Experimental Studies of Nutrition Symbols on Food Packages

0910-0655

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The need for this collection of information derives from the agency's objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393(d)(2)).

As a public health agency, FDA helps consumers make informed dietary decisions by regulating nutrition information in food labeling, initiating its own consumer education activities, and collaborating with public and private entities in conveying nutrition information to consumers. These activities are aimed at influencing consumer awareness, understanding, and behaviors related to diet and nutrition and ultimately health outcomes of the Nation.

With the increased interest in healthier foods, U.S. food processors and retailers have been adding nutrition information, particularly nutrition quality icons (e.g., Smart Choices Program) and selected nutrient level disclosures (e.g., Guideline Daily Amounts), in addition to other labeling statements (e.g., nutrient content claims), to the front of packages (FOP). This type of nutrition labeling schemes is seen in other countries (e.g., United Kingdom, Sweden, and Australia) as well. FDA believes the proliferation of these nutrition labeling schemes in the domestic market and the various nutrition criteria they use necessitate the agency's exercising the responsibility that Congress gave it to, among other things, carefully examine consumer understanding and use of the various schemes to evaluate how well they impart useful nutrition information to U.S. consumers and whether certain schemes or types of schemes are better ways to impart the information. The agency held a public hearing in September 2007 and completed a focus group study in April 2008 to obtain comments and information about many consumer issues related to FOP nutrition labeling schemes. We are also aware of recent consumer research conducted by foreign governments, non-governmental organizations and academics. The existing information, however, does not fill many of the gaps in our understanding of the impacts of FOP nutrition labeling schemes on U.S. consumers. Most importantly, there is a lack of publicly available quantitative consumer research on the relative effectiveness of existing and alternative labeling schemes in helping U.S. consumers make better dietary decisions. Therefore, the agency is proposing to conduct two

experimental studies to assess quantitatively consumer reactions to various FOP nutrition labeling schemes. The studies will be a critical input to ensure the usefulness of FOP nutrition information provided to U.S. consumers.

2. Purpose and Use of the Information Collection

The data collection will include two studies. The overall purpose of the studies is to help enhance FDA's understanding of consumer understanding and use of a selected sample of nutrition labeling schemes currently in use in the domestic market, and to examine whether certain schemes are better ways to impart useful nutrition information to U.S consumers. The studies are part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets.

2a. Study 1 (experimental study) -- The purpose of Study 1 is to help the agency primarily in understanding how U.S. consumers would perceive and choose products in response to five labeling conditions, described below. The study will also enhance the agency's understanding of the effect of consumer attitudes about food and nutrition, and their health status, on their reaction to FOP information. This information will help the agency in its future deliberation of FOP related labeling actions, such as regulations and consumer education, to provide better information to consumers to assist their dietary choices. This study will use a convenience sample of self-selected U.S. consumers, rather than a probability-based sample with known probability of the general population. Hence, the study is not intended to or will yield nationally representative population estimates. Even if the results are not nationally representative, the study design would provide valid and quantitative estimates of differences in consumer responses between various test

Study 1 will examine five labeling conditions:
(1) the presence on the front of the package of a Smart Choices Program scheme (currently used in the U.S. market);
(2) the presence on the front of the package of a Guideline Daily Amounts scheme (currently used in the U.S. market);
(3) the presence on the front of the package of a scheme similar to the Multiple Traffic Light, which is currently used in the U.K.;
(4) a control that shows only the Nutrition Facts (NF) label; and
(5) a control that shows no FOP nutrition information (see Appendix B for conditions (1)-(3)).

The study will focus on the following types of consumer reaction: (1) identification of the more nutritious product in a pair of products; (2) judgments about a food product in terms of its nutritional qualities, overall healthfulness, health benefits, and other characteristics such as taste; (3) judgments about a nutrition information scheme in terms of its credibility and helpfulness in conveying the product's nutritional qualities and in assisting intake decisions; (4)

impact of the nutrition information conditions 1-3 on the use of the NF label; and (5) time spent on product identification and judgment. To help understand consumer reaction, the study will also collect information on participants' background, including but not limited to consumption and perceptions of food products, nutrition attitudes and practice, food label use, and health status.

The study will randomly assign each of its 2,400 participants to view four labels from a set of forty FOP food labels that vary in the presence and type of labeling information, the type of food product, and the nutritional qualities of a product. The study will make the NF label for each of the foods available to all participants. The study will use three product categories, each including two products of different nutritional qualities: (1) breakfast cereal: shredded wheat (the healthier product) and raisin bran (the less healthy product); (2) savory snack: baked crackers (the healthier product) and corn chips (the less healthy product); and (3) frozen entrée: turkey breast dinner (the healthier product) and pepperoni pizza (the less healthy product).

The study will use the experimental data to test the following null hypotheses:

Hypothesis 1a: There is no difference between any of the three nutrition labeling schemes in these dependent measures: (1) identification of more nutritious products; (2) product judgments; (3) perceived credibility and helpfulness of a scheme; (4) likelihood of using the NF label; and (5) time spent on (1) and (2).

Hypothesis 1b: There is no difference between any of the three nutrition labeling schemes and the NF-only control in: (1) identification of more nutritious products; (2) product judgments; (3) perceived credibility and helpfulness of a scheme; (4) likelihood of using the NF label; and (5) time spent on (1) and (2).

Hypothesis 1c: There is no difference between any of the three nutrition labeling schemes and the no-FOP information control in: (1) identification of more nutritious products; (2) product judgments; (3) perceived credibility and helpfulness of a scheme; (4) likelihood of using the NF label; and (5) time spent on (1) and (2).

Hypothesis 2: There is no difference between the three food categories in: (1) identification of more nutritious products; (2) product judgments; (3) perceived credibility and helpfulness of a scheme; (4) likelihood of using the NF label; and (5) time spent on (1) and (2).

Hypothesis 3: There is no interaction effect between the labeling condition and food category in any of the dependent measures.

Study 1 will also explore the influences of individual background on the participants' understanding and use of food labeling in general and nutrition information schemes in particular. Cognitive response to labeling information

can be influenced not only by the information itself but also by prior perceptions of a product that, in turn, can be influenced by product experience and knowledge. In addition, cognitive response can be influenced by perception of the food label and label reading habit, dietary concerns, and other individual characteristics including demographics. Therefore, the study will collect information on these topics to obtain deeper insights about how individual differences may affect their reaction to FOP labeling schemes. In particular, we will use individual background information as covariates in hypothesis tests to isolate the effects of labeling information and foods on cognitive response.

2b. Study 1 (eye-tracking study) – Study 1 will also include a pilot eye-tracking study using a separate sample of consumers to explore their label viewing patterns when they judge product attributes and compare products. The purpose of the eye-tracking study is to explore the utility of this consumer research methodology for consideration in the agency's future research. Existing marketing research suggests attention may be a prerequisite for labeling information to exert influences on product perceptions. Academics and industry often use eye-tracking to obtain insights about what pieces of labeling information attract consumers and therefore may affect consumer decision-making processes and outcomes. Particularly, industry often uses this methodology in its development and design of labeling and advertising to gather evidence on how consumers view various labeling components, e.g., text, picture, graphic, and which components most attract consumer attention when they perform tasks related to a product, e.g., trying to decide how nutritious a product is. The agency is aware of this methodology and is interested in adding it to the agency's research toolbox for future labeling research. Therefore, the agency will conduct a pilot eye-tracking study to obtain first-hand knowledge of the potential utility of the methodology for the agency.

2c. Study 2 (experimental study) – The purpose of Study 2 is to help the agency compare the relative effectiveness of a wide range of nutrition labeling schemes along with certain specific design feature (e.g., color, presentation of calorie and serving size information) in helping consumers make healthier food choices. The strengths and weaknesses of the various schemes will be compared against two controls:
(1) a control that shows only the NF label; and (2) a "no FOP information" control. This study will use a convenience sample of self-selected U.S. consumers, rather than a probability-based sample with known probability of the general population. Hence, the study is not intended to or will yield nationally representative population estimates. Even if the results are not nationally representative, the study design would provide valid and quantitative estimates of differences in consumer responses between various test.

Study 2 will examine nine nutrition labeling schemes (Appendix C) in addition to the 2 controls:
(1) the presence of a "Nutrition Tips" scheme on the front of package that shows

(a) per-serving amounts of calories, total fat, saturated fat, sugar, sodium; and (b) interpretive words and colors of the amounts (high-red, medium-yellow, and low-green), with each word wrapped in a colored rectangle;
(2) same as (1) but in black and white;
(3) the presence of a "Nutrition Tips" scheme on the front of package that shows (a) per-serving amount of calories and % Daily Values (DV) of calories, total fat, saturated fat, sugar, sodium; (b) interpretive words of the % DV (high, medium, and low); and (c) is in black and white;
(4) the presence of a "Nutrition Tips" scheme on the front of package, patterned after one variant of the U.K. Multiple Traffic Light scheme, that shows (a) per-serving amounts of calories, total fat, saturated fat, sugar, sodium; (b) interpretive words and colors of the amounts (high-red, medium-yellow, and low-green) with each word wrapped in a colored circle; and (c) the measure of a serving (e.g., 1 cup);
(5) same as (4) except that a different set of colors is used (high-pastel red, medium-pastel green, and low-pastel blue);
(6) the presence of a "Calorie Count" scheme on the front of package that shows the amount of calories per serving and total amount of calories in the package;
(7) the presence of a "Calorie Count" scheme on the front of package that shows the amount of calories per serving and the number of servings per package;
(8) the presence of a "Nutrition Rating" scheme on the front of package that shows (a) the numerical value and number of stars (out of five stars) representing the overall nutritional quality of the product; and (b) the amount of calories per serving;
(9) the presence of a green "Healthy Check" scheme on the front of package that includes the word "healthy" and a separate box showing the amount of calories per serving and the number of servings per package.

Study 2 will use four product categories, each including three products with varying nutritional qualities in descending order from A, B, to C.
(1) breakfast cereal: shredded wheat type (A rated), cheerios type (B rated) and fruit loops type (C rated);
(2) savory snack: flavored popcorn type (A rated), corn chips type (B rated) and cheese puffs type (C rated);
(3) frozen dinner: chicken type (A rated), eggplant lasagna type (B rated) and beef type (C rated); and
(4) salad dressing: ranch dressing (A rated), oil and vinegar (B rated), and mayonnaise
(C rated).

In addition to the four product categories and 11 labeling conditions, the study will also independently manipulate the difficulty of the choice task by varying whether the pair of products in the choice task are fairly similar or fairly different in overall nutrition quality.

The study will include a range of dependent measures to assess the value of each

nutrition labeling scheme in enabling healthier food choices:
(1) accuracy and speed in a two product choice task that requires selection of the healthier product;
(2) cogency of reasons given for choice based on thematic coding of open-ended responses;
(3) perceptions of long term consequences of regularly including the chosen product in one's diet;
(4) perceptions of selected nutrient levels in the chosen product;
(5) likelihood of truncated information search when answering product perception questions; and
(6) perceptions of credibility and helpfulness of the labeling scheme.

Study 2 will randomly assign each of its 4,800 participants to the 88 experimental conditions (11 labeling conditions x 4 product categories x 2 levels of choice difficulty). The study will test the following null hypotheses:

Hypothesis 1: There is no difference between any of the nine nutrition labeling schemes and the labeling condition with no FOP nutrition information.

Hypothesis 2: There is no difference between any of the nine nutrition labeling schemes and the labeling condition with the mandatory NF label.

Hypothesis 3: The differences between the nine nutrition labeling schemes are the same for each of the six kinds of dependent measures.

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

Hypothesis 5: There is no interaction effect between difficulty of product choice and nutrition labeling scheme.

3. Use of Improved Information Technology and Burden Reduction

The proposed information collection will recruit respondents and conduct experiments via the Internet. FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's request. The Internet mode of data collection is more appropriate than telephone mode because (1) we aim to collect respondents' cognitive response to experimental conditions presented in pictures of mock food labels and the conditions cannot be described clearly on the telephone, and (2) the Internet mode avoids interviewer effects associated with telephone mode. The Internet mode is more appropriate than mail mode because branching and skipping in the instrument can be better controlled. The Internet mode is more appropriate than face-to-face mode because the Internet mode avoids interviewer effects and errors in assignments of experiment conditions. Moreover, by pre-loading condition assignments and relevant materials (e.g., labels) on Web pages, it is easier to control and verify data collection instrument

and process. The Internet mode facilitates recording of process information, such as time spent on a task, which can provide additional insights about the response. The Internet technology also facilitates efficient data collection.

4. Efforts to Identify Duplication and Use of Similar Information

The agency has contacted the public and knowledgeable researchers and conducted a thorough literature review. The agency concluded that the proposed data collection will not duplicate any similar study and the existing knowledge base and literature do not meet the agency's informational need, particularly about consumer understanding and use of nutrition symbols in the domestic marketplace.

FDA solicited information and comments in a September 10-11, 2007 public hearing on symbol-related consumer research issues such as consumer attitudes toward symbols and products with and without symbols, consumer interpretation and use of symbols, NF label, and claim statements, and consumer interpretation of multiple symbols in a given product category (72 FR 39815). The hearing, however, generated limited useful information on most of the issues we had asked in the public hearing notice. For more details on the agency's response to the public hearing, see ''FDA Comments on Symbols Public Hearing and Current Plans for Addressing Issues,'' Docket No. FDA–2007–N–0198.[1]

We are aware that many foreign governments, industry groups, food manufacturers, consumer advocacy groups, and academic researchers have conducted or are conducting consumer research on nutrition symbols. Most of the research remains unpublished and unavailable to the agency, however some notable examples of the literature include Malam *et al*. (2009)[2], Kelly et al. (2009)[3], Bormeier et al. (2009)[4], Feunekes *et al*. (2008)[5], Food Standard Agency

[1] http://www.cfsan.fda.gov/~dms/cfsup196.html.

[2] Malam, S., Clegg, S., Kirwin, S., and McGinigal, S, Comprehension and use of UK nutrition signpost labelling schemes, British Market Research Bureau, 2009, available at: http://www.food.gov.uk/multimedia/pdfs/pmpreport.pdf.

[3] Kelly, B., Hughes, C., Chapman, K., Chun-Yu Louie, J., Dixon, H., Crawford, J., King, L., Daube, M., and Slevin, T., Consumer testing of the acceptability and effectiveness of front-of-pack food labelling systems for the Australian grocery market, *Health Promotion International* 24: 120-9, 2009.

[4] Borgmeier I, and Westenhoefer, J. "Impact of Different Food Label Formats on Healthiness Evaluation and Food Choice of Consumers: a Randomized-Controlled Study." *BMC Public Health*, 9: 184, 2009.

[5] Feunekes, G. I. J., I. A. Gortemaker, A. A. Willems, and R. Lion. Front-of-pack nutrition labelling: Testing effectiveness of different nutrition labelling formats front-of-pack in four European countries. *Appetite* 50(1): 57-70, 2008.

(2005)[6], Which? (2006)[7], Scott and Worsley (1994)[8], and Young and Swinburn (2002)[9].

The literature, however, has three major limitations that restrict its usefulness to the agency. First, none of the existing studies has examined as wide a range of nutrition information schemes as the agency is interested in exploring (i.e., Schemes 1-9 in Study 2). Though the literature provides some general knowledge in this area, it provides very limited help in terms of the specific features that the agency is interested in (e.g., "Nutrition Tips," declaration of total calorie amount in a package). For example, some symbols, such as the Multiple Traffic Light in the United Kingdom, are nutrient specific (i.e., they show the amounts of individual nutrients) while other symbols, such as the Smart Choices Program, present a summary indicator of the overall nutritional characteristics of a product. Since the range of nutrition symbols in this country is much wider than in other countries, the agency does not feel the literature has provided sufficient information about how U.S. consumers may respond to symbols that are present in the domestic market. Second, except for Feunekes *et al*. (2008), studies seldom compare consumer responses to symbols of different characteristics.

The third major limitation of the literature is that labeling environments differ between domestic and foreign markets. Most of the published or publicly available research was done in Europe (e.g., the United Kingdom, the Netherlands) and other countries (e.g., Australia). Most of these countries, however, do not have the same labeling requirements and regulatory framework, e.g., mandatory NF label, as this country. Since U.S. and foreign consumers face different labeling environments, we are uncertain whether and how much findings derived from these studies are applicable to the U.S. market.

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

Without this collection of information, the agency will lack critical information on

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[6] Food Standards Agency. Quantitative Evaluation of Alternative Food Signposting Concepts: Report of Findings. London, United Kingdom, 2005. Available at http://www.food.gov.uk/multimedia/pdfs/signpostquanresearch.pdf.

[7] Which?. Healthy signs? Campaign report. London, United Kingdom, 2006.

[8] Scott, V. and A. F. Worsley. Ticks, claims, tables and food groups: a comparison for nutrition labelling. *Health Promotion International* 9(1): 27-37, 1994.

[9] Young, L., and B. Swinburn, Impact of the Pick the Tick food information programme on the salt content of food in New Zealand, *Health Promotion International* 17(1): 13-9, 2002.

consumer understanding and use of nutrition symbols and have little consumer science knowledge to help develop and evaluate any policy initiative(s) that it may undertake in the future regarding nutrition symbols.

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), in the Federal Register of June 1, 2009 (74 FR 26244) and December 1, 2009 (74 FR 62786), FDA published a 60-day and a 30-day notice, respectively, requesting public comment on the studies. The agency received seven responses, some of them containing multiple comments. Two comments raised issues that were outside the scope of the comment request on the information collection provisions; one of them asked that toxic chemicals and other things be removed from the food supply and the other requested for an extension of the comment period. These two comments will not be discussed here. The Office of Management and Budget (OMB) received and forwarded to FDA five responses to the 30-day notice, all of them containing multiple comments.

Among the relevant comments, all supported the proposed research. Below are a summary of the relevant comments and the agency's response to the comments. Many of the comments in response to the 30-day notice are similar in nature to those in response to the 60-day notice and are discussed together.

(Comment 1) One comment questioned the inclusion in Study 1 of questions about perceived taste and health benefits of products, dietary supplement use, self-rated health status, health conditions of concern, and functional health literacy, stating that these questions do not seem to focus on the study objective of discerning consumer use and understanding of nutrition symbols on food packages. One comment suggested that product choices are also influenced by factors other than nutrition, such as taste and cost. Another comment stated that "diabetes or high blood sugar" and "obesity or overweight" should be removed from perceived health benefits because FDA has not approved health claims for these conditions. Another comment questioned why the studies ask about nutrients that are not included in all test symbols.

(Response 1) First, we agree that product choices can be influenced by many factors other than nutrition. Yet, we disagree that questions about perceived health benefits and, perceived taste are outside the scope of the study. The purpose of the study is to understand consumer response to a sample of existing FOP nutrition labeling schemes. The study will help the agency evaluate the current situation and will provide information that will be important to any future

deliberations of the agency's response to the various nutrition information schemes. Product perceptions (including nutrient levels, health benefits, and taste) are inferences consumers often make from labeling information. It is well known that some consumers perceive a tradeoff between nutrition and taste. Hence, it is within the scope of the study to collect such information to obtain a more complete understanding of consumer response to nutrition information schemes and to use it to tease out the effects of these schemes on product choices and perceptions. In addition, such information will enhance our understanding of consumer response to food labeling in general. We note that we have decided to remove the questions on use of dietary supplements and functional health literacy due to the length of the questionnaire.

Second, we disagree that "diabetes or high blood sugar" and "obesity or overweight" should be removed from the list of possible perceived health benefits because the agency has not approved health claims for these conditions. Diabetes and obesity are health conditions that have been linked to dietary quality, which is influenced by consumer choices and perceptions of food products. Furthermore, perception of the relationships between a food product and the risk of these two health conditions are part of inferences consumers often make from labeling information. Whether there exist health claims for these conditions is irrelevant. We further disagree that self-rated health status and health conditions of concern are irrelevant to the objective of the study. These are among the individual characteristics that have often been found in the literature to affect consumer motivation, understanding, and use of nutrition information.

We also disagree that nutrients not included in the test symbols should not be included in the studies. Consumers can have inferences about the characteristics of a product not stated in an FOP symbol or any other labeling statement (e.g., a nutrient claim). Previous research suggests the possibility of "halo effects," i.e., FOP labeling statements cause some consumers to infer product attributes that are not featured on the statement and are not consistent with the actual product profile. Asking respondents their perceptions of nutrients absent from a symbol can provide the data to test halo effects in the study. Furthermore, as long as the same set of nutrients is asked about a give product, it is useful to examine if differences in the content of the symbol (summary vs. nutrient-specific) would cause differences in product inferences.

(Comment 2) One comment noted that the questions seem to be testing specific symbols, rather than the concept of front-of-package nutrition information schemes. The comment also noted along the same lines that the it was not clear how FDA decided which symbols to test but noted that the symbols to be tested include symbols that are used in labeling (e.g., store shelf), rather than on the front of the package. One comment asked about the nutrition criteria behind various "nutrient ranking" symbol systems, e.g., the five-star symbol and the Multiple Traffic Light symbol. Another comment questioned whether the action standard of the proposed research would include ruling out symbols that clearly

won't work, and doing more research on those that appear promising. Another comment suggested that the Guiding Stars symbol would be an important element in the proposed study. One comment suggested that Study 1 eliminate the Multiple Traffic Light symbol from the test because Study 2 already includes it. Another comment suggested that Study 2 should include other variants of the test symbols. Another comment suggested that FDA has presumed the results of the the studies will show that one symbol system is vastly superior to other systems.

(Response 2) We understand the concern about the decision making process in choosing the symbols to test in the studies and we recognize that there exist many other variants of the symbols we propose to test in Study 2. The decision process was not formal, but embodied some general principles. We wanted to evaluate a broad range of symbols, including ones currently in use and plausible proposed options. Because of the large number of possible types of symbols and possible variations within a given type, we tried to include examples representative of different types of symbol as a priority, with limited examples of varying features within a given type of symbol. This strategy will help us narrow down the alternatives for future research that can then address how to optimize specific features within a promising type of symbol. We have been monitoring developments and gathering information about FOP labeling for several years so we have sufficient expertise and information to make these judgments.

In terms of nutrition criteria for the symbols studied in these studies, FDA's approach to developing thresholds and cutoff points for characterizing the nutritional profiles of foods will be consistent with the approach it has taken to develop criteria for use of nutrient content claims and health claims and take into consideration the distribution of nutrients in foods and recommendations regarding the nutrients of public health concern.

We agree that the questions in this study are designed to test specific symbols used on packages, rather than the concept of front-of-package symbols. Smart Choices Program and Guideline Daily Amounts symbols have been selected because they are among the most widely used FOP symbols in the U.S. The Traffic Light type symbol has been selected because it is one of the FOP symbols used in the United Kingdom. The other two symbol schemes, NF only and no FOP scheme, have been selected to examine how product choice and perceptions would differ if consumers ignore the front package and turn to the NF label for product information or are not provided any nutrition information on the front of the package. We have decided to focus at the present time exclusively on FOP symbols rather than on FOP and shelf tag symbols because consumers are more likely to see FOP symbols on nationally distributed products than shelf-tag symbols that can only be found in limited locations. Therefore, we have omitted the Guiding Stars and NuVal symbols from the study.

We disagree that the Multiple Traffic Light symbol should be removed from Study 1. Our focus group research suggested consumers may react to this type of

symbol and some existing U.S. symbols differently. Study 1 provides the opportunity to explore any such differences.

We also disagree that we have predecided about which symbol system would work more effectively than others. Our study hypotheses are there are no statistically significant differences in the response to different test symbols. The rejection of these hypotheses does not lead to the conclusion that one system outperforms the other. We will examine the results closely to identify and verify any differences.

(Comment 3) One comment suggested that a question series could be developed in Study 1 to compare consumer response to three versions of labeling approaches: with no nutrition symbol, with a nutrition symbol, and with an FDA authorized health claim appropriate to the food.

(Response 3) We appreciate the suggestion to compare consumer responses to different versions of labeling approaches: with no nutrition symbol, with a nutrition symbol, and with claims that can be used under current regulatory framework, e.g., authorized health claims and nutrient content claims. Such research may be useful in the future. Nevertheless, due to the paucity of information regarding consumer understanding and use of existing nutrition symbols in the domestic market, we consider it most useful at this time to conduct the planned research, which does include a comparison between no nutrition symbol and the presence of a nutrition symbol.

(Comment 4) A comment recommended that Study 1 focus more broadly on consumer research issues that have not yet been fully answered by the limited research conducted to date. These issues include: consumers' focus on nutrition symbols; the nutrition symbols that are most helpful to consumers; the nutritional elements that a symbol should reflect; the ideal placement of a symbol on the package; the effects of multiple symbols on consumer decision-making; the effects of the presence of a health claim on consumer use of nutrition symbols or the NF label; whether public or private sector oversight has any impact on the effect on consumers of a nutrition symbol program; use of symbols and behavioral changes; and consumer interpretation of symbols. Another comment asked how FDA will evaluate whether scoring all foods in store or only some foods is a better approach.

(Response 4) We agree that these issues are important for understanding the impacts of nutrition symbols on consumers. In fact, the proposed study has been designed to help provide information on several of the recommended issues, such as whether consumers focus in on nutrition symbols (using the eye-tracking study) and how consumers interpret symbols (using the experimental study). In addition, we note that we have added Study 2 to examine which of a wide range of symbol schemes may be most helpful to consumers. We agree, however, that further research will be needed. Examples of future research that may be

considered include how consumers react to other existing symbols such as the American Heart Association Heart Check symbol, the relative effects of symbols and claims on consumer decision-making, how consumers use symbols in the supermarket, and whether scoring all foods in store or only some foods would influence consumers differently and how.

(Comment 5) A comment questioned whether a comparison, in Study 1, between a pair of products of the same product category and same type of symbol, but with different nutritional profiles, can be used to assess the various symbol systems and front-of-package vs. shelf-tag systems. The comment stated that different systems present different information on the label or tag.

(Response 5) We appreciate the comment. One of the objectives of the study is to examine identification of the more nutritious product in a pair of products. It is precisely because different systems present different information on the front of package that we want to use this comparison to examine whether and how much respondents can discern two nutritionally different products when they see FOP symbols of different content/design. The null hypothesis would be that there is no difference between different systems, e.g., product choices and perceptions are the same regardless of the type of symbol the shows on a product package. We also note that we have decided to omit shelf-tag symbols in this study.

(Comment 6) A comment questioned whether a comparison, in Study 1, between a pair of products of different product categories but with the same type of symbol and different nutritional profiles, can be used to assess the symbol systems to be examined in this study. The comment stated that these symbol systems are designed to allow comparisons between products within a category rather than comparisons of products between categories.

(Response 6) We disagree that the comparison in question cannot be used to assess the target symbol systems. Though one of the test systems, the Smart Choices Program, is designed to allow within-category comparisons, the other one, the Guideline Daily Amount, is not. In addition, it is unknown whether consumers are aware of the intent of a system. If consumers see the same type of symbol on various products, e.g., yogurt and cereal, some of them may infer these products possess the same or similar nutritional characteristics. In addition, the pair of products that will be compared have been selected because they are possible substitutes for each other for an eating occasion, e.g., yogurt and cereal. Unless these possibilities can be ruled out, it is within the scope of this study to include the comparison in question because it will provide information about consumer understanding of these symbols.

(Comment 7) One comment raised the issue of the representativeness of Study 1. It stated that the online sample should be balanced to reflect U.S. population demographics and controlled for grocery shopper status, category purchase and use status; that each test cell should be balanced accordingly; and that the study

should be conducted in both English and Spanish so not to under-represent non-English speaking demographics of the U.S. population. Another comment raised the issue of the realism of the studies, such as the impacts of forced exposure to test symbols on participant reaction, how the tested symbols fare in light of the limited time that consumers spend shopping, how likely that a symbol will break through the clutter of actual shelf sets and individual package graphics, what if participants use familiarity and past purchase history with categories and brands to shorten package review times, and how the mention of FDA in the study would affect participants' views of the test symbols because they may be skeptical of information they think that manufacturers are providing.

(Response 7) We disagree that the study sample as well as each test cell should be balanced to reflect the U.S. population. The study is an experimental study aimed at establishing valid comparisons of respondents' reactions to different symbols and foods, rather than generating reliable population estimates. Furthermore, balancing a non-probability sample (such as the sample used in this study and most other online samples) or each test cell generated from the sample, does not necessarily make the study results representative. Because the study is not intended to generate population estimates, we also disagree that the study should control for grocery shopper status, category purchase, and use status. We recognize the usefulness in and importance of understanding non-English speaking consumers' response to food labeling and will consider addressing this need in future studies.

We agree that one of the limitations of the studies is their generalizability to the real shopping experience. The studies have been designed to be as realistic as possible. We have developed mock package fronts that resemble real packages but without using any exisiting brandnames; we have revised the questionnaires to obtain participants' choices when the health reason is mentioned and when it is not, with the latter reflecting that product choices are subject to a myriad of factors and consumers do not always choose products with a health objective in mind. We have further refined our questionnaires so that participants are not directed to focus on the test symbols on packages when they are asked to report their product choices and perceptions. We also have included questions about the perceived trustworthiness of the tested symbols. We note that we are obligated to reveal the identify of the study sponsor, FDA, to all participants. Since this study element does not vary between participants, it is not expected to cause significantly differential responses among participants.

We also want to clarify that the objective of the study is to understand consumer reactions to one specific piece of labeling information, the nutrition symbol, rather than to all or other pieces of labeling information. We think that using forced exposure in a controlled environment increases the likelihood that observed outcomes are caused by symbols rather than prior knowledge and individual characteristics. Otherwise, it would be difficult to ascertain whether respondents have noticed the test symbols, which in turn would raise questions about the validity of the results. On the other hand, if the objective of the study

was to gather market- and population-representative results, then alternative methodologies such as modeling sales data,observing actual shopping behavior, and using nationally representative samples of all adults or primary grocery shoppers may be more appropriate. FDA will consider these other methodologies in its future research.

(Comment 8) A comment recommended that Study 1 consider asking about perceived levels of nutrients-to-encourage separately from perceived levels of nutrients-to-limit, and about how symbols reinforce basic information such as food groups and servings.

(Response 8) We agree that it is useful to examine consumer perceptions of nutrients-to-encourage in addition to nutrients-to-limit, and have included four nutrients-to encourage (calcium, fiber, Vitamin A, and Vitamin C) in the revised instrument. We also agree that it would be useful to examine in future research how symbols reinforce basic information such as food groups and servings.

(Comment 9) A comment stated that FDA should apply science and transparency in its research intentions and study design.

(Response 9) We appreciate the comment that FDA should apply science and transparency in its research intentions and study design. FDA's approach to developing thresholds and cutoff points for characterizing the nutritional profiles of foods will be consistent with the approach it has taken to develop criteria for use of nutrient content claims and health claims and take into consideration the distribution of nutrients in foods and recommendations regarding the nutrients of public health concern.

(Comment 10) A comment suggested that the word “nutritious” rather than “healthy” should be used in Study 1 because the latter could be associated by respondents with considerations other than nutrition and has a regulatory meaning.

(Response 10) We disagree that the word “healthy” should not be used because it has a regulatory meaning. We are not aware of any research that suggests consumers are aware that the word “healthy” has a specific regulatory definition when used in food labeling. We agree that “healthy” may be less precise than “nutritious” for what the study intends to measure. Existing consumer research, however, indicates that consumers associate “healthy” more with nutritional qualities of a food product than with other considerations such as freshness. Therefore, we will retain the word “healthy” in this study. At the same time, we will examine and compare participant responses when they see “healthy (or nutritious)” (in Study 1) and when they see “healthy.”

(Comment 11) A comment stated that the plan in Study 1 of “showing front panels which are full-color, three-dimensional, and patterned after existing labels

in the market" would not remove the effects of brands on responses but would confound the analysis.

(Response 11) We disagree with this comment. We have taken a great deal of care in developing the mock front panels by (1) omitting any pictures or words that may provide clues to the brand name of a product; (2) mixing graphic components from different existing labels or creating original graphics in an attempt to disassociate the mock label with any existing brands; and (3) using fictitious names and addresses of the manufacturer. We believe these actions will minimize potential confounding effects, if any, caused by brands.

(Comment 12) A comment suggested that the test symbols in Study 1 should be accurately represented and have NF declarations that support the symbol-product combinations; if a symbol is used on a product for study purposes, but not necessarily in the market, the comment states that the difference should be explained in the analysis.

(Response 12) We understand the concern. In designing the symbols for this study, the agency has used available information from symbol schemes' Web sites, created certain label information, and omitted symbols in some experimental conditions for the purpose the study. The agency will inform respondents that the labels they see in this study may or may not be the same as the ones they see in the marketplace and mention this in the analysis.

(Comment 13) A comment stated that some questions could be answered not because of one's understanding of the nutrition symbol but because of the respondent's previous knowledge or perception of the product or product category, and that some of the prior knowledge questions may prime symbol responses and should be moved to later in the instrument to minimize potential bias.

(Response 13) We agree that there is a possibility that some respondents may be able to answer some questions by drawing on their own previous knowledge or perception of the product or product category, rather than on their perception and understanding of the nutrition symbol on a test product. The study asks questions about respondents' previous knowledge or perception of the product or product category precisely because we want to minimize the risk for confounding as a result of previous knowledge.

We disagree that some of the prior knowledge questions should be moved to later in the instrument. Moving prior knowledge questions to follow symbol response questions can cause respondents to choose knowledge responses considered consistent with their symbol responses, thus increasing potential measurement errors in knowledge response. To minimize potential biases caused by asking prior knowledge before symbols response, we will have the two phases of the study (Phase 1 on prior knowledge and Phase 2 on label response and other

topics) administered separately and a week apart from each other to the same respondents. The agency has implemented this strategy in one of its previous experimental studies.

(Comment 14) A comment stated that the proposed product categories (cereal, savory snack, and frozen meal) in Study 1 would not be appropriate for product comparison tasks because they are not substitutes for each other in the diet.

(Response 14) We disagree that these product categories are not appropriate. We will use two similar products in a given category, e.g., chips and crackers in the savory snack category, for within-category product comparison; we will use two substitute products, e.g., cereal and yogurt, for between-category product comparison.

(Comment 15) A comment recommended that product consumption and purchase questions in Study 1 be moved from the beginning to a later section of the instrument and that these questions focus on at-home practices only.

(Response 15) We appreciate the suggestion. We have moved product consumption and purchase questions from before to after symbol reaction questions. We have revised the instrument to help respondents understand the questions ask about grocery shopping rather than food purchases at away-from-home eating establishments.

(Comment 16) A comment stated that it would be important for Study 1 to record label reading practices for the food categories included in the study.

(Response 16) We agree that it would be important to record label reading practices for the food categories included in the study. We have added two questions to collect this information.

(Comment 17) A comment offered suggestions for Study 1 on simplifying questions, improving response types, scales and response formats, and ways to distinguish responses to the front and back of a label.

(Response 17) We appreciate the comment and suggestions. We have incorporated many of the helpful suggestions in the revised instrument and will make other necessary and appropriate revisions to the instrument based on cognitive interviews and pretests.

(Comment 18) A comment stated that the proposed Study 1 is more likely to require close to 30 minutes, rather than the proposed 15 minutes, to complete. Another comment stated that the commenter's experience with a 20-minute online survey similar to the proposed study suggested there was no negative feedback on the burden of data collection.

(Response 18) We agree that the original estimate of Study 1 (15 minutes) was relatively low and has adjusted the content of the study so it will be completed in 20 minutes.

(Comment 19) One comment asked the agency to publish the revised instrument of Study 1 for public comment prior to initiating the study. Another comment asked the agency to make test stimuli available to the public.

(Response 19) We appreciate the suggestion for the agency to publish the revised instrument 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.

(Comment 20) A comment suggested that the agency should increase the sample size of the eye tracking study from 30 individuals to 100-200 individuals to provide results that are more reliable.

(Response 20) We appreciate the suggestion to increase the sample size of the eye tracking study from 30 individuals to 100-200 individuals to provide results that are more reliable. As stated above, the purpose of the eye-tracking component in this study is exploratory. We do not intend to use the information from this study to generate any reliable estimates of consumer labeling viewing behaviors. We will consider a larger eye-tracking study when resources become available and we have the need to collect reliable estimates of the behaviors.

(Comment 21) Another comment recommended that Study 1 consider using conjoint analysis to determine how consumers value different features of a given symbol.

(Response 21) We appreciate the suggestion to use conjoint analysis for this study. The purpose of the proposed study is to investigate how consumers understand various FOP labeling schemes. In contrast, conjoint analyses are employed in most studies to examine consumer preferences toward different objects, which may include FOP labeling schemes. Therefore, despite the wide use of conjoint analysis in academic and industry research, the agency will need to establish the appropriateness and feasibility of conjoint analysis for research with similar objectives as the proposed study before it adopts the methodology.

(Comment 22) A comment questioned whether open-ended questions on an Internet study such as Study 2 can elicit detailed explanation from participants about their product choices.

(Response 22) We recognize that open-end question on an Internet study may elicit more or less detailed information than a in-person study. Yet, detailed descriptions of product choice are not needed or expected. What is expected is

that a very simple coding scheme based on whether or not a respondent has a reason based on a true fact about what the FOP labeling represents about the product will be sufficient for the study purposes.

(Comment 23) Another comment raised the concern that continuously prompting participants that they can click on a button to read the NF label may confound the effects of FOP information on the study results.

(Response 23) The purpose of allowing respondents the option to view the NF label is primarily to evaluate whether FOP labeling would produce the "information search truncation effect" as observed in previous studies where respondents are less likely to examine the NF label if they have already looked at front panel claims. We want to see if FOP labeling systems have the same kind of effect. We will use statistical techniques to isolate the effect of FOP labeling scheme on responses from the effect of viewing the NF label.

As mentioned in Section A.4, the agency has contacted the public and knowledgeable researchers and conducted a thorough literature review. Though this effort failed to fulfill the agency's informational need, the effort helped generate many of the research ideas proposed in the data collection. We have also consulted with the following experts:

Mr. Derrick Jones
Food Standards Agency
Email: derrick.jones@foodstandards.gsi.gov.uk

Dr. Neal H. Hooker
Department of Agricultural, Environmental and Development Economics
The Ohio State University
Columbus, OH 43210
E-mail: hooker.27@osu.edu
Phone: 614-292-3549

Dr. Barry Weiss
Department of Family and Community Medicine
University of Arizona
Tucson, AZ 85719
E-mail: bdweiss@email.arizona.edu
Phone: 520-626-6975

The agency has considered and, when necessary and appropriate, incorporated in the attached instruments public comments and inputs from experts.

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 $40 to participate in a one-hour interview.

Study 1 respondents will be recruited from members of the Survey Sampling International (SSI) U.S. online consumer panel. Members have voluntarily agreed to join the panel and participate in regular online surveys conducted by SSI. All respondents to this 15-minute study will receive an entry in a quarterly prize drawing. Respondents between ages 18 and 34 will receive an additional $1.00 in cash.

Respondents of the eye-tracking study will be recruited from the database maintained by the contractor, EyeTracking, Inc. They will receive $40 in cash for a one-hour interview at the contractor's site.

Respondents in the cognitive interviews for Study 2 will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. Each respondent will receive a cash incentive of $40 to participate in a one-hour interview.

Study 2 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 independent contractors, SSI, Eyetracking, Inc. and 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. SSI limits the use of personal information only for legitimate market research purposes and in accordance with applicable Laws and Codes. 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 SSI's and Synovate's privacy policy can be found at http://www.surveysampling.com/nl/member-and-non-member-privacy-policy and https://www.globalopinionpanels.com/privacy_popup, respectively.

Eyetracking, Inc. will keep individual information confidential and will not share data or individual information with a third party (see http://www.eyetracking.com/privacy_policy/Default.aspx).

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

Study 1 will ask respondents their height, weight, perceived health, perceived weight status, special diets, and status and risk perception of chronic illnesses. This information is needed for two purposes. First, we are interested in investigating whether reaction to nutrition symbols differs between individuals of different degrees of motivation toward labeling information. Those who have higher body-mass-indices, who perceive themselves as overweight or in poor health, who are watching for calories or certain nutrients, or who are concerned about certain chronic illnesses may have different interpretations of information shown on symbols than others. Second, in that individual backgrounds may explain some of the variations in label response, the study will examine label response by controlling for these backgrounds. This strategy will help isolate the independent effects of the experimental conditions, i.e., type of symbols and foods, on symbol response.

The agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable in providing this information. For example, in the Experimental Study of Health Claims on Food Packages (OMB Control No. 0910-0565), the item non-response rates due to refusal were <1% for height, perceived weight status, special diets, and status and risk perception of chronic illnesses. Only the question of weight received a non-response rate of 6%.

Despite the evidence above, the experimental study will put a sentence before asking health status questions that reads "the next few questions may seem a bit

personal, but we need this information because this survey is about nutrition and health." We have used this sentence in previous data collections.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimated total hour burden of the collection of information is 3,613 hours (Table 1) plus 910 hours to repeat Study 1 (Table 2), for a total of 4,523 hours. To help design and refine the questionnaire to be used for Study 1, we will conduct cognitive interviews by screening 144 adult consumers in order to obtain 18 respondents in the interviews. Each screening is expected to take 5 minutes (5/60 hours) and each cognitive interview is expected to take 1 hour. The total for Study 1 cognitive interview activities is 30 hours (12 hours + 18 hours). Subsequently, we will conduct pretests of the Study 1 questionnaire before it is administered. We expect that 1,600 invitations, each taking 2 minutes (2/60 hours), will need to be sent to adult members of an online consumer panel to have 200 of them complete a 20-minute (20/60 hours) pretest. The total for the pretest activities is 120 hours (53 hours + 67 hours). For the Study 1 survey, we estimate that 12,800 invitations, each taking 2 minutes (2/60 hours), will need to be sent to adult members of an online consumer panel to have 2,400 of them complete a 20-minute (20/60 hours) questionnaire. The total for the survey activities is 1,227 hours (427 hours + 800 hours). To conduct the eye-tracking study, we expect to screen 240 adult consumers, each taking 5 minutes (5/60 hours), to have 30 of them participate in an one-hour interview. The total for the eye-tracking activities is 50 hours (20 hours + 30 hours).

To help design and refine the questionnaire to be used for Study 2, we will conduct cognitive interviews by screening 144 adult consumers in order to obtain 18 respondents in the interviews. Each screening is expected to take 5 minutes (5/60 hours) and each cognitive interview is expected to take 1 hour. The total for Study 2 cognitive interview activities is 30 hours (12 hours + 18 hours). Subsequently, we will conduct pretests of the Study 2 questionnaire before it is administered. We expect that 1,600 invitations, each taking 2 minutes (2/60 hours), will need to be sent to adult members of an online consumer panel to have 200 of them complete a 15-minute (15/60 hours) pretest. The total for the pretest activities is 103 hours (53 hours + 50 hours). For the Study 2 survey, we estimate that 25,600 invitations, each taking 2 minutes (2/60 hours), will need to be sent to adult members of an online consumer panel to have 4,800 of them complete a 15-minute (15/60 hours) questionnaire. The total for the Study 2 survey activities is 2,053 hours (853 hours + 1200 hours).

The total number of annual respondents is 52,528, the sum of Study 1 cognitive interviewer screener respondents (144), Study 1 pretest invitation respondents (1,600), Study 1 survey invitation respondents (12,800), Study 1 eye-tracking study screener respondents (240), Study 2 cognitive interviewer screener

respondents (144), Study 2 pretest invitation respondents (1,600), Study 2 survey invitation respondents (25,600) and the respondents involved in the repeated Study 1 (10,400).

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

Table 1. Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
(Study 1) Cognitive interview screener	144	1	144	5/60	12
(Study 1) Cognitive interview	18	1	18	1	18
(Study 1) Pretest invitation	1600	1	1600	2/60	53
(Study 1) Pretest	200	1	200	20/60	67
(Study 1) Survey invitation	12800	1	12800	2/60	427
(Study 1) Survey	2400	1	2400	20/60	800
(Study 1) Eye-tracking screener	240	1	240	5/60	20
(Study 1) Eye-tracking	30	1	30	1	30

(Study 2 Cognitive interview screener	144	1	144	5/60	12
(Study 2 Cognitive interview	18	1	18	1	18
(Study 2) Pretest invitation	1600	1	1600	2/60	53
(Study 2) Pretest	200	1	200	15/60	50
(Study 2) Survey invitation	25600	1	25600	2/60	853
(Study 2) Survey	4800	1	4800	15/60	1200
Total			42128		3613

Table 2. Estimated Annual Reporting Burden
Associated with Repeated Study 1

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
(Study 1) Pretest invitation	600	1	600	2/60	20
(Study 1) Pretest	200	1	200	15/60	50
(Study 1) Survey invitation	7200	1	7200	2/60	240

(Study 1) Survey	2400	1	2400	15/60	600
Total			10400		910

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $72,368 (4,523 x 16) at $16 per hour (the 2008 median wage rate in the U.S.). [10]

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

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

14. Annualized Cost to Federal Government

The estimated total cost to the Federal Government for this information collection $600,000. This includes the value of two task orders 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 information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We plan to complete data collection and analysis within two years from the date of OMB approval. The planned schedule for the project is shown in Table 3.

The purpose of tabulation is to quantitatively and qualitatively analyze the data and summarize findings to meet the informational needs. Commonly accepted statistical techniques such as descriptive analysis, analysis-of-variance (ANOVA), and regression will be used to analyze the experimental data.

Table 3. Project Schedule

Date	Activity
Within 1 day following OMB approval	Notification to contractor to proceed with

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

	data collection
Within 45 days following OMB approval	Completion of data collection (this must occur by March 1, 2010, the beginning date of Census blackout period
Within 75 days following OMB approval	Completion of data delivery by the contractors
Within 105 days following OMB approval	Completion of preliminary analyses
Within 120 days following OMB approval	Beginning of review, clearance, and dissemination of preliminary findings

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data does not provide nationally representative population estimates such as consumer attitudes, knowledge, or behaviors but provides valid and quantitative estimates of differences across experimental conditions. In addition, FDA will explain that the eye tracking study is exploratory and designed to provide some insights about the utility of the methodology but not quantitative estimates.

The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site.

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.