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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 *[insert date 30 days after date of publication in the Federal Register]*.

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: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review

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and clearance. In the **Federal Register** of December 18, 2006 (71 FR 75762), FDA published a notice entitled “Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel.” This notice contained an incorrect deadline for comments on the proposed collection of information in the **DATES** section. FDA is republishing the notice and providing a full 30-day comment period. Any comments previously submitted regarding this notice will be considered and do not need to be re-submitted.

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 (NFP) 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 NFP 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 NFP 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 using a convenience sample drawn from a large, national consumer panel of about one million households.

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 1 of the 54 experimental conditions derived from fully crossing 8 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 one million people. Participation in the experimental study is voluntary.

In the **Federal Register** of February 6, 2006 (71 FR 6079), FDA published a 60-day notice requesting public comment on the information collection that will take place as part of the experimental study. FDA received two letters in response to the notice, each containing multiple comments.

(Comment 1) One comment stated that the organization concurs with the objectives of the study and believes the information from this study will be useful to FDA in developing labeling policy to assist consumers with interpretation of trans fat claims in food labeling. Another comment expressed concern that the NFP of only one of the three product pairs (margarine) showed polyunsaturated fat and monounsaturated fat content and recommended that the NFPs for all three products tested in the study show the fuller fat profile.

(Response) FDA disagrees with the recommendation that the NFPs for all three products tested in the study disclose a fuller fat profile. Most NFPs do not include the optional polyunsaturated fat and monounsaturated fat content. Typically, this information is disclosed on NFPs for products that are entirely or largely composed of fat (e.g., butter, margarine, and cooking oils). In these cases, the fat profile may be shown in greater detail because consumers may use this information to select among alternative food products. The NFPs for the product pairs tested in the study are consistent with actual donut, margarine, and frozen lasagna labels. Because the recommended change would limit products tested in the study to those such as butter, margarine, and cooking oils, FDA will retain the NFPs as proposed.

(Comment 2) One comment suggested that the NFPs should not reflect rounding, to minimize potential consumer confusion. The comment specifically recommended that FDA edit the study NFPs containing declarations of polyunsaturated and monounsaturated fats (i.e., for the margarine product pair) to declare total fat grams in an amount equal to the sum of the four listed fatty acids.

(Response) FDA agrees that for the margarine labels, which include the four fatty acids under total fat, the fatty acids gram (g) amounts declared should add up to the total fat gram amount to avoid raising questions or distracting the participants in the margarine conditions. We made the requested change.

(Comment 3) One comment suggested that, for the margarine labels, FDA should edit the polyunsaturated and monounsaturated values to be as equal as possible in the product pairings to ensure that the focus is on the saturated fat and trans fat content.

(Response) FDA disagrees with the suggested change to the NFPs for the margarine product pairs. In order to keep the values for the polyunsaturated and monounsaturated fats identical in the margarine pairs, the saturated fat content would become unrealistically high in one label because it is the only fat component that could increase when trans fat equals zero. FDA will retain the NFPs as proposed.

(Comment 4) One comment noted that only one of the NFPs for the three products tested in the study showed some cholesterol present in the product; the other two products disclosed cholesterol as zero. In particular, the comment identified lasagna as unlikely to contain 0 milligrams of cholesterol.

(Response) FDA agrees that zero cholesterol is not likely to be a realistic amount of cholesterol disclosed on a NFP for a lasagna product and has revised the NFPs for the lasagna pairs. In addition, FDA changed a product category from cookies to donuts edited and the NFPs for the new donut product pair to add a disclosure of cholesterol.

(Comment 5) One comment critiqued the draft Full Information treatment language. The comment criticized the one-page summary because: (1) It did not identify calories in the discussion of fat as a major source of energy and (2) it did not relate the calorie contribution of fat to that of carbohydrates and protein. The comment also criticized the information about sources of trans fat because it omitted mention of natural sources of trans fat in the diet, which the comment suggested would help ensure factually correct and balanced information about sources of trans in the diet. The comment questioned the value of stating that trans fat extends shelflife and has desirable taste characteristics since many saturated fat sources are relatively shelf stable and have desirable taste characteristics.

(Response) FDA agrees and has revised the Full Information treatment in response to these concerns. Calories and other sources of energy are now mentioned in the introductory passage. Natural sources of trans fat are now mentioned and the similarity between trans fat and saturated fat in terms of shelflife and taste are now addressed. The revised draft will be included in the study pretest and further revisions will be made if FDA determines they are needed based upon pretest results.

(Comment 6) One comment suggested consumer confusion may be caused when a NFP for a product discloses 0g of trans fat but the ingredient list discloses an ingredient that contains trans fat, as is permitted by the trans fat labeling regulations. The comment concluded that FDA should add experimental conditions in which this occurs. The comment suggested that for this situation the study should test language for a footnote to the ingredient list to explain that there may be a trans fat ingredient in the product when the NFP shows trans fat as zero.

(Response) FDA disagrees with the proposed addition to the study's experimental conditions. Under existing trans fat labeling regulations, food manufacturers are allowed to list amounts of trans fat less than 0.5 g per serving as zero on the NFP. While such situations occur in the marketplace and are permitted by the trans fat labeling regulations, whether this causes consumer confusion is an issue outside the scope of the proposed research, which focuses on the effects of NFP footnotes and alternative presentations of trans fat information in the NFP on consumers' ability to correctly identify more healthful food products. The Office of Nutritional Products, Labeling, and Dietary Supplements has received and responded to a separate letter on this topic from the commenter.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	40	1	40	.25	10
Study	3,240	1	3,240	.25	810
Total					820

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

Dated: 2/28/07
February 28, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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COPY OF THE ORIGINAL**

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