EXPERIMENTAL STUDY OF NUTRITION FACTS LABEL FORMATS

OMB No. 0910-NEW

SUPPORTING STATEMENT

PART A

A. Justification

1. Circumstances Making the Collection of Information Necessary

Nutrition information is required on most packaged foods and this information must be provided in a specific format as defined in 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, 2, 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 (OWG) (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 response to the OWG plan, FDA issued two Advance Notices of Proposed Rulemaking (ANPRM) requesting comments on format changes to the Nutrition Facts label. One ANPRM requested comments on whether and, if so, how to give greater emphasis to calories on the Nutrition Facts label (Ref. 6) and the other requested comments on whether and, if so, how to amend the agency's serving size regulations (Ref. 7).

FDA is proposing to conduct an experimental study to quantitatively assess consumer reactions to potential options for modifying the Nutrition Facts label format. The purpose of the study is to help enhance FDA's understanding of consumer comprehension and preference for modifications to 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. The study results will be used to help the agency understand whether modifications to the Nutrition Facts label format could help consumers make informed food choices. Additionally, FDA wishes to gather baseline information on extent and reporting of adverse reactions to cosmetic products to help it design consumer education initiatives and messages.

2. Purpose and Use of the Information Collection

FDA is planning to conduct an experimental study to help enhance FDA's understanding of consumer reactions to potential options for modifying the Nutrition Facts (NF) label to make it easier for consumers to understand the number of calories and servings in the package. The study will focus on products that have more than one serving per container

but that are customarily consumed at a single eating occasion. Specifically, the study will focus on (1) consumer ability to use modified versions of the NF label for such tasks as calculating calories and estimating serving sizes needed to meet objectives; (2) consumer judgments about a food product, based on the NF label, in terms of its individual nutritional attributes and overall healthfulness; and (3) consumer preference for these changes. Additionally, the study will asses consumer awareness of the cosmetic adverse reporting system.

The study will randomly assign each of its 10,000 participants to the 60 experimental conditions (10 labeling conditions x 3 product categories x 2 nutrition profiles). The study will test the following null hypotheses:

Hypothesis 1: There is no difference in consumer ability to use the label for tasks such as estimating number of calories per serving and per container between any of the nine nutrition labeling schemes and the current control label.

Hypothesis 2: There is no difference in time it takes to use the label for various tasks between any of the nine nutrition labeling schemes and the current control label.

Hypothesis 3: There is no difference in preference between any of the nine labeling conditions and the control condition.

Hypothesis 4: There is no interaction effect between product category and nutrition labeling scheme.

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental studies. The studies will use convenience samples rather than probability samples.

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 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

In 2003 FDA conducted a series of eight focus groups, as part of the OWG initiative, to qualitatively explore consumer reactions to changes to the NF label. Including a new column on the NF label with nutrition information for the entire package (dual columns) were included in this design phase. Results from the focus groups indicated that dual column NF labels were promising for helping consumers understand that some products such as a 20 oz soda and large muffin may actually have more than one serving per container (Ref 4). Antonuk and Block (2006) found in an experimental study of college

students that compared to the standard, single-column NF labels, dual column labels have a greater impact on snack food consumption for non-dieters (Ref 8). While these studies provide some evidence about the benefits of dual column labeling, they are not without limitations. The first study is qualitative and the second is limited to a small sample of college studies looking at one type of snack food. FDA's proposed web based experimental study focuses on both dual column labeling, enlarging calorie font size, and changing serving size declarations. Therefore, there is no duplicative collection of this information. No comparable data have been collected by any other entities. The experimental study proposed here will provide valuable information specific to consumer reaction to these proposed changes to the NF label.

5. Impact on Small Businesses or Other Small Entities

This collection of information will not involve small businesses.

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 consumer comprehension and acceptance of modifications to the Nutrition Facts label format. This lack of information would impede FDA's ability to design potential options for modifying 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

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus two copies of the information; or retain records for more than 3 years. The design of the experimental study will not produce results that cannot be generalized to the response universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential 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), in the Federal Register of November 19, 2009 (74 FR 59553), FDA published a 60-day notice requesting public comment on the proposed

information collection. FDA received thirty-six letters in response to the notice, each containing one or more comments. The comments, and the agency's responses, are discussed in the following paragraphs. Some of the comments received were not responsive to the comment request on the four specified aspects of the collection of information. These non-responsive comments will not be addressed in this document.

(**Comment 1)** Several comments cited the importance of studying ways to improve the Nutrition Facts label on packaged foods and commended FDA for doing it.

(**Response 1)** FDA agrees that the study will help FDA learn how consumers react and respond to Nutrition Facts label modification options presented.

(**Comment 2**) One comment suggested adding questions about product purchase intent, amount the consumer would likely eat, and impression of the product's taste and safety.

(**Response 2**) FDA agrees that these questions are worthwhile and has included questions on product purchase intent. However, given the study designs focus solely on the nutrition label for use to choose healthier and lower calorie products and mode of data collection (internet), questions on amount of product likely to be eaten and on taste are not meaningful to include.

(Comment 3) One comment suggested that the study include various formats with different methods of presenting nutrition information be tested so that the format can be found which helps consumers understand the total nutrition package without causing confusion regarding the other properties of the product.

(Response 3) FDA agrees that various formats should be tested that help consumers make more informed decisions about the healthfulness of the product. We will include questions about the product to test how consumers use the Nutrition Facts label for making those evaluations.

(**Comment 4**) One comment suggested the inclusion of real-time, one-on-one chats between live moderators and respondents during the fielding of the study to enhance the quality of the quantitative data collected.

(**Response 4**) FDA disagrees with this suggestion. FDA has already conducted a series of eight focus groups to learn how and why consumers react to the formats being tested. Also, prior to conducting the on-line experiment, FDA will conduct at least nine one-on-one interviews where we observe respondents taking the questionnaire, and get their feedback about what they were thinking as they answered each question. We believe that, taken together, the focus groups and the one-on-one interviews will give us a good feel as to why respondents answer the questions as they do.

(**Comment 5**) A number of comments asked the agency to publish the revised instrument and mock stimuli for public comment prior to initiating the study. They had questions and recommendations about the design of the experiment, for example, whether there will be a control group and how many designs will be shown to the consumers and how many label formats will be tested and whether the subjects will be asked to rank the different formats in terms of preference.

(**Response 5**) We appreciate the suggestion for the agency to publish the instrument and stimuli for public comment prior to initiating the study. Per the PRA, a copy of the revised instrument is attached to the supporting statement for public comment. We will also include examples of stimuli as an appendix of the supporting

document. FDA will have a control group for this experiment. Ten different label formats will be tested. Each subject will only perform two tasks – an evaluation of a single label and a label comparison task.

(Comment 6) Several comments were about who should be included in the study. One comment said that FDA should give careful consideration to the gender and age distribution of the study subjects and that older subjects may have difficulty in using the web. One comment said it was important to include people with special health concerns, those that do the majority of grocery shopping or food preparation for their households, and groups that may be underrepresented online.

(Response 6) FDA agrees that demographic factors such as age and gender, health concerns, grocery shopping and food preparation experiences are important factors. FDA will collect the above information and include them in the analyses. FDA will aim to have a sample resemble the American adult population. FDA will do pre-tests to make sure everyone can read and understand the survey.

(Comment 7) One comment suggested that FDA should consider as part of the proposed study how consumers interpret the Nutrition Facts label in the context of all the other information on the package, and raised the question of whether the information on the Nutrition Facts label would be lost, diluted, or confounded by all of the other information that appears on the package. The comment suggested that, as part of the study design, FDA could present the Nutrition Facts label by itself and also how it would appear alongside the other package information, to see if consumers view or interpret the Nutrition Facts label differently in light of the total package.

(Response 7) While FDA agrees that the Nutrition Facts label is perceived in the context of the entire package, the goal of this study is to test various modifications to the Nutrition Fact label that would be suitable for all food products regardless of the context of the package. The study design proposes to test different options of modified Nutrition Fact label without other aspects of the food package.

(Comment 8) One comment stated that, in selecting the final sample for the experimental study, FDA should consider whether a certain percentage of the subjects should be recruited based on their concerns about allergy information. The comment stated that although most of the information on the Nutrition Facts label has relevance to all consumers, label information about allergens may be of interest only to a relatively small number of subjects who have food allergies. The comment suggested that the responses from this group could be analyzed separately, in addition as part of the total sample.

(Response 8) It is estimated that the prevalence of food allergies ranges from approximately 1% to 10% of the population (Ref. 1). The study will use a convenience sample (not a representative sample) consisting of members of an online panel, 18 years of age or older. Therefore, the number of respondents who have food allergies or are caretakers of children who have food allergies would be too small for the purpose of statistically sound analysis.

(Comment 9) One comments asked that FDA consider ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

(Response 9) FDA has taken steps to minimize the burden of data collection on respondents. Participants of the study will be members of the existing online panel and

data will be collected through the internet. Respondents will be sent email invitations to participate in the study.

(Comment 10) One comment asked whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(Response 10) FDA believes that collecting this information is necessary for FDA's regulatory oversight of the Nutrition Facts label. Since one of the purposes for initially developing and implementing the Nutrition Facts label was to help consumers make informed food choices, it is important for FDA to be able to evaluate whether consumers understand how to properly interpret the label, especially for health purposes.

(Comment 11) One comment requested that FDA consider using some or all of the label format changes suggested by the Center for Science in the Public Interest (CSPI) (Ref. 2).

(Response 11) CSPI suggested extensive changes to the Nutrition Facts label that affect many parts of the label. In this research, the agency is focused on how consumers use labels for products that are customarily consumed at one eating occasion but may contain more than one serving per container as well as on how consumers react to different ways that calorie information is declared on the label. FDA believes these changes have the potential to be among the most useful changes to help consumers make informed choices. Therefore, FDA identified and chose the proposed formats, such as dual column formats and prominence of calorie formats, for this study. The variety of different experimental conditions for just these changes requires a very large number of respondents. It is not feasible to test the additional extensive changes such as those suggested by CSPI in this study because the number of respondents needed would become unmanageable.

9. Explanation of Any Payment or Gift to Respondents

Respondents in the cognitive interviews for Study 1 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 contractors 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 passing 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 consistency 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, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

To help design and refine the questionnaire to be used for the experimental study, we plan to conduct cognitive interviews by screening 96 adult consumers in order to obtain 12 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hours) and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 20 hours (8 hours + 12 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1000 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 experiment, we estimate that 50000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the experiment activities is 4150 hours (1650 hours + 2500 hours). Thus, the total estimated burden is 4241 hours. The current estimate is 2646 hours higher than that estimated in the 60-day notice of November 18, 2009 (1595 hours). The difference is due to a re-examination of our original study

design. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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

Table 1.--Estimated Annual Reporting Burden[1]

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview screener	96	1	96	0.083	8
Cognitive interview	12	1	12	1	12
Pretest invitation	1000	1	1,000	0.033	33
Pretest	150	1	150	0.25	38
Experiment invitation	50000	1	50000	0.033	1650
Experiment	10000	1	10000	0.25	2500
Total					4241

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

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $67, 856 (4,241 x 16) at $16 per hour (the 2008 median wage rate in the U.S.). [1]

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to 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

[1] http://www.bls.gov/oes/2008/may/oes_nat.htm#b00-0000.

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. The new burden hours are due to a one-time data collection and its related pre-test and screener.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency will use the study results to help inform proposed regulations for the possible 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

No exceptions are requested.

References:

(1) Levy A., S. Fein, and R. Schucker, "Nutrition Labeling Formats: Performance and Preference," Food Technology 45: 116-121, 1991.

(2) Levy A., S. Fein, and R. Schucker, "More Effective Nutrition Label Formats Are Not Necessarily Preferred," Journal of the American Dietetic Association 92: 1230-1234, 1992.

(3) Levy A., S. Fein, and R. Schucker, "Performance Characteristics of Seven Nutrition Label Formats," Journal of Public Policy and Marketing 15: 1-15, 1996.

(4) Lando A. and J. Labiner-Wolfe, "Helping Consumers to 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 39: 157-163, 2007.

(5) U.S. Food and Drug Administration, Calories Count: Report of the Working Group on Obesity, 2004 (http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm).

(6) 70 FR 17008, April 4 2005.

(7) 70 FR 17010, April 4 2005.

(8) Antonuk, B. and L.G. Block. “The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food.” Journal of Nutrition Education and Behavior 38: 365-370, 2006.

(9) Schnieder Chafer, J.J., Newbery, S.J., Riedl, M.A., Bravata, D.M., Maglione, M., Suttorp, M.J., Sundaram, V., Paige, N.M, Towfigh, A., Hulley, B.J., Skekelle, P.G. “Diagnosing and Managing Common Food Allergies: A Systematic Review.” Journal of the American Medical Association 303(18):1848-1856.

(10) Silverglade, B and I.R. Heller. “Food Labeling Chaos: The Case for Reform”, Center for Science in the Public Interest. March, 2010. Available at: http://www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf.