DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0133]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs

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 (the PRA).

DATES: Fax written comments on the collection of information by April 13, 2007.

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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs—(OMB Control Number 0910–0591)

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. Under the act, a drug is misbranded if its labeling or advertising is false or misleading. In addition, section 502(n) of the act (21 U.S.C. 352(n)) specifies that advertisements for prescription drugs and biological products must provide a true statement of information ''in brief summary'' about the advertised product's ''side effects, contraindications, and effectiveness.'' The prescription drug advertising regulations (§ 202.1(e)(3)(iii) (21 CFR 202.1(e)(3)(iii))) specify that the information about risks must include ''each specific side effect and contraindication'' from the advertised drug's approved labeling. The regulation also specifies that the phrase ''side effect and contraindication'' refers to all of the categories of risk information required in the approved product labeling written for health professionals, including the warnings, precautions, and adverse reactions sections. Thus, every risk in an advertised drug's approved labeling must be included to meet these regulations.

In recent years, FDA has become concerned about the adequacy of the brief summary in Direct-to-Consumer (DTC) print advertisements. Although advertising of prescription drugs was once primarily addressed to health professionals, increasingly consumers have become a target audience, as DTC advertising has dramatically increased in the past few years.

Because the regulations do not specify how to include each risk, sponsors can use discretion in fulfilling the brief summary requirement under § 202.1(e)(3)(iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, or prescribing information). This labeling is written for health professionals, using medical terminology. FDA believes that while this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, this method is difficult for consumers to understand and therefore may not be the best approach to communicate this important information to them.

In 2004, FDA published a draft guidance entitled ''Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements'' (available at *http://www.fda.gov/cder/guidance/5669dft.htm*). This guidance outlined possible options for improving the communication of risk information to consumers in specific promotional pieces. When discussing the current professional prescribing information format, the guidance states that the ''volume of the material, coupled with the format in which it is presented... discourages its use and makes the information less comprehensible to consumers.'' The draft guidance suggested three possible presentations for the brief summary, including the current prescribing information format, an approved patient package insert, or highlights from the physician labeling rule.

In the content study, FDA plans to investigate the role of context in providing useful risk information to consumers. It has been theorized that long lists of minor risks may detract from the understanding of more serious risks, as stated in the draft guidance. Nonetheless, if the risk information is presented with proper supporting context, people may find the information facilitates rather than distracts from the understanding of the risk information. One of the two proposed studies in this notice will investigate the context that may contribute to this facilitation.

In addition to context, format also plays a role in the clarity and understanding of the brief summary. FDA proposes to collect information on the usefulness of different formats suggested in the draft guidance. In addition to the patient package insert, which is usually presented in a question and answer format, FDA proposes to test a consumer-friendly highlights format, as well as a format based on the drug facts labeling used for over-the-counter drugs.

Data from these two studies will converge to allow a better assessment of various ways to present risk information in a print advertisement for a prescription drug.

FDA estimates that 1,800 individuals will need to be screened to obtain a respondent sample of 900 for the content study and that 600 individuals will need to be screened to obtain a respondent sample of 300 for the format study. The screener is expected to take 30 seconds, for a total screener burden of 41 hours. The 1,200 respondents in the two studies will then be asked to respond to a series of questions about the advertisement. We estimate the response burden for each of the two studies to be 20 minutes, for a burden of 396 hours. The estimated total burden for this data collection effort is 437 hours.

In the **Federal Register** of April 25, 2006 (71 FR 23921), FDA published a 60-day notice requesting public comment on the information collection provisions. Seven comments were received, and none were PRA related.

Five comments were from individual citizens, one comment was from AstraZeneca, a member of industry, and

one comment was from a health care coalition, the Clear Language Group. Most of the comments addressed the proposed content study.

The five comments from individual citizens were identical. They stated, ''Deny the drug industry petition. Show all side effects.'' These comments show a lack of understanding of the relevant issues. This proposed information collection is not a pharmaceutical industry petition; it is a research project supported by funds received from the Office of Medical Policy within the Center for Drug Evaluation and Research, part of FDA. The goal of this research is to further the public health by improving the readability and functionality of the brief summary in print ads, an easily accessed forum for information. Research in cognitive psychology overwhelmingly suggests that people have limited capacity for information and cannot process endless lists.[1] Recent research has suggested that providing a small number of the more minor side effects may actually improve the understanding of the benefit-risk tradeoff of the drug as a whole.[2] FDA wants to ensure that the presentation of risk information is in the best interests of consumers. This research will provide empirical evidence to support the optimal presentation of side effects.

In the sixth comment, AstraZeneca supported the proposed research as a method to create more consumer-friendly brief summaries. They requested that the research be delayed, however, until the data from study 1 is collected. If this were not possible, they requested that the comment period remain open until commenters have the ability to look at the questionnaire materials. Study 1 is currently in the field and we expect to have data available by the midpoint of the year. These results will be analyzed in the next several months. Given the interest in the finalization of the brief summary guidance,[3] which in part relies on information from these studies, we cannot delay the development of studies 2 and 3 until data from study 1 are analyzed and interpreted. Questionnaire materials are available for public comment through FDA's Office of Information Review Management. Comments may be submitted to the docket at any time, even after the docket has closed.

The final comment was submitted by Sarah Furnas as a representative of the Clear Language Group, a consortium of plain language consultants, and involved two primary concerns. The first concern regarded our plan to recruit and divide respondents into education groups of completed college or some college or less. This division may limit our ability to make finer distinctions among educational groups. Moreover, Furnas suggests that people who struggle with obesity fall disproportionately into the lower education groups. If FDA chose a division point that represents a fairly high level of education, they may recruit more people from the highest education group, thus leaving out an appropriate proportion of lower education individuals. Furnas suggests using the educational breakdown used by the American Obesity Association: 4+ years of college, some college, high school graduate, and some high school. FDA agrees and will incorporate this suggestion into the questionnaire.

This commenter also expressed concern that the options in our research design require high numeracy and document literacy skills. Furnas suggested that FDA omit some of the design options and perhaps add other, easier options. First, although FDA shares the goal of making documents easier to read and would like to make the brief summary accessible to the greatest number of people possible, at some level, people who have difficulty reading will not seek out a written explanation of risks. In its guidance *Consumer Directed Broadcast Advertisements*,[4] the agency suggested a number of ways complete risk information could be obtained by consumers, including a toll-free telephone number, making this option a good choice for those who have difficulty reading health information.

Consumers who have difficulty reading may not seek out medical information in a print advertisement, especially in its current form. However, the very nature of the information in the brief summary is the communication of risk information which is at its heart probability-based. By limiting their options, FDA not only fails to empirically determine the best option for the greatest number of people, but they may fail to appropriately inform the people who are most likely to read the advertisement and the brief summary. Therefore, FDA is testing ways to better communicate this information.

Second, FDA does not agree that table formats are more difficult to read than lists of information in paragraph format. The over-the-counter labeling change of 1999 (21 CFR 201.66), requiring a presentation of Drug Facts in a table format, has received positive reviews for its improvement over older labels.[5] Moreover, the Nutrition Facts label required as part of the Nutrition Labeling and Education Act of 1990 has also received praise for its easier-to-understand format.[6] These two table-based formats have been in the public domain for several years now, making them familiar to consumers. Nonetheless, FDA has changed its design based on other factors and will not be examining a chart or table format.

FDA acknowledges that placebo may be a fairly complex concept for many people. One of the research goals is to determine whether the addition of context may improve the understandability or usefulness of the brief summary as a whole. The value of an experimental design is that FDA will be able to empirically test whether or not their manipulations have an effect. Therefore, FDA has chosen two other forms of context, the frequency of side effects, and the temporal nature of side-effects, in place of placebo rate. FDA will be able to determine which groups have more or less difficulty with each condition. It is likely that at least some people will value the addition of this information.

In the interest of communicating to as many people as possible, FDA has changed the format of the rate information. Instead of providing this

[1] Lavie, N. (2001). Capacity limits in selective attention: Behavioral evidence and implications for neural activity. In Braun, J., Koch, C., et al. (Eds.), *Visual attention and cortical circuits*. Cambridge, MA: The MIT Press (pp. 49–68); Shapiro, K. (Ed.) (2001). *The limits of attention: Temporal constraints in human information processing*. London: Oxford University Press.

[2] See, e.g., Stotka, J.L., Rotelli, M.D., Dowsett, S.A., Elsner, M.W., Holdsworth, S.M., et al. (2007). A new model for communicating risk information in direct-to-consumer print advertisements. *Drug Information Journal, 41*, 111–127.

[3] See, e.g., *http://www.fda.gov/ohrms/dockets/dockets/05n0354/05N-0354-EC444-Attach-1.pdf*; Washington Legal Foundation response to the Division of Drug Marketing, Advertising, and Communications regarding WellSpring Pharmaceutical Corp. at *http://www.wlf.org/Resources/DDMAC/default.asp*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[4] Available at *http://www.fda.gov/cder/guidance/1804fnl.htm*. (Last accessed March 8, 2007.)

[5] For example, the Association of Clinicians for the Underserved states, ''These new labels should assist consumers in the selection of Over the Counter (OTC) products by enabling them to assess drugs' risks and benefits more easily.'' (*http://www.clinicians.org/programsandservices/rxfiles/patient_education_safety.html*) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[6] Marietta, A.B., Welshimer, K.J., and Anderson, S.L. (1999). Knowledge, attitudes, and behaviors of college students regarding the 1990 Nutrition Label Education Act food labels. *Journal of the American Dietetic Association, 99*, 445–449.

information in percentages, FDA will provide this information as, ''x out of 100.'' FDA thanks this commenter for bringing these issues to their attention.

As a result of the comments, the agency received and some further thought on the design of the studies, FDA has altered the designs somewhat. The following are the revised designs.

Content Study

Design Overview: This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. We will manipulate the minor side effect section, varying the presence of frequency information and the presence of framing, and the efficacy section, varying the presence of frequency information. We are interested in how these changes influence the understanding of the risks of the product as a whole, particularly the more serious risk sections. If these changes enhance or, at the very least, do not detract from the major risks, then these additions of context may be something to include in future brief summaries. In the best case scenario, we find context that enhances the total picture of the drug and does not interfere with the processing of the major risks.

Primary Research Questions

a. Will the presence of information on the frequency of minor side effects influence the readers' comprehension of the major risks? Will the comprehension of major risks vary depending on whether the frequencies are high or low?

b. Will the presence of information on the temporal duration of minor side effects influence the comprehension of the major risks?

c. Will the presence of clinical efficacy information influence readers' comprehension of the major risks? Will the comprehension of the major risks vary depending on whether clinical efficacy is high or low?

d. Will clinical efficacy and frequency of minor side effects interact to influence comprehension of major risks? Will clinical efficacy and temporal duration interact to influence comprehension of major risks?

Procedure: Participants will be shown one advertisement. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the brief summary, including perceived riskiness of the drug, comprehension of information in the brief summary, and perceived usefulness of brief summary information. Finally, demographic and health care utilization information will be collected. Interviews are expected to last approximately 20 minutes. A total of 900 participants will be involved. This will be a one-time (rather than annual) collection of information.

Format Study

Design Overview: This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. Four print advertisements will be created using four different formats: Traditional long format, Question and Answer, Highlights (71 FR 3922, January 24, 2006), and Drug Facts (21 CFR 201.66). As much as possible, the information in the formats will be constant across conditions. Participants who self-identify as being in the target market for the condition will be asked to read a single print advertisement for a new prescription drug. After reading the advertisement, they will be asked questions about their comprehension and evaluation of the information presented in the advertisement. Lastly, participants will be shown all four versions and asked to rate them relative to one another on measures assessing visual appeal, preference, and information accessibility.

Primary Research Questions

a. Will alternative formats influence the comprehension of major risks, behavioral intentions, and/or self-efficacy?

b. Which format will consumers prefer?

Procedure: Participants will be shown one advertisement. Then a structured interview will be conducted with each participant to examine a number of important perceptions about the brief summary, including perceived riskiness of the drug, comprehension of information in the brief summary, and perceived usefulness of brief summary information. Finally, demographic and health care utilization information will be collected. Interviews are expected to last approximately 20 minutes. A total of 300 participants will be involved. This will be a one-time (rather than annual) collection of information.

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

FDA estimates that 1,800 individuals will need to be screened to obtain a respondent sample of 900 for the Content study, and 600 individuals will need to be screened to obtain a respondent sample of 300 for the Format study. The screener is expected to take 30 seconds in each study, for a total screener burden of 41 hours. The 1,200 respondents in the two studies will then be asked to respond to a series of questions about the advertisement. We estimate the response burden for each of the two studies to be 20 minutes, for a burden of 396 hours. The estimated total burden for this data collection effort is 437 hours. The respondent burden is listed in table 1 of this document.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,800 (content study: screener)	1	1,800	.017	31
900 (content study: questionnaire)	1	900	.33	297
600 (format study: screener)	1	600	.017	10
300 (format study: questionnaire)	1	300	.33	99
Total				437

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

Dated: March 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4556 Filed 3–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Home Centered Coordinated Cancer Care System.

Date: April 4, 2007.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Conference Room 706, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329. 301/496–7987. *lovingeg@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel, Quantiative Assay for O6—Carboxymethyl Guanine DNA Adducts.

Date: April 5, 2007.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Conference Room 611, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8057, Bethesda, MD 20892–8329, 301–496–7421. *kerwinm@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel, CA 07–032, ''Improved Measures of Diet and Physical Activity for the Genes and Environment Initiative (GEI) (UO1)''.

Date: April 18–19, 2007.

Time: 9 a.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Marriott Gaithersburg Washingtonian Center, 951 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Thomas M. Vollberg, PhD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 7142, Bethesda, MD 20892. 301–594–9582. *vollbert@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 7, 2007.

Anna Snouffer,

Acting Director, Officer of Federal Advisory Committee Policy.

[FR Doc. 07–1190 Filed 3–13–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Conference Grants (R13).

Date: April 6, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Valerie L. Prenger, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7214, Bethesda, MD 20892–7924. 301–435–0270. *prengerv@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Ancillary Studies in Clinical Trials.

Date: April 11, 2007.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Yingying Li-Smerin, MD, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924. 301–435–0277. *lismerin@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 6, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–1184 Filed 3–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.