Background Information Sheet for Emergency Clearance

Title
Experimental Study of Proposed Changes to the Nutrition Facts Label Formats

Explanation of Need for Emergency Approval
A normal clearance is likely to cause a statutory or court-ordered deadline to be missed.

Background:
On March 3, 2014, FDA issued two proposed rules to amend its labeling regulations for conventional foods and for dietary supplements to provide updated nutrition information to assist consumers in maintaining healthy dietary practices.

Need for consumer research:
Many of the proposed modifications to the Nutrition Facts label (NFL) are based on broad literature and design principles on labeling and communication. There is little empirical evidence on how and to what extent the proposed modifications may help consumers in understanding products' nutrition characteristics and in using the label to make dietary choices. There are several major components in the proposals that warrant close investigation including: (1) Increasing the prominence of calories and serving size; (2) Changing the order of "Serving Size" and "Servings Per Container;" (3) Right-justifying the quantitative amounts declared in the "Serving Size" statement; (4) Changing the "Amount Per Serving" statement; (5) Removing the "Calories From Fat" declaration; (6) Changing the presentation of Percent DVs from the right to the left side of the label; (7) Requiring the declaration of "Added Sugars" on the label; (8) Requiring the declaration of absolute amounts of vitamins and minerals; and (9) Changing the Footnote section of the label.

FDA also requested information on an alternative labeling format that indicates "quick facts" (e.g., amount of total carbohydrate, fat and protein) about a product's nutrient content first, and then explicitly points out nutrients to "avoid too much" of as well as nutrients to "get enough" of as a way to categorize the nutrient declarations in the Nutrition Facts label.

There is currently no empirical evidence to show how consumers may react to the proposed NFL or the alternative NFL. Therefore, we are proposing to conduct a new consumer experimental study to collect the necessary data and develop evidence needed for the final decisions.

Need for emergency OMB clearance:
Under normal circumstances, we would follow the notice-and-comment process described in the Paperwork Reduction Act (PRA). Unfortunately, since the administration would like to publish the Final Rules by March, 2015, we have only nine months to complete the proposed study and make results available to the public. Therefore, we are requesting emergency approval so that we may complete the study in this timeframe.

Purpose of Study
To help enhance FDA's understanding of consumer reactions to proposed format changes to the Nutrition Facts (NF) label.

Focus of Study
1. Consumer judgments about a food product, based on the NF label, in terms of its individual nutritional attributes and overall healthfulness.
2. Consumer ability to use modified versions of the NF label for such tasks as calculating calories and estimating serving sizes.

Study design
There will be two components of this study – an online experiment and an eye-tracking study. We will conduct these two studies simultaneously.

Measures and Stimuli
1. Online experiment:

   Each respondent will be asked to do two tasks (a single product evaluation and a two-product choice task). Nutrition profiles will be evaluated for products such as frozen meals or ice creams where the serving sizes or servings per container vary. At least two nutrition profiles (a better and worse profile) will be used for each product selected.

   In addition to the nutrition profile variations, the label features will vary with the goal of comparing the functionality of the current label to the proposed and alternate label formats.

2. Eye-tracking study:

   Each participant will be asked to first view an array of current and proposed labels without using the label to perform any tasks and to then use labels to do the same two tasks as those included in the online experiment. The same labels as listed above will be included, with priorities given to # of columns, placement of %DV, and the nutrient section of the label.

Potential Participant Universe
1. Online experiment -- The planned participant universe is English-speaking non-institutionalized adults (18 years or older) members of an established online consumer panel in the United States.

2. Eye tracking study – The planned participant universe is English-speaking non-institutionalized adults (18 years of age or older) residing in up to four test locations (in different cities in the continental United States.)

Sampling Methodology
1. Online experiment -- The target sample size for the study is 5,000 respondents. Members of the online panel will be sent email invitations to participate in the study. A convenience

sample will be constructed so that the distribution of those who complete the study will resemble that of the panel in gender, age (18-34, 35-54, and 55+), education (high school graduate or less education, and one year or more college education). As part of the panel procedures, respondents will be entered into a prize drawing after completing the study, but will not be paid specifically for their participation in this study.

2. Eye tracking study -- The target sample size is 160 respondents from up to four locations across the United States. Population-representative sampling is not required, but a reasonable degree of demographic diversity of participants' gender, age, and education is expected.

Information Collection Methodology

1. Online experiment -- All information will be collected via the Internet. Respondents will self-administer the study via an Internet link to the questionnaire. The planned length of the study is 15 minutes. Each respondent will be randomly assigned an experimental condition. A condition is the combination of a product, a label format, and product profile.

2. Eye-tracking study – All participants will be brought to a central location and asked to look at the Nutrition Facts labels on a computer screen. Eye movements and where on the label participants look when answering questions will be measured via an eye tracker.

Key Dependent Measures

1. Online experiment -- The planned measures include: perceived levels of nutrients, healthfulness ratings, purchase intent, calculations of calories and serving size information per serving (and per container for 1 and 2 serving products), dietary calculations testing understanding of how the product fits into the daily diet, and label perceptions. Time needed to complete each task will also be measured.

2. Eye-tracking study— The planned measures include what participants look at on the label and for how long, as well as what and for how long they look at different parts of the label when asked to do certain tasks. Accuracy of performing tasks will also be measured.

Covariates – both studies

Covariates will be collected and used to help understand responses to the NF label. The planned measures include whether the respondent buys the type of food they are asked about in the study, prior label use, level of nutrition motivation, level of nutrition knowledge, recent dieting, and health status.

Methods to maximize participation and data quality – both studies

Cognitive interviews and pretests will be conducted to refine the questionnaire and to improve implementation of the fieldwork. Reminders will be sent to encourage participation. Regular feedback from the contractor will be instituted to monitor sample assignment and study progress.