Eye Tracking Experimental Studies to Explore

Consumer Use of Food Labeling Information and Consumer Response to Online Surveys

0910-NEW

ABSTRACT FOR USE IN ICRAS

This data collection is designed to assist the Agency in generating research hypotheses in the context of future consumer research that may be used to inform the development and/or updating of food label information to help consumers make informed dietary decisions. Two independent studies, both use state-of-the-art eye-tracking equipment and techniques, will collect data on how consumers view and use labeling information Study 1 is an experimental study in which 200 consumers at five different geographical locations will view a series of label images on a computer screen and be asked to (1) choose between two products, (2) rate the nutrition characteristics of a single product, or (3) calculate intakes of selected nutrients. Participants' eye movements will be recorded to examine their viewing patterns (e.g., notice of selected label components and time spent on various label components). The labeling information will vary in the presence and type of nutrition symbol, claim, and other statements, product, nutrition profiles, and format of the Nutrition Facts label. Study 2 is an observational study in which 60 grocery shoppers at two different geographical locations will be asked to shop as they would normally do. The study will be conducted in real stores. Participants' eye movements will be recorded to provide data on the label information consumers' use in food shopping.

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that food labels are truthful and not misleading. In addition, the FDA is responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

FDA conducts research, educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the Act.

Part of the Agency's mission is to help the public get accurate and science-based information they need to use foods to maintain and improve their health (Ref. 1). To help accomplish this mission, the Agency states in its 2011-2015 Strategic Plan that it will strengthen social and behavioral sciences to help consumers make informed decisions about regulated products (Ref. 2). As part of the strategy, the plan identifies needs for knowing the audience, ensuring audience understanding of information, and evaluating effectiveness of communication about regulated products (Ref. 2).

As a public health agency, the FDA helps consumers make informed dietary decisions by regulating nutrition information on food labels, among other activities. An understanding of how visual elements (e.g., labeling statements such as claims, disclosure statements, logos, and Nutrition Facts label) influence consumers' perceptions and choices of products can assist the Agency in developing labeling information to help consumers make informed dietary decisions. In addition, FDA uses self-administered questionnaires in online experimental studies to assess consumer reactions to nutrition information on food packages. An understanding of how respondents react to survey materials that are presented visually will enhance the agency's ability in collecting better consumer data to help it fulfill its missions.

The proposed data collection will use eye-tracking research to examine consumers' eye movements to achieve three goals: (1) to better understand consumer reaction to specific food labeling information; (2) to better understand survey respondent reaction to specific survey questions related to nutrition and health; and (3) to better understand how time pressure influences the priority and quality of decision making and survey response. The results will be used by the Agency in generating research hypotheses in the context of future consumer research that may be used to inform the development and/or updating of food label information to help consumers make informed dietary decisions.

Eye tracking is a consumer research technique often used to determine where a person is looking while interacting with a visual display, such as a product package and elements of information on the package. The technique collects eye movement data, i.e., fixations and saccades (jumps of the eye), which may be superimposed on the display image to reveal: (1) which parts of the display captured the viewer's attention; (2) the order and path in which visual elements were seen; and (3) the length of time they were viewed These data provide detailed information on what individuals pay attention to on product packages, how long they spend looking at different package elements, and how visual attention may be related to their reaction to the images (Refs. 3-6, 9). Data from eye tracking studies can also help improve questionnaire design. Different respondents may pay differing degrees of attention to the elements of a survey question or response options. Eye tracking data can help to identify the need and strategies for improving the design (Refs. 7 and 8). Finally, eye tracking data can provide information on the decision strategies that individuals use under different levels of time pressure, which can help reveal the influence of time on busy individuals' food choices (Refs. 6 and 9).

In order to observe consumers' eye movement in different types of settings, we propose to conduct two separate studies, one in each of two different settings. Study 1 is a laboratory study that will ask participants to view on a computer screen mock-ups of food labels and perform tasks as well as answer other survey questions. Study 2 is an in-store study that will record eye movement data from grocery shoppers while they shop for pre-selected product categories. The studies will use two different survey instruments. Study participants will come from two separate convenience samples.

Both the laboratory study (Study 1) and the in-store study (Study 2) are part of the Agency's continuing effort to enable consumers to make informed dietary choices. The agency will use the studies to assess consumer attention to and use of various pieces of information on food packages and the information's influence on product perceptions and choices. The assessment will provide the Agency background information to help identify and develop more effective labeling information and education in the future. In addition, the Agency will use Study 1 to assess consumer behaviors when they are asked to respond to a sample of questions used in the agency's consumer research. The assessment will help enhance FDA's ability to conduct research that provides useful information. Wherever possible, the agency will also attempt to compare findings from the two studies to assess how much results

observed in the laboratory reflect actual behaviors in the market. For example, do laboratory and in-store participants pay attention to different labeling elements when they make a shopping choice? The results of the studies will neither be used to develop population estimates nor be directly used to inform policy.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The data collection is part of the Agency's continuing effort to provide consumers with information to assist them in making informed dietary choices and constructing healthful diets. Results of the study will enhance the Agency's understanding about consumers' current perceptions and use of information appearing on the Principal Display Panel (PDP) and the Nutrition Facts label (NFL). Part of the Agency's mission is to help the public get accurate and science-based information they need to use foods to maintain and improve their health. To fulfill its mission, the Agency has been using and will use consumer research information as part of the input to developing and updating label information and requirements. Eye tracking information collected in this proposed research will help the Agency in exploring what label information consumers pay attention to, use, or both. The Agency plans to use the results obtained in this data collection to generate research hypotheses in the context of future consumer research that may be used to inform the development or updating of food label information. Ultimately, the data collection will help strengthen the relevance of future consumer research as well as the quality of consumer science behind its decisions. This data collection itself, however, is not intended to be used directly in informing any new labeling decisions.

Study 1 (laboratory study)

Study 1 is a controlled randomized experiment. It has two objectives. In this proposed study, we will focus specifically on the following food label characteristics: (1) presence and type of nutrition symbols, together with presence of claims, on the Principal Display Panel (PDP) of a conventional food; (2) presence of a disclosure statement (21 CFR 101.13(h)(1)-(3)) on the PDP of a conventional food that makes a nutrient content claim; (3) format of the Nutrition Facts label on a conventional food product; (4) presence of a Dietary Supplement Health and Education Act disclaimer on the PDP of a dietary supplement product that makes a structure/function claim; (5) presence and length of a qualified health claim on the PDP of a dietary supplement product; and (6) type of product.

The second objective of Study 1 is to examine how time pressure affects information processing. The data will be used to test the hypothesis that time pressure will cause variations in participant reactions (notice, attention, use, perception, and intention) to information. For some participants, the study will impose at certain selected questions a time limit that they are provided to answer a question.

The primary dependent variables in the experiment will include:

1. Notice of area of interest, order that various label components are viewed, and length of viewing time spent on various label components;

2. Input and output of information processing:

    2.1. label components viewed before a response is selected,
    2.2. product choices, and
    2.3. product judgments such as healthiness of a product and its nutrient contents, perceived likelihood of product benefits, and correctness of judgments (when applicable).

The primary hypotheses of interest in the study are that there is no difference in the dependent variables between variations in each of the following experimental factors.

1. Nutrition symbol and claim information on the PDP of a conventional food product:
    1.1. absence of any nutrition symbol,
    1.2. presence of one of the three design concepts proposed by the Institute of Medicine (IOM) (Ref. 10),
    1.3. presence of the same type of IOM symbol as described in 1.2 and two claims,
    1.4. presence of a basic+plus+2 Facts Up Front (FUF) nutrition symbols developed by the food industry (Ref. 11), and
    1.5. presence of the same FUF symbol as described in 1.4 and the same two claims used in 1.3.

2. Disclosure statement on the PDP of a conventional food product that makes a nutrient content claim: presence or absence of a disclosure statement.

3. Format of the NFL on a conventional food product:
    3.1. the current format (without the footnote or the ingredient list),
    3.2. the current format with the font size of the calorie content enlarged, and
    3.3. the current format with the font size of the calorie content enlarged and the order of the serving size and number of servings reversed.

4. Dietary Supplement Health and Education Act (DSHEA) disclaimer statement on the PDP of a dietary supplement product that makes a structure/function claim: presence or absence of a DSHEA disclaimer.

5. Qualified health claim (QHC) on the PDP of a selenium product:
    5.1. claim only,
    5.2. a QHC that states “Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that taking selenium may produce anticarcinogenic effects limited to reducing the risk of bladder, colon, prostate, rectal, and thyroid cancer. However, this evidence of risk reduction is

inconclusive. Selenium does not treat, cure, or completely prevent any kind of cancer," and

5.3. a QHC that states "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that taking selenium may reduce the risk of bladder, colon, prostate, rectal, and thyroid cancers, but not other kinds of cancer. However, FDA has determined that the evidence about reduced risk of these cancers in inconclusive."

6. Type of product:
   6.1. two conventional food products (a cereal product and a snack product) for hypotheses on nutrition symbols and claims,
   6.2. two other conventional food products (a frozen meal product and a snack product) for hypotheses on disclosure statements, and
   6.3. two dietary supplement products (a fish oil product and a fictional "Lysoton" product) for hypotheses on the DSHEA disclaimer.

7. Time limit: no limit versus limited (at selected questions).

The experimental conditions included in the study are but a small set of examples of the products and label components that are available and found in the marketplace or variations of the current NFL format. Due to resource limitations, we have decided to keep the scope of the study at a manageable level. We recognize that there are additional factors that may influence consumer viewing and cognitive responses to labeling. The agency may consider extending the study in the future to include other variations, to focus on certain variations, or both.

Study 2 (in-store study)

In Study 2, we plan to collect observations of what information grocery shoppers notice and pay attention to while they do their shopping in the store. The study will gather eye-movement data to provide an in-depth understanding of subconscious and conscious factors that influence food purchases. Specifically, the study will explore the role that the Principal Display Panel and other label information and components play in purchase decisions. The data will be used in an attempt to explore relationships between information seeking behaviors and, among other things, product familiarity, personal needs, and design elements (e.g., prominence of an information item on a package, textual vs. graphical information).

3. Use of Improved Information Technology and Burden Reduction

Study 1 will be administered on a computer, equipped with built-in state-of-the-art eye tracking capacities. The technology is non-intrusive and allows participants to interact with the experimental stimuli freely and minimizes participant burden.

Study 2 will be administered in grocery stores. Participants will be asked to wear a pair of light-weight glasses equipped with built-in state-of-the-art eye tracking capacities and

a light-weight headset to record participants' physical reactions during their shopping experience.

4. Efforts to Identify Duplication and Use of Similar Information

   The proposed studies are not duplicative of existing information. It is known that many academic and industry projects have used the eye-tracking technology to understand consumer reactions to label and other information. Yet, we are not aware of any published research that has focused on the topics that this data collection will investigate.

5. Impact on Small Businesses or Other Small Entities

   No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

   This is a one-time data collection. If this information is not collected, FDA will not have an understanding of how consumers may view label components and make inferences about the components. This knowledge would enhance the Agency's ability to develop and provide more useful labeling information to help consumers make optimize educational activity related to Nutrition Facts label information. The study is consistent with the Agency's 2011-2015 Strategic Plan in that it will strengthen social and behavioral sciences at the Agency to help consumers make informed decisions about regulated products.

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 the Federal Register of June 15, 2012 (77 FR 35983), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received two three responses containing multiple comments. One of the responses raised issues that were outside the scope of the comment request on the information collection provisions and will not be discussed here. Below are a summary of the relevant comments and the agency's response to the comments.

   (Comment 1) A comment supported the information collection. The comment suggested that the Agency examine the accuracy of the eye-tracking methodology in identifying label reading patterns before considering applying the methodology more broadly.

   (Response 1) FDA agrees that it is important to assess the degree of accuracy the methodology can provide before any broader use of the methodology.

   (Comment 2) A comment questioned whether the Agency's use of eye-tracking methodology is essential to the regulation of food labeling.

   (Response 2) Part of the Agency's mission is to help the public get accurate and science-based information they need to use foods to maintain and improve their health (Ref. 1).

To help accomplish this mission, the Agency states in its 2011-2015 Strategic Plan that it will strengthen social and behavioral sciences to help consumers make informed decisions about regulated products (Ref. 2). As part of the strategy, the plan identifies needs in knowing the audience, ensuring audience understanding of information, and evaluating effectiveness of communication about regulated products (Ref. 2). The agency will use the proposed studies to assess consumer attention to and use of various pieces of information on food packages and the information's influence on product perceptions and choices. These findings can extend and compliment findings from other consumer research the Agency conducts and help the Agency identify and develop more effective food labeling information and education in the future. Therefore, the use of eye-tracking methodology is essential to the Agency's mission in providing the public accurate and science-based information.

(Comment 3) A comment questioned the practical utility of the information to be collected in the proposed studies. The comment stated that Study 1 would not yield nationally representative results because it uses a convenience sample and suggests this limitation be noted in the supporting statement accompanying the Federal Register 30-day notice. The comment also questioned whether the sample size of Study 2 (60 participants) would be sufficient to yield detailed conclusions.

(Response 3) The Agency stated in the 60-day notice that the studies would not be used to develop national estimates. The Agency will repeat this statement in the supporting statement. Though the sample size of Study 2 is constrained by the available resource, the study will provide preliminary yet useful insights into consumer viewing experiences with food shopping.

(Comment 4) A comment asserted that wearing eye tracking eyeglasses and a headset for biometric measurement in Study 2 would cause study subjects to behave differently from how they shop typically and thus weakening the reliability of the data. Instead, the comment suggests using a virtual-store methodology in a computer-assisted central location test.

(Response 4) The Agency is not persuaded by the comment, which provided no evidence to support its concern or to illustrate the advantages of a virtual-store methodology over an eye-tracking methodology. Therefore, we do not plan to change the methodology for Study 2.

(Comment 5) A comment questioned the use of the word "healthy" in certain questions because the word has a regulatory meaning and consumers may not understand the regulatory criteria for the claim "healthy." The comment suggested replacing "healthy" with "nutritious." The comment also expressed concern about questions that ask participants their inferences about the relationships between a product and the risk of diabetes and obesity or overweight. The comment reasoned that these health conditions should not be asked because there are no current authorized health claims permitted for these conditions.

(Response 5) The Agency disagrees with this comment. The studies are not to examine whether or how consumers understand labeling regulations. Rather, part of the purpose of the studies is to better understand how consumers infer from labeling the characteristics of food products. As stated in the comment, consumers may not understand regulatory criteria for claims, including "healthy," and there are no authorized health claims that link a food to diabetes or obesity. Yet, consumers make product inferences and decisions based on their own experiences and knowledge, with or without any understanding about labeling regulations. Hence, for consumer research purposes, it is valid and meaningful to include these terms and relationships as a measure of consumer product inferences.

(Comment 6) A comment questioned the relevance of a series of Study 1 questions related to participants' inferences of what health conditions a product may be related to. The comment explained that these questions are not consistent with established policy regarding health claims.

(Response 6) The Agency understands and acknowledges this concern. Upon further consideration of the purposes of the study and the time length of the interview, we have revised the content of the study and removed the questions the comment discussed.

(Comment 7) A comment made several editorial suggestions and clarifications to the proposed questionnaires.

(Response 7) The Agency has considered and incorporated the suggestions, when appropriate, in the revised questionnaires.

(Comment 8) A comment suggested that the Agency make the label and package designs available for public review.

(Response 8) The Agency has included the label and package designs in the supporting statement.

9. Explanation of Any Payment or Gift to Respondents

Study 1 respondents will be recruited from the database maintained by a contractor. They will receive $60 in cash for participation in the study.

Study 2 respondents will be recruited at store front and receive a $50 store gift card each.

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, EyeTracking, Inc. and TNS, 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.

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

11. Justification for Sensitive Questions

The studies do not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We plan to conduct pretests of the Study 1 questionnaire before the full study is administered. We expect that 30 invitations, each taking 2 minutes (0.033 hours), will need to be sent to members on a contractor's database to have 15 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 16 hours (1 hour + 15 hours). For the full study, we estimate that 500 invitations, each taking 2 minutes (0.033 hours), will need to be sent to the members of the same database to have 200 of them complete a 15-minute (0.25 hours) study. In Study 2, we estimate that 300 shoppers will need to be invited through a screening invitation, each taking 5 minutes (0.083 hours), in order to recruit 60 of them to participate in the 45-minute (0.75 hours) study. The total for Study 2 is 70 hours (25 hours + 45 hours). Thus, the total estimated burden is 170 hours.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Laboratory pretest Invitation	30	1	30	.033 (2 minutes)	1
Laboratory pretest	15	1	15	1	15
Laboratory study invitation	500	1	500	.033 (2 minutes)	17
Laboratory study	200	1	200	.333 (20	67

				minutes)	
In-store study invitation	300	1	300	.083 (5 minutes)	25
In-store study	60	1	60	.75 (45 minutes)	45
Total					170

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

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $2,890 (170 x $17/hour) at the 2012 median wage rate in the U.S.[1]

13. Explanation for Program Changes or Adjustments

This is a new data collection.

14. Plans for Tabulation and Publication and Project Time Schedule

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 reported to the Agency internally, in peer-reviewed scientific journals and presentations at professional conferences. The planned project schedule 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 60 days after notification to contractor	Completion of data collection	Not applicable
Within 90 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 4 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 12 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 and as needed	Response to information requests	FDA and public

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed April 2013.

Within 24 months after receipt of final data files	Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	Public

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 studies are not intended or to be used for developing nationally representative population estimates of consumer attitudes, knowledge, or behaviors and that the studies provide valid and quantitative estimates of differences across experimental conditions.

15. 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.

16. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

   The respondent universe of Study 1 is members of Eyetracking, Inc.'s Participant Database. Consumers who are 18 or older in locations across the U.S. voluntarily sign up for the database via an advertisement or word of mouth. Currently, there are over 100,000 participants in the Database. Eyetracking, Inc., the Agency's contractor, plans to establish convenience samples of 200 residents evenly distributed among five different locations. The study will aim to have a reasonable degree of diversity in participant gender, age, and education.

   The respondent universe of Study 2 is grocery shoppers in two stores, each in a different locations. The study will aim to have a reasonable degree of diversity in participant gender, age, and education. The target sample size is 60 participants.

   As discussed in Section A2, the primary hypotheses in the studies relate to between-label differences in participants' viewing behaviors and cognitive responses to the labels they view. We will impose no a priori direction of differences, if any (i.e., we assume all tests are two-tailed). For Study 1, the target sample size is projected to yield at least 48 observations per experimental condition, for the majority of experimental factors, in pair-wise comparisons. With dependent variables measured as proportions or means, we expect the target sample size will provide adequate power ($\alpha = 0.05$ and $\beta = 0.2$) to identify main effects of a medium size.

   The Agency does not intend to generate nationally representative results or precise estimates of population parameters from either study. The strength of Study 1, an experimental study, lies in its internal validity, on which meaningful estimates of differences across experimental conditions can be produced and generalized. As discussed in the following sections, the Agency has taken commonly accepted measures to enhance internal validity of the study. Examples of these measures include random assignment of respondents and conditions, use of control groups, and use of comparison conditions and relevant covariates.

2. Procedures for the Collection of Information

   Study 1: The contractor will send emails to invite members of its database in the Washington, D.C. metropolitan area to go to a central location to participate in a pretest of the study (Appendix A – laboratory pretest invitation). The recruitment will target for diversity in participants' gender, age, race, and education. Eligible respondents will be asked to complete a draft questionnaire on a computer, which is equipped with eye-tracking capacities to record respondents' eye movements. Once a respondent completes the questionnaire (Appendix B – laboratory pretest study), a moderator will ask the participants about their impressions of the study, explanations of actions during the study, and other feedback about the study. Except with regard to geographical diversity, the

contractor will use the same approach to recruit respondents for the full study (Appendix C – laboratory study invitation, Appendix D – laboratory study).

The study is designed to help test hypotheses listed in A.2 above. The questions, tasks, and purpose of questions are shown in Table 3. Proposed label images and information are shown in Appendix E.

Table 3. Structure of Study 1

Question	Task and Purpose
A0	Free scans of label images (participants will not be asked to perform any tasks with any of the images). Purpose: to test hypotheses related to viewing pattern dependent variables: notice of area of interest, order that various label components are viewed, and length of viewing time spent on various label components. All PDPs and NFLs will be used in the free scan.
A1 and A2	Consumption and purchase experiences with the three conventional food products covered in the study. Purpose: warm-up and background information.
A3–A6	In each question, a pair of the front-of-pack (FOP) label of two conventional food products of the same category will be shown. Each question involves a choice between the two products, based on perceived healthfulness, per container amount of calories, and per serving amount of added sugars, respectively. A4-A5 use a different product/FOP pair than A6-A7. Each pair of products will have the same design (no nutrition symbol, an Institute of Medicine (IOM) nutrition symbol, an IOM symbol and two claims, an Facts-Up-Front (FUF) nutrition symbol, and an FUF symbol and two claims) The Nutrition Facts label (NFL) associated with each product will be made available to respondents who may select to view it to help answer the questions. The NFL will be presented with three variations: the current format, the current format with the amount of calories enlarged, and the current format with the order of serving size and number of servings per container reversed. When the IOM FOP is used, the IOM-suggested NFL is also used. A time limit will be imposed on half of the respondents.

	Purpose: to test hypotheses related to all dependent variables (viewing pattern and information processing).
A7	(Asked of "time limit" respondents) Self-assessed time pressure when they answered questions.
A8-A9	In these two questions, an FOP label of a conventional food product that was not asked in A3-A6 is shown to the respondents. The questions ask respondents to rate the healthfulness and nutrient content of the product. The product has two FOP designs, one includes a nutrient content claim and another includes the same nutrient content claim but with a disclosure statement. The NFL of the product will be provided to respondents. Purpose: to test hypotheses related to all dependent variables (viewing pattern and information processing).
A10-A11	In these two questions, a Nutrition Facts label will be shown to the respondents. The questions will ask them to calculate the calorie amount in the entire container and the amount of the product they may consume if they were told to limit their carbohydrate intake, respectively. Purpose: to test hypotheses related to all dependent variables (viewing pattern and information processing).
A12	In this question, an FOP label of a dietary supplement product that makes a structure/function claim will be shown. The label either contains a DSHEA disclaimer or it does not. Respondents will be asked about the perceived likelihood that the product will deliver the benefit claimed on the package. Purpose: to test hypotheses related to all dependent variables (viewing pattern and information processing).
B1-B7	Individual background information such as label reading practices, dietary interests, and dietary supplement experience. Purpose: background information.
E1-E3	Debriefing questions about respondents' reactions when they were asked about perceived product characteristics, self-reported use of label information, and self-reported time pressure. Purpose: background information.

Study 2: The contractor will intercept and screen shoppers at the store front (Appendix F). Eligible shoppers will be invited to participate in the study. Participants will first undergo a trial shopping experience to familiarize them with the eye-tracking equipment. Then, they will be told to shop as they normally do but buy at least one product in each of two selected food categories. Finally, they will be administered a short interview to

collect information on their food shopping criteria, use and perception of label information, and other background information. The script for Study 2 is shown in Appendix G.

3. Methods to Maximize Response Rates and Deal with Non-response

   We will conduct pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance interview administration. We will keep the study questionnaire at a reasonable length to minimize non-completion.

   In addition, the Study 1 contractor will (1) identify FDA as the sponsor of the study and state the purpose of the study; (2) provide an email address and a toll-free number for prospective participants to inquire about the authenticity of the interview and other questions; and (3) monitor all interviews and sample assignment and solve any problems daily throughout the course of the collection of information.

4. Test of Procedures or Methods to be Undertaken

   In Study 1, we will conduct a pretest to examine the length of the questionnaire, and to identify and solve any potential problem with field administration of the study and respondent burden.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

   The Agency has consulted with statisticians and operation experts at its contractors, EyeTracking, Inc. and TNS. Chung-Tung Jordan Lin, Ph.D., at the FDA will lead data analyses.

List of Appendices

A Laboratory pretest invitation
B Laboratory pretest questionnaire
C Laboratory study invitation
D Laboratory study
E Label images and information
F In-store study invitation
G In-store study script