



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0345]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars

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: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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

Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars--(OMB Control Number 0910-New)

I. Background

Under the Nutrition Labeling and Education Act of 1990 (Public Law 101-535), the Nutrition Facts label is required on most packaged foods, and this information must be provided in a specific format in accordance with the provisions of § 101.9 (21 CFR 101.9). When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 to 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in the Federal Register of November 2, 2007 (72 FR 62149) FDA issued an

advance notice of proposed rulemaking (ANPRM) entitled "Food Labeling: Revision of Reference Values and Mandatory Nutrients" (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels. In the 2007 ANPRM, the Agency included a request for comments on how consumers use the Percent Daily Value in the Nutrition Facts label when evaluating the nutritional content of food items and making purchases.

Research has suggested that consumers use the Nutrition Facts label in various ways, including, but not limited to, using the Nutrition Facts label to determine if products are high or low in a specific nutrient and to compare products (Ref. 6). One component of the Nutrition Facts label that serves as an aid in these uses is the Percent Daily Value. Early consumer research indicated that the Percent Daily Value format improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (Ref. 3), which led FDA to require both quantitative and percentage declarations of nutrient Daily Values in the Nutrition Facts label in the 1993 Nutrition Labeling final rule (58 FR 2079, January 6, 1993).

Research in subsequent years, however, suggested that consumers' understanding and use of Percent Daily Value may be somewhat inconsistent (Refs. 7 and 8). Additionally, FDA has received several public comments suggesting that further research on Percent Daily Values may be warranted, along with research on other modifications to the Nutrition Facts label. Suggested research on potential modifications includes research on: (1) The removal of the statements, "Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs"; (2) the removal of the table in the footnote that lists the Daily Values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets as described in § 101.9(d)(9); and (3) changes to the

presentation of and amount of information provided in the Nutrition Facts label. Therefore, FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to various food label formats for the footnote area of the Nutrition Facts label, including those that exhibit information such as various definitions for Percent Daily Value, a succinct statement about daily caloric intake, and general guidelines for high and low nutrient levels.

This study will also explore how declaring the added sugars content of foods might affect consumers' attention to and understanding of the sugars and calorie contents and other information on the Nutrition Facts label. FDA is contemplating requiring the amount of added sugars to be declared under sugars with a double indentation format because added sugars are a component of sugars. This new requirement would be the first time that the mandatory declaration of a nutrient is shown in this format on the Nutrition Facts label. Because added sugars have been linked to obesity, a significant public health problem in the country (Ref. 9), it is important that this new requirement is supported by evidence so that consumers can correctly use the information. The Agency is not aware of any existing consumer research that has examined this topic and is therefore interested in using this study to enhance understanding of how consumers would comprehend and use this new information.

In the Federal Register of May 23, 2011 (76 FR 29758), FDA published a 60-day notice requesting public comment on the proposed collection of information. In that notice, the Agency announced its intention to examine consumer reactions to the declaration of vitamins and minerals on the Nutrition Facts label. The intention was prompted by the 2003 Institute of Medicine report that recommended declaration of weight amounts of all nutrients, including vitamins and minerals, on the label (Ref. 10). As the report noted, public health advice on

nutrient intake is often given in absolute amounts, but in the case of a nutrient such as calcium, consumers may not be able to determine the amount of calcium in a food when it is listed only as Percent Daily Values on the Nutrition Facts label. Block and Peracchio (Ref. 11) demonstrated this difficulty and the potential merits of providing consumers with easy-to-use information in helping them increase their calcium intakes. The Agency considers the recommendation of the Institute of Medicine as well as the findings by Block and Peracchio adequate support for requiring the weight amounts of vitamins and minerals be declared on the Nutrition Facts label. On the other hand, consumer evidence on the effects of declaring added sugars is lacking. Therefore, the Agency has determined that the utility of the study would be enhanced by replacing the examination of declaring amounts of vitamins and minerals with the examination of declaring amount of added sugars. This change would have minimal effects on the planned length and respondent burden of the study and would not change the study's primary focus, which remains on examining footnote options.

The proposed collection of information is a controlled, randomized, experimental study. The study will use a Web-based survey, which will take about 15 minutes to complete, to collect information from 10,000 English-speaking adult members of an online consumer panel maintained by a contractor. The study will aim to recruit a sample that reflects the U.S. Census on gender, education, age, and ethnicity/race.

The study will randomly assign each of its participants to view a series of label images from a set of food labels that will be created for the study and systematically varied in the presence or absence of: (1) A definition for Percent Daily Value, (2) a general guideline for "high" and "low" nutrient levels, and (3) a declaration for added sugars. A sample definition for Percent Daily Value may include, for example, "The Percent Daily Value is the amount of a

nutrient listed above that one serving of this product contributes to the daily diet." A sample guideline for high and low nutrient levels may include, for example, "Five percent or less is low, and 20 percent or more is high." Finally, the study will also examine effects of including reference to FDA within the Nutrition Facts footnote and a succinct statement about daily caloric intake. All label images will be mockups resembling food labels that may be found in the marketplace. Images will show product identity (e.g., yogurt or frozen meal) but not any real or fictitious brand name.

The survey will ask its participants to view label images and answer questions about their understanding, perceptions, and reactions related to the viewed label. The study will focus on the following types of consumer reactions: (1) Judgments about a food product in terms of its nutritional attributes and overall healthfulness, (2) ability to use the Nutrition Facts label in tasks such as identifying a product's nutrient contents and evaluating the Percent Daily Values for specific nutrients, and (3) label perceptions (e.g., helpfulness and credibility). To help understand consumer reactions, the study will also collect information on participants' background, including but not limited to, use of the Nutrition Facts label and health status.

The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to enhance the Agency's understanding of how various potential modifications to the Nutrition Facts label may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

In the Federal Register of May 23, 2011, FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received two

comments. One of the comments was outside of the scope of the proposed collection of information described in the 60-day notice and is not addressed here.

(Comment 1) The comment suggested that, in place of the proposed research, an educational effort be undertaken to inform consumers about the meaning of Percent Daily Value as it is currently presented on the Nutrition Facts label. The comment also questioned whether a study sample obtained from the proposed online consumer panel would sufficiently reflect the demographic diversity of the U.S. adult population.

(Response) FDA agrees that consumer education is important to help consumers understand Percent Daily Value and has been conducting and sponsoring this type of education through its Web site (Refs. 12 to 16) and programs such as the "Spot the Block" campaign (Ref. 16 and 17). FDA does not agree, however, that consumer education about how to use the food label can substitute for consumer research, which is the primary approach for generating empirical and scientifically valid evidence about consumer understanding in response to any considered modifications to the Nutrition Facts label. Consumer research allows the Agency to evaluate objectively which considered modifications to the Nutrition Facts label are most likely to help consumers; additionally, such research may help enhance the design and utility of consumer education efforts. Although the study will use an online consumer panel, the Agency expects that, based on prior experience with these types of panels, this approach will achieve a sample of participants that is reflective of the Census distributions in key demographic characteristics (gender, age, education, and race/ethnicity). As in our previous online research, we will develop a Census-balanced sample (Ref. 18) by setting a quota prior to the study so that the overall sample of panelists who participate in the study will be balanced against the U.S. Census in gender, age, education, and race/ethnicity, i.e., inbound-balanced. The planned

balancing categories are: (1) Gender: female and male; (2) age: 18-34, 35-54; and 55+, (3) education: high-school graduate or less and 1 year or more college education; and (4) race/ethnicity: non-Hispanic white and other.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour), and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 150 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 71 hours (33 hours + 38 hours). For the survey, we estimate that 40,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10,000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the survey activities is 3,820 hours (1,320 hours + 2,500 hours). Thus, the total estimated burden is 3,906 hours. This estimate is 1,352 hours lower than the 5,258 hours published in the 60-day notice and reflects 20 fewer hours for the pretest invitation, 12 fewer hours for the pretest, and 1,320 fewer hours for the survey invitation. Recent evidence available to the Agency suggests the study will not need to send as many pretest or survey invitations as originally estimated to achieve its target sample sizes in the pretest and survey. The number of pretests was changed from 200 to 150 to correct an error that was made in the 60-day notice.

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

Table 1.--Estimated Annual Reporting Burden ¹					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive Interview Screener	72	1	72	0.083 (5 min.)	6
Cognitive Interview	9	1	9	1	9
Pretest Invitation	1,000	1	1,000	0.033 (2 min.)	33
Pretest	150	1	150	0.25 (15 min.)	38
Survey Invitation	40,000	1	40,000	0.033 (2 min.)	1,320
Survey	10,000	1	10,000	0.25 (15 min.)	2,500
Total					3,906

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

II. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Levy, A.S., S.B. Fein, and R.E. Schucker, "Nutrition Labeling Formats: Performance and Preference," Food Technology, vol. 45, pp. 116-121, 1991.
2. Levy, A.S., S.B. Fein, and R.E. Schucker, "More Effective Nutrition Label Formats Are Not Necessarily Preferred," Journal of the American Dietetic Association, vol. 92, pp. 1230-1234, 1992.
3. Levy, A.S., S.B. Fein, and R.E. Schucker, "Performance Characteristics of Seven Nutrition Label Formats," Journal of Public Policy and Marketing, vol. 15, pp. 1-15, 1996.

4. Lando, A.M. and J. Labiner-Wolfe, "Helping Consumers Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," Journal of Nutrition Education and Behavior, vol. 39, pp. 157-163, 2007.
5. Food and Drug Administration, "Calories Count: Report of the Working Group on Obesity," (<http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm>), 2004.
6. Food and Drug Administration, "2008 Health and Diet Survey--Topline Frequencies (Weighted)," (<http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm>), 2010.
7. Li, F., P.W. Miniard, and M.J. Barone, "The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information," Journal of the Academy of Marketing Science, vol. 28, pp. 425-436, 2000.
8. Levy, L., R.E. Patterson, A.R. Kristal, et al., "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" American Journal of Health Promotion, vol. 14, pp. 157-160, 2000.
9. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Dietary Guidelines for Americans, 2010," 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.
10. Institute of Medicine, "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification," (http://www.nap.edu/catalog.php?record_id=10872), 2003.
11. Block, L.G. and L.A. Peracchio, "The Calcium Quandary: How Consumers Use Nutrition Labels," Journal of Public Policy and Marketing, vol. 25, pp. 188-196, 2006.

12. Food and Drug Administration, "A Key to Choosing Healthful Foods: Using the Nutrition Facts on the Food Label," (<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079449.htm>), 2011.
13. Food and Drug Administration, "The Food Label and You--Video," (<http://www.fda.gov/Food/ResourcesForYou/Consumers/NFLPM/ucm275409.htm>), 2011.
14. Food and Drug Administration, "How to Understand and Use the Nutrition Facts Label," (<http://www.fda.gov/Food/ResourcesForYou/Consumers/NFLPM/ucm274593.htm>), 2011.
15. U.S. Food and Drug Administration, "Using the Nutrition Facts Label. A How-to Guide for Older Adults," (<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm267499.htm>), 2010.
16. Food and Drug Administration, "Spot the Block Using the Nutrition Facts Label to Make Healthy Food Choices--A Program for Tweens," (<http://www.fda.gov/Food/ResourcesForYou/Consumers/NFLPM/ucm281746.htm>), 2011.
17. Food and Drug Administration, "Spot the Block: Cartoon Network and the FDA Encourage Kids to SPOT THE BLOCK," (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048815.htm>), 2011.
18. American Association for Public Opinion Research (AAPOR). "AAPOR Report on Online Panels," (http://www.aapor.org/AM/Template.cfm?Section=AAPOR_Committee_and_Task_Force_Reports&Template=/CM/ContentDisplay.cfm&ContentID=2223), March 2010.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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