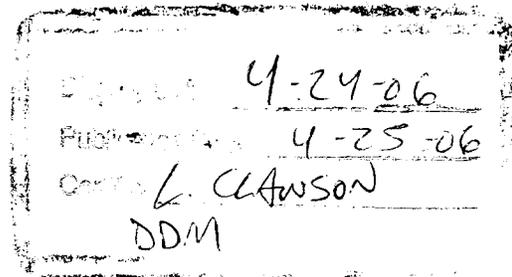


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0133]



**Agency Information Collection Activities; Proposed Collection; 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a 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 information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on two studies of consumer evaluations of variations in content and format of the brief summary in direct-to-consumer (DTC) prescription drug print advertisements.

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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:** Karen Nelson, Office Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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, including each proposed extension of an existing 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 each of 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 Evaluation of Variations in Content and Format of the Brief Summary in DTC Print Advertisements for Prescription Drugs**

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 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. Results of FDA's 2002 survey on DTC advertising (available at <http://www.fda.gov/cder/ddmac/researchka.htm>) show that 41 percent of respondents in 2002 reported they do not usually read any of the brief summary that accompanies the main print ad. Use of the brief summary was a function of whether they have an interest in the condition; about 45 percent of those having a particular interest in the advertised drug read all or almost all of the brief summary. Despite their interest, about half of these individuals described the brief summary as somewhat or very hard to understand.

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.

## II. Studies

### A. Content Study

#### 1. Design Overview

This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. Ten print advertisements will be created using two levels of drug side effect information and five levels of context. Thus, the factors will be the amount of side effect information (short; long) and amount of supportive context for the side effect information (paragraph only; paragraph rate; paragraph rate plus placebo rate; chart rate; chart rate plus placebo rate). Other information will be constant across conditions. Respondents 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.

#### 2. Factors

a. *Participants.* Consumers will be screened and recruited by the contractor to be self-identified as being moderately overweight or more. We chose to limit our investigation to this one disease condition (weight loss) because it has a high prevalence rate in the population (<http://www.cdc.gov/nccdphp/dnpa/obesity/faq.htm>) and is likely to occur both in males and females. We chose to accept this decrease in generalizability to maximize our ability to detect subtle differences in content variation. Participants will be screened to represent a range of education levels (some college or less; completed college or more). Because the task presumes basic reading abilities, all screened

participants will speak English as their primary language and, as appropriate, have reading glasses available when participating in the study.

b. *Amount of side effect information.* The number of side effects will be varied to create “short” and “long” levels as follows:

Short: “Side effects include a, b, and c. This is not a complete list. Talk to your doctor for more information.”

Long: “Side effects include a, b, c, d, e, f, g, and h. Talk to your doctor for more information.”

c. *Context.* The context for the side effect information will be varied to create five levels ranging from least supportive to most supportive as follows:

Paragraph only: Listing of side effects in paragraph form.

Paragraph rate: Listing of side effects and their rate of occurrence in paragraph form.

Paragraph rate plus placebo rate: Listing of side effects, their rate of occurrence, and the rate of placebo effects in paragraph form.

Chart rate: Listing of side effects and their rate of occurrence in table form.

Chart rate plus placebo rate: Listing of side effects, their rate of occurrence, and the rate of placebo effects in table form.

### 3. Procedure

Participants will be shown one ad. 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.

## *B. Format Study*

### 1. Design Overview

This study will employ a between-subjects crossed factorial design using a mall-intercept protocol. Three print advertisements will be created using three different formats: Question and answer, highlights (71 FR 3922, January 24, 2006), and drug facts (21 CFR 201.66 and Appendix A). 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.

### 2. Factors

a. *Participants.* Consumers will be screened and recruited by the contractor to be self-identified as being moderately overweight or more. As in the content study described previously in this document, we chose to limit our investigation to one disease condition—weight loss. Participants will be screened to represent a range of education levels (some college or less; completed college or more). Because the task presumes basic reading abilities, all screened participants will speak English as their primary language and, as appropriate, have reading glasses available when participating in the study.

b. *Type of format.* The format of the information in the brief summary will be varied as follows: Question and answer, highlights, and drug facts. Please refer to Appendix A for examples of the different format variations.

### 3. Procedure

Participants will be shown one ad. 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 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. The respondent burden is listed in table 1 of this document.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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

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

Dated: APR 18 2006  
April 18, 2006.

Jeffrey Shuren

Jeffrey Shuren,  
Assistant Commissioner for Policy

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