National Coordinator for review and coordination in the Eligibility/Enrollment Systems APD approval assignment. The information requested on the Checklist will be used to determine and approve enhanced FFP to States and to determine how States are complying with the seven standards and conditions; *Form Number:* CMS–10385 (OMB#: 0938–1125); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 204. (For policy questions regarding this collection contact Richard Friedman at 410–786–4451. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *August 1, 2011.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: June 28, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–16599 Filed 6–30–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities; Notice of Committee Meeting via Conference Call

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of committee meeting via conference call.

DATES: Tuesday, July 19, 2011, from 1 p.m. to 2:30 p.m. EST. This meeting, to be held via audio conference call, is open to the public.

Details for accessing the full Committee Conference Call are cited below: Toll Free Dial-In Number: 800–779–1436. Pass Code: PCPID.

Individuals who will need accommodations for a disability in order to participate in the PCPID Meeting via audio conferencing (assistive listening devices, materials in alternative format such as large print or Braille) should notify Genevieve Swift, PCPID Executive Administrative Assistant, at *Edith.Swift@acf.hhs.gov,* or by telephone at 202–619–0634, no later than Tuesday, July 12, 2011. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline.

Agenda: Committee Members will discuss the potential topics, themes, and trends for the PCPID 2011 Annual Report to the President.

Additional Information: For further information, please contact Laverdia Taylor Roach, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202–619–0634. Fax: 202–205–9519.

E-mail: *LRoach@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: June 27, 2011.

Laverdia Taylor Roach,

PCPID.

[FR Doc. 2011–16604 Filed 6–30–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0417]

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

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 August 1, 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 Format Variations in the Brief Summary of Direct-to-Consumer Print Advertisements.'' 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.

Experimental Study of Format Variations in the Brief Summary of Direct-to-Consumer Print Advertisements—(OMB Control Number 0910–New)

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) specifies that ads 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 FDA-approved labeling, including the Warnings, Precautions, Adverse Reactions, and other relevant sections. Some of the current approaches to fulfilling the brief summary requirement, while adequate from a regulatory perspective, result in ads that may be difficult to read and understand when used in consumer-directed promotion.

In recent years, FDA has become concerned about the adequacy of the brief summary in direct-to-consumer (DTC) print advertisements for prescription drugs. Because the regulations do not specify how to address 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, prescribing information, and direction circular). This labeling is written for health professionals, using medical terminology. While adequate to fulfill the brief summary requirement for print advertisements, this method may not be the most ideal. Research has shown that while many consumers will make the effort to read the brief summary in prescription drug print advertisements if they are especially interested in the drug, as a general rule consumers typically read little or none of the brief summary information (Ref. 1). Health practitioners themselves have indicated they often have difficulty finding information they actively seek in package inserts (see 65 FR 81082, December 22, 2000, for a discussion of studies supporting the use of a highlights section in physician labeling). There may be other ways to fulfill this requirement that improve consumers' ability to find and comprehend the information in this important document.

There is evidence suggesting that both information content and the format in which it is presented will impact comprehension. For instance, research with the format of over-the-counter (OTC) drug labels (Refs. 2 and 3), the nutrition facts label (Ref. 4), and other information formats (Refs. 5 to 7) 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.

Research conducted by FDA and others has examined the content and format of the brief summary specifically. For instance, FDA conducted a series of relevant studies (OMB control numbers 0910–0591 and 0910–0611). Schwartz, Woloshin, and Welch have compared one format for adding quantitative and qualitative benefit and risk information to the brief summary (Ref. 8). Specifically, Schwartz *et al.* designed a prescription drug facts box similar in format to the nutrition facts panel and OTC drug facts panel. The box contains a number of elements, including qualitative and quantitative (both absolute frequency and absolute difference) information about benefits and risks. This study showed that consumers who were provided efficacy information in a prescription drug facts box were more likely to correctly choose the product with the higher efficacy than consumers who saw the brief summary using medical language from the prescribing information. However, it is unclear which elements of the drug facts box are necessary to improve consumer understanding. For instance, it is not known whether simply adding efficacy rate information to a consumer-friendly brief summary would be sufficient to enable consumers to understand a product's efficacy or whether qualitative summations are necessary as well.

The current study will add to previous research by systematically examining these different elements to determine whether and how to add qualitative and quantitative benefit and risk information to the brief summary. The results of this study will inform FDA of the usefulness and parameters of various format and content options for the brief summary.

Design Overview: This study will be conducted in two concurrent parts; one examining variations on the benefit information presented in DTC print advertisements and the other examining variations on the risk information presented in DTC print advertisements. The factors studied will be the type of information (*i.e.,* the addition of quantitative and qualitative information in a box format) and the level of efficacy or risk. We will vary the level of efficacy and risk such that the largest effect is noticeably different from the placebo, whereas the smallest effect is minimally different from the placebo. These factors will be combined in a factorial design as follows:

TABLE 1—PROPOSED DESIGN (4x5 + 2)

Information type	Efficacy level				
	Smallest effect	Smaller effect	Mid-size effect	Larger effect	Largest effect
Absolute Frequency	81% vs. 82%	61% vs. 82%	41% vs. 82%	21% vs. 82%	1% vs. 82%.
Absolute Frequency + Qualitative Label.	Fewer 81% vs. 82%	Fewer 61% vs. 82%	Fewer 41% vs. 82%	Fewer 21% vs. 82%	Fewer 1% vs. 82%.
Absolute Difference + Qualitative Label.	Fewer (1%)	Fewer (21%)	Fewer (41%)	Fewer (61%)	Fewer (81%).
Absolute Frequency + Absolute Difference + Qualitative Label.	Fewer (1%) 81% vs. 82%.	Fewer (21%) 61% vs. 82%.	Fewer (41%) 41% vs. 82%.	Fewer (61%) 21% vs. 82%.	Fewer (81%) 1% vs. 82%.

Note: Two other cells will be tested: (1) No information and (2) Qualitative label only (fewer). This design (22 cells) will also be used to test risk information (for a total of 44 cells). The specific numbers in the table are placeholders only. Qualitative label example: ''Fewer people taking drug X had disease/symptom Y.''

The test product will be for the treatment of a high prevalence medical condition and modeled on an actual drug used to treat that condition. Participants will be consumers who have been diagnosed with the medical condition of interest. They will be randomly assigned to read one ad version. After reading the ad, participants will answer a series of questions about the drug. We will test how the information type affects

perceived efficacy, perceived risk, behavioral intention, and accurate understanding of the benefit and risk information.

Interviews are expected to last no more than 20 minutes. A total of 11,750 participants will be involved in the study. This will be a one-time (rather than annual) collection of information.

In the **Federal Register** of August 31, 2010 (75 FR 53312), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four responses were received, each of which included several comments.

I. Study Design

(Comment 1) Several suggestions related to participant demographics, measuring health literacy, and determining what our primary research questions are. One question related to the test DTC advertisements to be used in the study.

(Response) We agree that the study design should include the variables of age, education, ethnicity, and race; these are included in the questionnaire. We will ask whether participants can read, understand, and speak English.

We will measure subjective health literacy and the related concept of numeracy, which is relevant for this research as we are studying the comprehension of quantitative information. To clarify, we will not limit our sample to those who are currently being treated with a prescription drug for the condition being assessed; however, the questionnaire includes questions about prescription drug use.

Regarding the primary research questions, as stated in the 60-day notice, the current study will add to previous research by systematically examining the different elements in the drug facts box tested in previous research (Ref. 8) to determine whether and how to add qualitative and quantitative benefit and risk information to the brief summary. Specifically, we will test whether the inclusion of a qualitative label and/or the inclusion of quantitative information affects consumers' understanding of the information and their perceptions of the product.

We have contracted with an organization that produces realistic ads and stimuli to ensure that we will show respondents realistic materials.

(Comment 2) This comment states that there was not enough detail in the 60-day **Federal Register** notice, such as no description of the criteria for determining the amount and type of risk and benefit information to provide in the box format. Another question noted that qualitative terms depend on many factors. This comment also recommends that we consider implementing a cross-over study design to address interpatient variability. This comment suggested considering caregivers and consumers who do not have the medical condition treated by the drug. The final question in this comment asked how the tools were qualified or validated for their intended use.

(Response) The questionnaire, which has information about how questions will be asked and how behavioral intention will be assessed, was available upon request during the first comment period and will continue to be available during the second comment period. Information about how risk information will be portrayed, what statistical analyses will be performed, subject recruitment, and pretest content is addressed in this document.

We agree that a major challenge of the drug facts box format is deciding the amount and content of risk information to include; however, this type of study cannot address this issue. To replicate and extend past research, we will use the drug facts box from a previous study (Ref. 8) with slight modifications to the risk information (*e.g.,* the addition of a serious risk, different rates of side effects in the placebo and active drug groups).

We agree that qualitative terms depend on many factors; however, this study does not address the feasibility of creating qualitative terms but rather tests whether qualitative terms affect consumer comprehension. As requested, we will note this in our conclusions.

Conducting a cross-over design would significantly increase study length, and repeated exposure to the same stimuli with minor changes may affect participants' responses. We have conducted power analyses and believe we can find interpretable results without conducting a cross-over design.

To ensure that our participants are motivated to consider the information presented in the study and to conserve resources, we will limit our sample to people who have the medical condition of interest.

Cognitive testing will be used to test questionnaire items prior to their use, and similar items have been used in our previous studies. The items have face validity, and several are drawn from well-tested items used in the psychology literature (for example, behavioral intentions; Ref. 9). Finally, we will pretest the study manipulations.

(Comment 3) This comment included three statements about the details of the proposed study. First, the comment questioned why we chose to test percents and frequencies and not relative differences in this study. Second, this comment pointed out that the differences in the stimuli should be stated as percentage points, not as percentages. Third, the comment asks whether the risk and benefit information will be presented in the same mathematical expression and whether they will be presented independently.

(Response) We focus on percents and frequencies because we are replicating and extending previous research on a drug facts box (Ref. 8), which included percents and frequencies but not relative differences. The study found that the drug facts box outperformed a traditional brief summary. The drug facts box tested had several elements that differed from the traditional brief summary, including percents, frequencies (*i.e.,* XX/100), and qualitative labels. From these results, it is not possible to tell which elements of the drug facts box were responsible for the effects found. This study aims to test systematically the elements of the drug facts box to determine which, if any, improves consumer comprehension.

We will change percentages to percentage points in our stimuli.

To clarify, when participants see benefit information in a certain information type (or mathematical expression, for example, percents), they will also see risk information in that same information type (for example, percents). However, the efficacy level (from smallest to largest effect) will be manipulated in one design, and the risk level (from smallest to largest effect) will be manipulated in a separate design.

(Comment 4) The comment suggested that we redesign the study such that participants would view the study materials and then answer questions about the materials only after consulting with a physician. This comment lists a number of practical issues surrounding how to create drug facts boxes and notes that this study will provide limited practical information on how to format the brief summary for drugs with multiple indication, multiple studies, or multiple outcomes. Another recommendation from the comment is to include conditions that test relative difference. The comment suggests eliminating the ''largest effect'' cells.

(Response) We cannot ask participants to incur the financial and personal (time) cost of visiting a doctor to discuss a treatment for the purposes of research. This is not feasible or ethical. We cannot ethically ask them to go to their doctor to discuss a fictitious drug (nor would the doctor be able to discuss a fictitious drug with them), and

we cannot ethically recommend a real product for them to discuss with their doctor. Aside from the feasibility and ethical issues, this is an unnecessary step to answer our research questions about participants' comprehension of a widely disseminated written form of information. Moreover, the assumption behind this recommendation, that physician consultations are the ''context in which prescription drug advertisements are actually used,'' is questionable. DTC advertising does not exist solely in the confines of a doctor's office; rather, DTC advertising targets consumers outside of a doctor's office, with the goal of prompting consumers to ask their physicians about the product. Therefore, clear communication of risks and benefits is needed for consumers before a consultation with a physician.

We agree that there are several practical issues surrounding the utility of the drug facts box; however, these issues are outside the scope of the proposed study. This study does not address how information would be chosen for inclusion in drug facts boxes but rather whether and how consumers can understand the information presented. As stated in the response to comment 7, our first step will be to study a simple version of the drug facts box, with one indication.

We agree that relative difference is an interesting way to present quantitative information and are currently studying this presentation in another study (Refs. 10 and 11). However, as noted in the response to comment 3, in this study we are systematically testing the elements of the drug facts box presented in past research (Ref. 8) to determine which, if any, improves consumer comprehension.

We agree that these ''largest effect'' cells may be unrealistic and plan to use pretests to determine the number of levels and the content of the levels (*e.g.,* the differences used) to be included in the main study.

II. Publication of the Study

(Comment 5) This comment requested that FDA provide clarity on the timing and strategy for the conduct of this study with respect to other planned studies.

The comment recommends that FDA publish findings from this study and previous studies on the Division of Drug Marketing, Advertising, and Communications (DDMAC) Web page (Ref. 12).

(Response) To clarify, this study will begin after two related studies (Refs. 10 and 11) have been conducted. The results from these studies may inform the execution of this study. The study will not be superseded by related research results, as none of the other research examines the drug facts box format for the brief summary.

We agree and have taken steps to publish reports from our previous research on the DDMAC Web page (Ref. 12). When the current project is concluded, we will post the findings on the DDMAC Web page as well.

(Comment 6) Much of this comment focused on previous research. First, this comment requests that we disclose the results of previous research. Second, this comment recommends that we wait to begin new studies until results of previous research have been publicly reported.

(Response) As stated in the response to comment 5, we agree and have taken steps to publish findings from our previous research on the DDMAC Web page (ref. 12). Unfortunately, the lengthy research process does not allow us to comply with the second request. To continue having an active research program, we must submit new proposals while previous projects are ongoing. As stated in response to comment 5, as research projects develop, we will take results of previous research in account.

III. Product Labeling

(Comment 7) A comment noted that product labeling is multifaceted and recommended that conclusions should be flexible to address these wide variations in product attributes. Another suggestion was to consider a label format that includes multiple endpoints.

(Response) We agree that product labeling is multifaceted and will tailor our conclusions to acknowledge that we tested one simple version of the drug facts box.

As a first step, we plan to study a simple version of the drug facts box, with one indication. If consumers cannot understand the information in a drug facts box with one indication, they are not likely to understand the information in the drug facts box with multiple indications. In addition, testing an ad with one endpoint is realistic as drug ads often promote only one indication even if a drug has multiple indications.

(Comment 8) Another comment suggested that, along with testing the qualitative label, ''fewer people taking Drug X had symptom Y,'' we should also test the qualitative label, ''more people taking Drug X received effective relief from symptom Y.''

(Response) Unfortunately, we do not have the resources to test multiple qualitative labels in this study; however, we will test the qualitative label suggested by the comment in place of our original language.

IV. Revised Study Design

This study will be conducted in two concurrent parts; one examining variations on the benefit information presented in DTC print advertisements and the other examining variations on the risk information presented in DTC print advertisements. The factors studied will be the type of information (*i.e.,* the addition of quantitative and qualitative information in a box format) and the level of efficacy or risk. We will vary the level of efficacy and risk such that the largest effect is noticeably different from the placebo, whereas the smallest effect is minimally different from the placebo. We plan to use pretests to determine the number of levels and the content of the levels (*e.g.,* the differences used) to be included in the main study. We will also pretest whether participants should have access to the ad while completing the questionnaire. The following design includes the maximum number of levels we would include. These factors will be combined in a factorial design as follows:

TABLE 2—BENEFIT DESIGN (4 × 5 + 2)

Information type	Efficacy level				
	Smallest effect	Smaller effect	Mid-size effect	Larger effect	Largest effect
(1) Absolute Frequency.	19% vs. 18%	39% vs. 18%	59% vs. 18%	79% vs. 18%	99% vs. 18%.
(2) Absolute Frequency + Qualitative Label.	More 19% vs. 18% ...	More 39% vs. 18% ...	More 59% vs. 18% ...	More 79% vs. 18% ...	More 99% vs. 18%.

TABLE 2—BENEFIT DESIGN (4 × 5 + 2)—Continued

Information type	Efficacy level				
	Smallest effect	Smaller effect	Mid-size effect	Larger effect	Largest effect
(3) Absolute Difference + Qualitative Label.	More (1 percentage point).	More (21 percentage points).	More (41 percentage points).	More (61 percentage points).	More (81 percentage points).
(4) Absolute Frequency + Absolute Difference + Qualitative Label.	More (1 percentage point) 19% vs. 18%.	More (21 percentage points) 39% vs. 18%.	More (41 percentage points) 59% vs. 18%.	More (61 percentage points) 79% vs. 18%.	More (81 percentage points) 99% vs. 18%.

Note: Qualitative label example: ''More people taking drug X had heartburn relief.'' There are two additional conditions: a no information condition and a qualitative label only (More) condition.

TABLE 3—RISK DESIGN (4 × 5 + 2)

Information type	Risk level				
	Smallest effect	Smaller effect	Mid-size effect	Larger effect	Largest effect
(1) Absolute Frequency.	3% vs. 2%	23% vs. 2%	43% vs. 2%	63% vs. 2%	83% vs. 2%.
(2) Absolute Frequency + Qualitative Label.	More 3% vs. 2%	More 23% vs. 2%	More 43% vs. 2%	More 63% vs. 2%	More 83% vs. 2%.
(3) Absolute Difference + Qualitative Label.	More (1 percentage point).	More (21 percentage points).	More (41 percentage points).	More (61 percentage points).	More (81 percentage points).
(4) Absolute Frequency + Absolute Difference + Qualitative Label.	More (1 percentage point) 3% vs. 2%.	More (21 percentage points) 23% vs. 2%.	More (41 percentage points) 43% vs. 2%.	More (61 percentage points) 63% vs. 2%.	More (81 percentage points) 83% vs. 2%.

Note: Qualitative label example: ''More people taking drug X had side effect Y.'' There are two additional conditions: a no information condition and a qualitative label only (More) condition.

In the benefit design, we will use the mid-size effect for the risk information in all conditions and vary the information type to match the benefit information type (*e.g.,* participants who see absolute frequency benefit information will also see absolute frequency risk information). Similarly, in the risk design, we will use the mid-size effect for the benefit information in all conditions and vary the information type to match the risk information type.

The test product will be for the treatment of gastroesophageal reflux disease and modeled on an actual drug used to treat this condition. Participants will be consumers who have heartburn or acid reflux disease. They will be randomly assigned to read one ad version. After reading the ad, participants will answer a series of questions about the drug. We will test how the information type affects perceived efficacy, perceived risk, behavioral intention, and accurate understanding of the benefit and risk information. The questionnaires for the risk and benefit designs will have identical questions; however, the order will differ. In the risk design, questions about risk will appear before questions about benefits; in the benefit design questions about benefits will appear before questions about risks.

Data will be collected using an Internet protocol. Consumers who have heartburn or acid reflux disease will be recruited for the study. Because the task presumes basic reading abilities, all selected participants must speak and read English fluently. Participants must be 18 years or older. We will use Levene's test of homogeneity of variances, analysis of variances, and regressions to test hypotheses.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)[2]	Total hours
Screener	30,000	1	30,000	2/60	1,000
Pretest	750	1	750	20/60	250
Main Study	11,000	1	11,000	20/60	3,667
Total	.....	.....	.....	.....	4,917

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60.''

V. References

FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Aikin, K.J., J.L. Swasy, and A.C. Braman, ''Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—

Summary of FDA Survey Research Results, Final Report, November 19, 2004,'' accessed online at *http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf.*

2. Aikin, K.J., ''Consumer Comprehension and Preference for Variations in the Proposed Over-the-Counter Drug Labeling Format, Final Report,'' 1998.
3. Vigilante, W.J. and M.S. Wogalter, ''The Preferred Order of Over-the-Counter (OTC) Pharmaceutical Label Components,'' *Drug Information Journal,* vol. 31, pp. 973–988, 1997.
4. Levy, A.S., S.B. Fein, and R.E. Schucker, ''More Effective Nutrition Label Formats Are Not Necessarily More Preferred, '' *Journal of the American Dietetic Association,* vol. 92, pp. 1230–1234, 1992.
5. Lorch, R. and E. Lorch, ''Effects of Organizational Signals on Text-Processing Strategies,'' *Journal of Educational Psychology,* vol. 87, pp. 537–544, 1995.
6. Lorch, R. and E. Lorch, ''Effects of Organizational Signals on Free Recall of Expository Text,'' *Journal of Educational Psychology,* vol. 88, pp. 38–48, 1996.
7. Lorch, R., E. Lorch, and W. Inman, ''Effects of Signaling Topic Structure on Text Recall,'' *Journal of Educational Psychology,* vol. 85, pp. 281–290, 1993.
8. Schwartz, L.M., S. Woloshin, and H.G. Welch, ''Using a Drug Facts Box to Communicate Drug Benefits and Harms: Two Randomized Trials,'' *Annals of Internal Medicine,* vol. 150, pp. 516–527, 2009, accessed online at *http://www.annals.org/cgi/content/full/0000605-200904210-00106v1.*
9. Webb, T.L. and P. Sheeran, ''Does Changing Behavioral Intentions Engender Behavior Change? A Meta-Analysis of the Experimental Evidence,'' *Psychological Bulletin,* vol. 132, pp. 249–268, 2006.
10. ''Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs,'' **Federal Register**, vol. 75, pp. 373–379, January 5, 2010.
11. ''Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer Print Advertisements for Prescription Drugs,'' **Federal Register**, vol. 75, pp. 34142–34146, June 16, 2010.
12. FDA, About the Center for Drug Evaluation and Research Page, DDMAC Research, (*http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090276.htm*).

Dated: June 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–16552 Filed 6–30–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2011–N–0457]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Comparative Direct-to-Consumer Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising. This study is designed to explore how consumers understand and interpret DTC ads that explicitly compare the efficacy, dosing, and risks, among other items, of two similar drugs whether comparisons are named or unnamed.

DATES: Submit either electronic or written comments on the collection of information by August 30, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising Regulatory Background—(OMB Control No. 0910–New)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 FD&C Act.

Regulations specify that sponsors cannot make comparative efficacy claims in advertising for prescription drugs without substantial evidence, most often in the form of well-controlled clinical trials, to support such claims (21 U.S.C. 202.1(e)(6)(ii); 21 U.S.C. 314.126). FDA has permitted some comparisons based on labeled attributes, such as indication, dosing, and mechanism of action. When substantial evidence does not yet exist, sponsors may use communication