advertisements. To justify future regulatory changes, we need to have better empirical data about consumers' perceptions of the information in both types of ads and how inclusion of such promotional devices can impact consumers' perceptions of the risks and benefits of advertised prescription drugs.

Design Overview: This study will employ a between-subjects crossed factorial design and will focus on consumer print advertising. Fifteen print advertisements will be created using three levels of ad type and five levels of promotional offer. Thus, the factors will be ad type (DTC print reminder; DTC print full product; over-the-counter print full product) and offer type (free trial offer; buy one, get one free; money off prescription/purchase cost; money back guarantee; no promotion). Product name and indication will be constant across conditions. Side effect and risk information will be constant across full product DTC ad conditions. Participants will be asked to read a single print advertisement for a new drug. After reading the advertisement, they will be asked questions about their evaluation of the information presented in the advertisement.

Factors: (*1*) *Participants*. Consumers will be screened and recruited by the contractor to be currently diagnosed with insomnia or at risk of developing insomnia. Participants will be randomly assigned to experimental cells. Each condition will be balanced with respect to gender.

Because this is the first investigation of this issue with DTC ads, we chose to limit our investigation to one disease condition. We chose to accept this decrease in generality to maximize our ability to detect a subtle difference between promotion types. Participants will be screened to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all participants will have English as their primary language and, as appropriate, be required to have reading glasses when participating in the study.

(*2*) *Type of Ad*. Three types of ads will be tested: A full-product ad for a prescription drug, a reminder ad for a prescription drug, and an ad for an over-the-counter (OTC) drug. An ad for an OTC drug, which typically includes benefit but not risk information, is included to see if prior research findings in the area of consumer package goods can be replicated. It is expected that consumer processing of information in the ad may vary by presence of a promotion. For instance, consumers may assign more weight to benefit claims in cases where a promotional coupon is included.

(*3*) *Type of Promotion*. Five types of promotion will be tested: Free trial offer, buy one, get one free, money-off prescription/purchase cost, money back guarantee, and a no promotion condition. With the exception of buy one, get one free, these are promotional variations that have been used in drug advertising. We ask for comment on other promotional types that could be tested.

Procedure: Participants will be shown one ad, for example, a reminder ad for a prescription drug with a free-trial offer coupon attached. Then the participant will be asked to answer questions examining a number of important perceptions about the product, including perceived riskiness of the drug, likelihood of benefits, and behavioral intent (talking to doctor, product purchase). Finally, demographic and health care utilization information will be collected. Interviews are expected to last approximately 15 minutes. A total of 1,350 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 2,025 individuals will need to be screened to obtain a respondent sample of 1,350. The screener is expected to take 30 seconds, for a total screener burden of 17 hours. The 1,350 respondents will then be asked to respond to a series of questions about the advertisement. We estimate the response burden for the consumer part of the survey to be 15 minutes, for a burden of 337.5 hours. The estimated total burden for this data collection effort is 354.5 hours. The respondent burden chart is listed below:

ESTIMATED ANNUAL REPORTING BURDEN

No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
2,025 (screener)	1	2,025	.008	17
1,350 (questionnaire)	1	1,350	.25	337.5
Total		3,375		354.5

Footnote: there are no capital costs or operating and maintenance costs associated with this data collection.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1521 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0036]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on

an experimental study of possible footnotes and cueing schemes intended to help consumers understand and apply quantitative *trans* fat information they might see on the Nutrition Facts Panel of a food product. The experimental study will estimate the communication effectiveness of quantitative *trans* fat information in terms of its ability to help consumers make heart-healthy product decisions in realistic label usage situations for a range of products.

DATES: Submit written or electronic comments on the collection of information by April 7, 2006.

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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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, including each proposed reinstatement 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 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 Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel (OMB Control Number 0910–0532)—Reinstatement

FDA is requesting OMB approval of an experimental study of possible footnotes and cueing schemes intended to help consumers interpret quantitative *trans* fat information on the Nutrition Facts Panel of a food product. The purpose of the experimental study is to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure.

In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA issued a final rule requiring disclosure on the Nutrition Facts Panel of quantitative *trans* fat information on a separate line without any accompanying footnote. At the same time, the agency issued an advance notice of proposed rulemaking entitled, ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,'' (68 FR 41507) which requested comments about possible footnotes to help consumers better understand *trans* fat declarations on the product label. The agency sought comments about whether it should consider requiring statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote on the Nutrition Facts Panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use information on the label to make healthy food choices. Comments received in response to the notice contained suggested footnotes and cueing schemes. The proposed experimental study will evaluate the ability of several possible footnotes and cueing schemes to help consumers make heart-healthy food choices. The results of the experimental study will provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

FDA or its contractor will use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible footnote and cueing schemes. The distinctive features of Internet panels for the purpose of the experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible footnotes and cueing schemes while controlling for individual differences between subjects. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. The study will be conducted from a sample drawn from a large, nationally representative consumer panel with 800,000 households. The sample size and population pool are adequate to ensure that results can be generalized.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 42 experimental conditions derived from fully crossing 7 possible footnotes/cueing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the experimental study to evaluate regulatory and policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this experimental study will be used to estimate consumer comprehension and the behavioral impact of various footnotes and cueing schemes intended to help consumers better understand quantitative *trans* fat information.

The experimental study data will be collected using participants of an Internet panel of approximately 600,000 people. Participation in the experimental study is voluntary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of survey	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Internet survey	3,240	1	3,240	.25	810
Total					810

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed in this document.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1522 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0032]

Referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the conduct of pediatric studies to the Foundation for the National Institutes of Health (the Foundation). FDA referred the ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests to the Foundation on August 29, 2005, and is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BPCA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 1613, Silver Spring, MD 20993–0002, 301–796–2200, e-mail: *carmouzeg@cder.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied under the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that on August 29, 2005, it referred to the Foundation the written requests for pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). On July 14, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for RELPAX (eletriptan) that have market exclusivity. The studies described in the written request were for the acute treatment of migraines in adolescents. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RELPAX (eletriptan) in the pediatric population.

On June 17, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for ZINECARD (dexrazoxane) that have market exclusivity. The studies described in the written request were for cardioprotection in children receiving doxorubicin therapy. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of ZINECARD (dexrazoxane) in the pediatric population.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1520 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the