Center for Environmental Health (NCEH). Information was collected from adult smokers of full-flavor, light and ultralight cigarettes, however, the target number of respondents was not achieved during the initial project period.

CDC requests OMB approval to reinstate the information collection in order to meet recruitment goals and complete the data analysis as planned. Changes include a reduction in the number of respondents and a corresponding reduction in the total estimated burden hours. In addition, minor changes will be made to account for changes in cigarette labels, which no longer use descriptors such as full-flavor, light or ultralight. There are no changes to the data collection instruments or the estimated burden per response.

Respondents will be asked to participate in a descriptive study of smoking behavior that involves two laboratory visits. Established smokers who are interested in participating will be screened for eligibility during a brief five-minute computer-assisted telephone interview (CATI). We estimate screening approximately 150 individuals annually to yield complete data collection on the annualized goal of 61 respondents. After completing the CATI, individuals who express continued interest in study participation will undergo five additional minutes of eligibility screening at the first laboratory visit.

Each respondent who enrolls in the study will make two one-hour visits to an assessment laboratory. The visits will occur on two consecutive days: Visit 1 will be scheduled in the morning of the first day, and Visit 2 will be scheduled in the afternoon of the second day. Samples, measurements, and behavioral information will be collected at each visit. Visit 1 will include biologic sample collection (urine, saliva, breath carbon monoxide), smoking behavior of smoking one cigarette, ventilation hole blocking procedure and breath measurements. Visit 2 will include discussion of quit opportunities if requested, biologic sample collection (urine, saliva, breath carbon monoxide), smoking behavior of smoking one cigarette, ventilation hole blocking procedure and breath measurements. In addition, at Visit 2, each respondent will submit the cigarette butts of all cigarettes smoked since Visit 1 and a completed Smoking Diary Form. The estimated burden for the Smoking Diary Form is ten minutes.

The goals of this project are to characterize the range of human smoking behavior for a variety of cigarette categories and machine-smoked yields, and to estimate the levels of biomarkers of exposure with the various cigarette styles.

OMB approval is requested for two years. Participation in the study is voluntary. There are no costs to respondents other than their time. The total estimated burden hours are 151.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Smokers	CATI Screener	150	1	5/60
	Visit 1 Screener	70	1	5/60
	Smoking Diary	61	1	10/60
	Laboratory Visit	61	2	1

Dated: August 23, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–21723 Filed 8–30–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0417]

Agency Information Collection Activities; Proposed Collection; 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 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 Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements (ads). This study is designed to test different ways of presenting benefit and risk information in the brief summary in DTC print ads.

DATES: Submit either electronic or written comments on the collection of information by November 1, 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 Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, 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 Format Variations in the Brief Summary of Direct-to-Consumer Print Advertisements—New

Section 502(n) of the Federal Food, Drug, and Cosmetic Act 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 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.[1] Health practitioners themselves have indicated they often have difficulty finding information they actively seek in package inserts (see 65 FR 80733 at 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
(OTC) drug labels,[2] the nutrition facts label,[3] and other information formats[4] 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.[5] 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:

[1] Aikin, K.J., Swasy, J.L. and Braman, A.C. (2004). Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results, Final Report. Available at *http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf*. Last accessed March 26, 2009.

[2] Aikin, K.J. (1998). Consumer Comprehension and Preference for Variations in the Proposed Over-The-Counter Drug Labeling Format, Final Report; Vigilante, W.J. & Wogalter, M.S. (1997). The preferred order of overt-the-counter (OTC) pharmaceutical label components. *Drug Information Journal*, *31*, 973–988.

[3] Levy, A.S., Fein, S.B. & Schucker, R.E. (1992). More effective nutrition label formats are not necessarily more preferred. *Journal of the American Dietetic Association*, *92*(10), 1230–1234.

[4] Lorch, R. & Lorch, E. (1995). Effects of organizational signals on text-processing strategies. *Journal of Educational Psychology*, *87*(4), 537–544; Lorch, R. & Lorch, E. (1996). Effects of organizational signals on free recall of expository text. *Journal of Educational Psychology*, *88*(1), 38–48; Lorch, R., Lorch, E. & Inman, W. (1993). Effects of signaling topic structure on text recall. *Journal of Educational Psychology*, *85*(2), 281–290.

[5] Schwartz, L.M., Woloshin, S., & Welch, H.G. (2009). Communicating drug benefits and harms with a drug facts box: Two randomized trials. Annals of Internal Medicine, 150(8). Available online at *http://www.annals.org/cgi/content/full/0000605-200904210-00106v1*. Last accessed March 26, 2009.

TABLE 1.—PROPOSED DESIGN (4 X 5 + 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 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.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	750	1	750	20 minutes	250
Main Study	11,000	1	11,000	20 minutes	3,667
Total					3,917

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

Dated: August 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21629 Filed 8–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0084]

Determination of Regulatory Review Period for Purposes of Patent Extension; PRISTIQ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRISTIQ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the