipulation will vary the primacy of the boxed warning information versus the paragraph about the uses to the drug. In terms of Format, the Drug Facts format will follow the conventions of the existing OTC labeling. The Minimal Column condition will contain information in two columns with only basic information in the sections regarding information patients should tell their doctors. The Column Plus condition will also present information in two columns, but will include additional contextual information in the sections about what information patients should report to their doctors.

Participants with relevant medical conditions will be randomly assigned to one of the six experimental conditions and each participant will see only one version of the patient information. Participants will be prescreened to represent a range of health literacy levels, including a portion with low literacy. Thus, all participants in the study will have been diagnosed with rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis and at least 30 percent of the sample will fall in the lower range of literacy. Because the average reading level in the United States is estimated to be 8th grade [9] and it is recommended that consumer medication information be written at a 5th grade reading level,[10] the low literate cohort will consist of consumers who have 5th to 8th grade reading skills. Education level is not a reliable substitute for literacy testing. At screening, the participants will be assessed for literacy level using a validated instrument.

An additional small study will be conducted via the Internet to determine whether electronic prototype presentation alters the processing of the information in any way. Two-hundred individuals with the same characteristics of the original sample (*e.g.,* medical condition and literacy levels) will be recruited over the Internet and will complete the same questionnaire as original participants.

FDA is undertaking this study because it does not yet have sufficient evidence-based research relating to patient needs, or whether those needs are being effectively met. Research related to the functionality and effectiveness of written patient information consistently identifies the importance of performance-based testing as well as content based testing, which enables the evaluation of materials in order to assure their utility and identify issues in content format, or design. Development of new prescription drug patient materials must be based on consumer testing that focuses on utility to the patient and comprehension of material in the broadest audience possible. FDA has developed three prototypes in order to user test prescription drug information with consumers in order to achieve this goal. For further information, contact Elizabeth Berbakos (*see* **FOR FURTHER INFORMATION CONTACT**).

In the **Federal Register** of May 4, 2010 (75 FR 23775), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five comments. In the following section, we outline the observations and suggestions raised in the comments and provide our responses. Four of the five comments expressed support for the conductance of the research to explore issues of quantitative benefit information. They all described the collection of data as a worthy endeavor which will provide useful information on how best to communicate information to patients about their prescription drugs.

(Comment 1) The first comment stated that FDA's approach to examining the content and format of the prototypes is reasonable. This comment provided minor suggestions regarding how to improve the study, most of which are currently addressed in the questionnaire. For example, we have included time measurement, questions about the safe use of the product, and scenario-based questions in the questionnaire for the second phase of our study. We have incorporated other suggestions into the qualitative first phase of our project. In this phase, we will present participants with all versions of the prototypes to assess their preferences and will able to probe participants more thoroughly about their reactions and responses to the prototypes.

(Comment 2) This comment provided a statement of support for the approval

[9] Cotunga N., C.E. Vickery, K.M. Carpenter-Haefele, "Evaluation of Literacy Level of Patient Education Pages in Health-Related Journals," *Journal of Community Health,* 30(3), 213–219, 2005.

[10] Andrus, M.R., M.T. Roth, "Health Literacy: A Review," *Pharmacotherapy,* 22(3), 282–302, 2002.

of this data collection, claiming the study will have practical utility.

(Comment 3) This comment provided support for the research proposed in this document and reported that the components identified by FDA are consistent with those found in their own research. The comment suggested the inclusion of a visual system for identifying drug products and the inclusion of a variety of font sizes for people with visual impairments. FDA fully supports the presentation of information for special populations. However, the scope of the present study is to determine one format out of several that works with a range of participants. After this step, we can move toward incorporating special features, such as pictures or large font, to accommodate patients with varying needs.

(Comment 4) Part of comment 4 was outside the scope of the proposed data collection; i.e., regarding the proper channels for distribution of Patient Medication Information (PMI). Regarding the parts of the comment that focused on the proposed research, the comment generally discussed omissions in the current proposed prototypes. These additional pieces of information have all been discussed at length at various public and expert meetings, including the public workshop in September 2009, the Brookings Institute Expert Workshop in July 2010, and the Part 15 hearing in September 2010. When improving medication documents for patients, there is always a trade-off between the desire to keep it simple and the desire to provide more information. Although a small number of individuals reported the desire for exhaustive information, the great majority of the feedback FDA has received and the literature the Agency has reviewed suggests that the information in the currently proposed prototypes is a reasonable collection of the important information that patients need to safely use their medications. Moreover, research suggests that providing large amounts of information will not serve patients well, but may instead impede their understanding of the information.[11] Finally, the proposed research itself is designed to address the issue of whether the information in the prototypes is optimal. The first phase of the research will involve qualitative interviews, wherein participants will have ample opportunity to tell us what they want and need to know. The second phase of the research will involve quantitative assessment of the comprehension of important information in the document. Thus, we believe our two-pronged approach will address some of the concerns raised in this comment and we must defer to the volumes of other feedback we have received regarding the limiting of information in PMI.

(Comment 5) Comment 5 had five main concerns with the study. First, the comment suggested that FDA reach out to Consumer Medication Information (CMI) publishers as early as possible in the development of the prototypes. FDA concurs with the importance of doing this and, in fact, has already done so multiple times and in multiple venues. Several CMI publishers participated in the public workshop held in September 2009 and spoke at the Part 15 hearing in September 2010.

Second, the comment claims that FDA has not used an evidence-based strategy to develop the PMI prototypes. We disagree. FDA developed the prototypes based on the scientific literature. As described in the first section of this document, the prototypes were based on recommendations to include chunks of information that would reduce cognitive load and facilitate processing by including plenty of white space, headings, and maintaining a readable font size. From this first step, public feedback was obtained and incorporated, and feedback from communications experts was obtained and incorporated, resulting in the current prototypes. At this stage, we are proposing the continuation of the gathering of evidence by conducting the proposed two-part study to examine the PMI prototypes.

Third, the comment expresses concerns that the use of a fictitious drug (and only one) may limit the generalizability of the findings of the study. The use of a fictitious drug eliminates the confound of prior knowledge when asking participants about the information they see. Rheutopia was selected to be a very close amalgam of an existing class of drugs. This class was chosen because it has a complicated set of risks, it is given by injection (an unusual administration), and it has multiple indications. FDA's reasoning is that if successful PMI can be developed for such a complex drug, PMI for drugs with simpler profiles will be attainable. It is true we are investigating only one drug in the current study; this decision was based on resource constraints. One research study cannot accomplish all goals. Future studies may be used to assess the applicability of the results in other drug classes.

Fourth, the comment expresses concern that the research will not include a variety of different populations and that the lack of detail provided in the **Federal Register** notice suggests that very little knowledge will be gained from the research. Regarding the first part, the revised research proposed in this document includes low literacy individuals with chronic disease, general population individuals, and individuals with one of the medical conditions that Rheutopia treats. FDA believes these are the populations most relevant to this particular type of drug, as well as other chronic diseases. In terms of the detail provided, the questionnaire, which provided extensive detail about the exact questions proposed, was available upon request during the first comment period and will continue to be available during the second comment period.

Fifth and finally, the comment suggested that comparing variations of a short, one-page document limits the findings because there will be no comparison to a longer document, which may perform better. FDA concurs. In the revised research currently proposed, we have included a control condition. A subset of individuals will be randomly assigned to see the Medication Guide format for Rheutopia. Thus, we will compare two proposed one-page prototypes with an existing document that would be currently required for Rheutopia if it were a real drug.

External Reviewers

In addition to public comment, FDA's Division of Drug Marketing, Advertising, and Communications discussed the prototypes and the research design and protocol with a panel of 19 experts convened by the Brookings Institution on July 21, 2010. The names of these individuals can be found in Appendix A. After the workshop, several experts provided detailed written feedback to FDA, which was incorporated into the design of the study.

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

[11] See, for example, Day, R.S, *PMI: From Concept to Compliance,* Development and Distribution of Patient Medication Information for Prescription Drugs: Part 15 Public Hearing, FDA White Oak Campus, Silver Spring, MD, (September 27, 2010).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
540	1	540	20/60	180
900	1	900	25/60	375
200	1	200	25/60	83
Total				638

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

The burden chart reflects up to 3 pretests of 180 individuals each, 900 participants in the main study, and 200 participants in the followup study involving electronic administration.

Dated: December 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31388 Filed 12–14–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Public Health Notification Readership Survey (Formerly Known as the Safety Alert/ Public Health Advisory Readership Survey)

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 14, 2011.

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:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0341. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 301–796–3793.

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.

Food and Drug Administration Public Health Notification Readership Survey (Formerly Known as the Safety Alert/ Public Health Advisory Readership Survey)—(OMB Control Number 0910–0341)—Reinstatement

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners in order for them to make informed clinical decisions about the use of a device or device type when that information may not be readily available to the affected target audience in the health care community. CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners in order for them to make informed clinical decisions about the use of a device or device type. However, two additional conditions exist that make use of this type of notification preferable: (1) CDRH's understanding of the problem, its cause(s), and the scope of the risk; the Center believes that health care practitioners need the information they can provide, however incomplete, as soon as possible, and (2) the problem is actively being investigated by the Center, private industry, another Agency, or some other reliable entity, so that the Center expects to be able to update the PPHN when definitive new information becomes available. Notifications are sent to organizations affected by risks discussed in the notification, such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to publish notifications.

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. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients.

Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly notifications for reducing risks are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risks as a result of the information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content and the format and method of dissemination.

In the **Federal Register** of August 24, 2009 (74 FR 42674), FDA published a 60-day notice requesting comments. No comments were received. However, FDA is republishing this 30-day notice for public comment, due to the amount of time that has passed for submission of this information collection request to OMB.

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