

Approximately 30,000 respondents of a Web-based consumer panel will be screened (3 waves (independent surveys)) for each of 5 incidents; 2,000 respondents per wave). We estimate that it will take a respondent 20 seconds (0.0055 hours) to complete the screening questions, for a total of 165 hours. We will conduct a pre-test of the first survey with 40 respondents; we estimate that it will take a respondent 10 minutes (0.167 hours) to complete the pre-test, for a total of 7 hours. Fifteen thousand (15,000) respondents will complete the surveys (3 waves (independent surveys)) for each of 5 incidents; 1,000 respondents per wave). We estimate that it will take a respondent 10 minutes (0.167 hours) to complete the survey, for a total of 2,505 hours. Thus, the total estimated burden is 2,677 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar to these.

II. References

1. Cuite, C., S. Condry, M. Nucci, et al., "Public Response to the Contaminated Spinach Recall of 2006," Publication no. RR-0107-013, New Brunswick, NJ: Rutgers, the State University of New Jersey, Food Policy Institute, 2007.
2. Hallman, W., C. Cuite, N. Hooker, "Consumer Responses to Food Recalls: 2009 National Survey Report," Publication no. RR-0109-018, New Brunswick, NJ: Rutgers, the State University of New Jersey, Food Policy Institute, 2009.
3. Acheson, D., "Outbreak of *Escherichia coli* 0157 Infections Associated With Fresh Spinach—United States, August–September 2006," 2007 (http://first.fda.gov/cafdas/documents/Acheson_Spinach_Outbreak_2006_FDA_pres.pptf).

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0184]

Agency Information Collection Activities; Proposed Collection; 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 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 for research entitled "Experimental Study of Patient Information Prototypes." This study is designed to determine based on different prototype testing whether consumers are able to comprehend serious warnings, directions for use, drug indications and uses, contraindications, and side effects in the material that is presented.

DATES: Submit written or electronic comments on the collection of information by July 6, 2010.

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 Management Programs (HFA-250), Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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.

Experimental Study of Patient Information Prototypes—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 Guides² 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

¹ Public Law 104-180, August 6, 1996, Title VI. Effective Medication Guides.

² 21 CFR part 208.

³ 21 CFR 310.501 and 310.515.

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. 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 at 66396), 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 formats⁶ 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. Additional information on the September 24 and 25, 2009, public workshop, is available at <http://www.fda.gov/Drugs/NewsEvents/ucm168106.htm>.

Given the information obtained from workshop participants, the working 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.

II. 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 3 x 2 design. The independent variables are Format (3 levels: Drug Facts, Minimal Column, and Column Plus) and Order (2 levels: Warning first and Indication first).

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.

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.

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 grade⁹ 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**).

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

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

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
	540	1	540	20/60	178
	900	1	900	25/60	369
	200	1	200	25/60	82
Total					629

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

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0190]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

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

⁹ Cotunga N., C.E. Vickery, K.M. Carpenter-Haeefe, "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.