Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) regulates the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law No. 101–535). NLEA specified that most packaged foods must bear nutrition labeling, including certain nutrients and food components that may be added or deleted by regulation as necessary to assist consumers in maintaining healthy dietary practices. In response to NLEA, when FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 through 3). In 1993, FDA issued rules (codified in 21 CFR part 101) describing the content and format of nutrition labeling, including the mandatory and standardized Nutrition Facts label. When the Agency issued those rules, it considered the diet and health information that was current at that time. Since then, new information has become available, including but not limited to the Dietary Guidelines for Americans, 2010 (Ref. 4) and various Institute of Medicine (IOM) reports that update recommendations for the intake of vitamins, minerals, and macronutrients (Refs. 5 through 11). In addition, research has examined how consumers use the Nutrition Facts label and how consumers respond to specific components of the label such as the percent Daily Value (Refs. 3, 12 through 14). In light of this accumulation of new information, and given the documented rise in the incidence and prevalence of diet-related chronic diseases and health concerns such as diabetes, hypertension, and obesity, the Agency considers it necessary to update information on the Nutrition Facts label to assure that consumers have the information necessary to make healthful dietary choices.

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 response to the 2007 ANPRM, the Agency received many comments that recommended removing the Nutrition Facts label footnote (§ 101.9(d)(9)(i)), and many suggested replacing it with simpler information that can be more readily understood by consumers. These comments and existing research evidence have persuaded the Agency that much of the footnote information—specifically, the table listing that displays Daily Values for total fat,

saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets—is not well understood or used by consumers as expected.

On June 26, 2000, the Agency published a notice of availability of a petition received on August 3, 1999 from the Center for Science in the Public Interest (CSPI) that requested the Agency to establish a daily reference value for "added sugars" (Docket No. FDA-1999-P-0158). Subsequent to making that petition available, the Agency received more than 1,200 comments from individuals, industry, academic institutions, advocacy groups, and health care groups. The vast majority of comments were in support of declaring the amount of added sugars on the Nutrition Facts label. The Agency also received comments to the 2007 ANPRM related to the labeling of added sugars; some comments favored such labeling, whereas other comments opposed it. The Agency has tentatively concluded that it does not have enough information at this time to understand how declaring the added sugars content of foods might affect consumers' attention to and understanding of other information on the Nutrition Facts label.

Based on the submitted comments and emerging information noted above, the Agency has determined that research should be conducted to assess consumer reactions to various statements explaining percent Daily Values and how to use them, declaration of added sugars, and other potential options for modifying the Nutrition Facts label format. The proposed study therefore aims to assess whether providing clarifying information in the footnote area may help consumers make healthful dietary selections.

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 indention 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. Since added sugars have been linked to obesity, a significant public health problem in the country (Ref. 4), it is important that this new requirement is supported by evidence 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. 15). 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. 16) 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 IOM as well as the findings by Block and Peracchio adequate support for requiring the weight amounts of vitamins and minerals to 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.

2. Purpose and Use of the Information Collection

The study is part of the Agency's continuing effort to optimize the Nutrition Facts label to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will inform the Agency's decisions related to modifying the Nutrition Facts label by enhancing the Agency's understanding of how various potential modifications to the Nutrition Facts label may affect how consumers perceive a product or a label, perceptions which may in turn affect consumers' dietary choices.

The data collection will include a single experimental study whose overall objective is to examine consumer reactions to two main categories of modifications to the Nutrition Facts label: (1) replacement of the existing information in the footnote area with other statements; and (2) insertion of a separate declaration for added sugars below the declaration for sugars. Appendix A lists the specific footnote statements to be tested, which include a definition for percent Daily Value, a general guideline for high and low nutrient levels, and a statement about daily caloric intake. The test label format that declares added sugars is included Appendix B.

The study will include a range of dependent measures to assess the value of each nutrition labeling modification in enabling healthier food choices:

(1) Consumer ability to perform label usage tasks, including identifying a product's nutrient contents and evaluating the % Daily Values for specific nutrients.
(2) Consumer perceptions about a food product including nutritional attributes and overall healthfulness.
(3) How footnote messages influence consumer use of other information in the Nutrition Facts label.
(4) Consumer understanding of Nutrition Facts label formats that include a declaration for added sugars in addition to the required nutrients.
(5) Influences of amount of added sugars, when declared, relative to information about calories, "sugars" (i.e., total sugars), and other nutrients, in product comparisons.
(6) Consumer judgments about a label format in terms of its helpfulness, personal relevance, and credibility in conveying information for dietary decisions and the product's nutritional attributes.

Each of the planned 10,000 participants will be randomly assigned to one of 56 experimental conditions, 36 of which will focus on evaluating footnote modifications (9 footnotes × 2 product categories × 2 nutrition profiles) and 20 of which will focus on evaluating the effects of an added sugars declaration (2 labeling conditions × 2 product categories × 5 nutrition profiles). Additional details about the study design are provided in Section B2 of this information collection request.

The study will test whether the following null hypotheses hold:

Hypothesis 1: There is no difference in perceptions about a food's nutritional attributes or overall healthfulness between any of the seven footnote message conditions and a control labeling condition with the current footnote.

Hypothesis 2: There is no difference in perceptions about a food's nutritional attributes or overall healthfulness between any of the seven footnote message conditions and a control labeling condition with no footnote.

Hypothesis 3: The patterns of responses on the dependent measures do not differ among the seven footnote message conditions.

Hypothesis 4: There is no interaction between the footnote message and a product's nutritional profile in how people respond to the dependent measures.

Hypothesis 5: There is no difference in consumer comparisons, comprehension, or perceptions about a food's nutritional attributes or overall healthfulness between a label condition that includes a declaration for added sugars and a control label condition with no such declaration.

Hypothesis 6: The patterns of perceptions about a food's nutritional attributes or overall healthfulness do not differ when the amount of added sugars differs but other nutrients are held constant.

Hypothesis 7: There is no interaction between products' overall nutritional profile and added sugars content in how people respond to the dependent measures.

Results of this study will be used to inform the Agency's deliberations about final rulemaking regarding updates to the Nutrition Facts label, including what, if any, statement should be used in the footnote of the revised label. The study results will also enhance the Agency's understanding of how various potential modifications to the Nutrition Facts label, such as the declaration of added sugars, may affect how consumers perceive a product or a label, perceptions which may in turn affect consumers' dietary choices.

3. Use of Improved Information Technology and Burden Reduction

The study will use web-based surveys. Web-based surveys not only reduce the burden on respondents, but also minimize possible administration errors and expedite the timeliness

of data collection and processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

   The proposed experimental study is not duplicative of existing information. The proposed study builds on and updates earlier quantitative research conducted around the time that NLEA was implemented, and augments findings from more recent but primarily exploratory qualitative research conducted by the Agency. For example, in an FDA-sponsored experimental study of seven label formats conducted in the 1990s (Ref. 3), the percent Daily Value format produced the best performance among participants when the task required making judgments about a food in the context of a total daily diet. Around a decade later, FDA conducted a series of eight focus groups as part of the Obesity Working Group initiative (Ref. 17). This qualitative research suggested that some participants had difficulty understanding percent Daily Values, whereas other participants believed this information was useful for estimating their nutrient intakes from the foods they consumed (Ref. 18). Additional consumer research on nutrition labeling reported in the literature (including Refs. 3, 12 through 14) has produced similarly mixed information about how consumers interpret percent Daily Values and to what extent understanding may be improved. The proposed study, which includes various footnote statements for the purpose of examining to what extent clarifying information about percent Daily Values may help consumers make healthful dietary selections, will therefore address currently unmet information needs. Moreover, the proposed study focuses on research questions that have not been experimentally or otherwise quantitatively evaluated, including the effects of added sugars declarations on consumers' understanding of nutritional information and product perceptions. Thus, the experimental study proposed here will provide valuable information about the potential effects of changes to the NF label that are under consideration.

5. Impact on Small Businesses or Other Small Entities

   No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

   This is a one-time data collection. If this information is not collected, FDA will not know how proposed modifications to the Nutrition Facts label may affect consumer comprehension and perceptions. This lack of information would impede FDA's ability to select optimal modification options for the Nutrition Facts label format. The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of May 23, 2011 (76 FR 29758). FDA 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 in order 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 1) 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 website (Refs. 19 through 23) and programs such as the "Spot the Block" campaign (Refs. 23 and 24). 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 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. 25) 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: (a) gender: female and male, (b) age: 18-34, 35-54, and 55+, (c) education: high-school graduate or less and one year or more college education, and (d) race/ethnicity: non-Hispanic white and other.

9. Explanation of Any Payment or Gift to Respondents

Respondents in the cognitive interviews will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. Each respondent will receive a cash incentive of $75 to participate in a one-hour interview.

Study respondents will be recruited from members of Synovate's Consumer Opinion Panel. Members have voluntarily agreed to join the panel and participate in regular online surveys conducted by Synovate. Synovate offers panelists two main incentive programs: Sweepstakes and a Points Rewards Program. The sweepstakes draw is conducted quarterly or monthly, depending on the market. Panel members receive an entry into the draw for registering for the panel, and for each survey they complete during this time period. Each time a member completes a survey, the individual is automatically entered into the current month's drawing to win one of the following cash prizes: one cash prize of $1,000, 10 prizes of $100, 15 prizes of $50, 30 prizes of $25, and 150 prizes of $10. In

the Points Rewards Program, panelists earn points for every survey they complete and can redeem these points for cash in their native currency. Panelists receive 50 points for every survey minute anticipated. One thousand points = $1.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the Agency. FDA will keep the study data confidential to the extent permitted by law.

Confidentiality will be assured by using an independent contractor, Synovate, Inc., to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The contractors will only share data and/or information with the Agency in an aggregated form or format, which does not permit the Agency to identify individual respondents. Synovate will not share personal information with a third party unless it requests and is granted the panelists' permission to pass on the information. Details of Synovate's privacy policy can be found at https://www.globalopinionpanels.com/privacy_popup.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in accordance with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The survey does not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order 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 one 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	Number of respondents	Number of responses per respondent	Total annual responses	[2]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.

2 Burden estimates of less than one hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $62,496 (3906 x 16) at $16 per hour (the 2010 median wage rate in the U.S., rounded to the nearest dollar).[1]

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection $200,000. This includes the value of the task order to develop and conduct the collection of information and the value of a Full-Time-Employee to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed August 2011.

The Agency will use the study results to help inform proposed regulations for the modification of Nutrition Fact label on food products. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. Final results of the study may be summarized for publication in a peer-reviewed scientific journal. The planned schedule for project activities is shown in Table 2.

Table 2. -- Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 135 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	Delivery of a written final report of summaries and analytical findings	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professionals, academics, and industry and consumer organizations. The dialogues will help improve the effectiveness of the Agency's regulatory and education initiatives in promoting and protecting the public health.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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