requirements for nutrient content claims.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of survey	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Internet Survey	2880	1	2880	.25	720
Total					720

[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 here.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1517 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0317]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of November 15, 2005 (FR 70 69344), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0428. The approval expires on January 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1518 Filed 2–3–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N–1269] (formerly Docket No. 00N–1269)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 22, 2000 (65 FR 81082), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0572. The approval expires on January 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1519 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–0029]

Agency Information Collection Activities; Proposed Collection; Comment Request; Impact of Coupons on Consumer Perceptions of Products in Prescription Drugs in Direct-to-Consumer Prescription Drug 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 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of the impact of coupons (such as price incentives or rebate offers) on consumers' perceptions of product risks and benefits in direct-to-consumer (DTC) print ads.

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

ADDRESSES: Submit electric comments on the collection of information to: *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. 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: 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 collections of information set forth in this document.

With respect to each of the following collections of information, FDA invites comments on: (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.

Impact of Coupons on Consumer Perceptions of Products in Direct-to-Consumer Prescription Drug Print Advertisements

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)). FDA is responsible for enforcing the act and implementing regulations.

FDA regulations require that prescription drug advertisements that make claims about a product must also include risk information in a ''balanced'' manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. Advertisements that draw attention to the name of the product but do not make representations about the product's indication(s) or dosage recommendations are called reminder advertisements. Reminder ads may mention the proprietary and established name of the product and (optionally) contain information about the product's ingredients, dosage form, quantity, price, or manufacturer (21 CFR 202.1(e)(2)(i)). Graphic presentation and information is not prohibited in reminder ads as long as that information does not make a representation or suggestion about the product beyond those permitted.

The exemption for reminder ads was originally intended to allow distribution of price sheets, pens, notepads and other minor giveaways featuring the name of the drug product to physicians and other healthcare professionals without requiring a full disclosure of the product's risks. As DTC promotion has increased, sponsors have chosen to create reminder ads for consumers.

Sponsors may use ads as a vehicle to offer price incentives or coupons to consumers (e.g., ''free trial,'' ''buy six get one free''). Coupon promotions are widely used in many product categories and have been the topic of many academic studies. Coupons are primarily offered to increase the sales of the brand relative to their level without coupons.[1] Certain types of coupons, most notably those that appear in the body of an advertisement itself, can positively impact perceptions of the brand.

People tend to rate owned objects more favorably than those they do not own, even when those objects have been assigned to them at random.[2] This has been termed the ''mere ownership'' or ''mere possession'' effect. An interesting extension of this effect is provided in research by Sen and Johnson[3] which has shown that consumers rate a product more favorably when they are simply given a gift certificate or a coupon for that product or service. Other research has examined the effect of warranties. People who viewed an ad with a high warranty perceived the product as being less risky compared to people who saw an ad with a medium or low warranty.[4]

Based on this body of consumer research, the inclusion of coupons or other price incentives in DTC ads may impact consumers' perceptions of the risks and benefits of the prescription drug. For ''simple'' consumer products, coupons and free trial offers may enable the customer to test new products while minimizing their financial risk of testing the product. For products that consumers can readily test and ones where performance can be adequately verified (termed ''search'' goods by economists), coupons and free trial offers provide both the consumer and manufacturer an efficient mechanism for matching consumers and products. For more complex products such as prescription drugs where supervision of a physician is required to evaluate both appropriateness and performance, coupons and free trial offers may send different signals. These signals may foster consumer misperceptions about the advertised prescription drug product by exploiting general beliefs. Thus, prescription drugs promoted with coupons or free trial offers may be seen as more widely indicated, more appropriate and/or less risky than they really are. Inclusion of a mechanism that affects consumers' perception of the product's risks is especially problematic in reminder ads because this type of ad contains no accompanying risk information. Furthermore, coupons and price promotions may imply superior drug efficacy.

The proposed study will examine the impact coupons have on consumers' perceptions of risks and benefits and the overall impression of the product in DTC full-product and reminder

[1] LeClerc, France and John D.C. Little ''Can advertising copy make FSI coupons more effective?'' *Journal of Marketing Research*, 34(4), 473-484, 1997.

[2] Beggan, James K., ''On the social nature of nonsocial perception: The mere ownership effect,'' *Journal of Personality and Social Psychology*, 62(2), 229-237, 1992.

[3] Sen, Sankar and Eric J. Johnson, ''Mere-possession effects without possession in consumer choice,'' *Journal of Consumer Research*, 24 (June), 105-117, 1997.

[4] Shimp, Terrence A. and William O. Bearden, ''Warranty and other extrinsic cue effects on consumers' risk perceptions,'' *Journal of Consumer Research*, 9 (June), 38-47, 1982.

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]

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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