B. Statistical Methods

1. Respondent Universe and Sampling Methods

Web-based experimental study:
The planned respondent universe for the on-line experimental study is IPSOS's i-Say Panel. In the US, the i-Say panel includes over one million individual panelists. For the 9 cognitive interviews used to test the study instrument, respondents will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. We will recruit approximately 15 to 20 respondents to make sure at least 12 of them will show up for the interviews.

The target sample size is 5,000. A quota will be developed prior to sampling so that the overall sample of panelists who are sent invitations to participate in the study are reflective of the Panel in gender, age, and education. The planned balancing categories are: (a) gender: female and male, (b) age: 18-34, 35-54, and 55+, and (c) education: high-school graduate or less and one year or more college education. At the end of the field period, each treatment condition will have the requisite number of respondents, balanced, as directed, by the three demographic variables. Since the main hypothesis tested is to look for differences between the current, proposed, and alternative Nutrition Facts labels, the sample size of 5,000 will be adequate to test small differences between labels formats as well as look at interaction effects between label formats and respondent characteristics.

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental study. The study will use a convenience sample rather than a probability sample. Despite the attempt to match between the study's sample and the respondent universe in three demographic characteristics, matching is used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics.

Rather, the strength of the experimental study lies in its internal validity, on which meaningful estimates of differences across experimental conditions can be produced and generalized. The agency will take commonly accepted measures to enhance internal validity of the study. Examples of these measures include random assignment of respondents and conditions, counterbalancing condition assignments within the sample, and use of comparison conditions and relevant covariates.

Eye-tracking study
The planned respondent universe of the eye tracking study is English-speaking non-institutionalized adults (18 years of age or older) residing in four different locations of the continental United States. The contractor will use telephone to randomly recruit prospective participants from convenience samples of local residents. The study will aim to have a reasonable degree of diversity in participant gender, age, and education.

The primary hypotheses in the eye tracking study relate to between-label differences in participants' viewing behaviors and cognitive responses to the labels they view.

Therefore, we will impose no a priori direction of differences (i.e., we assume all tests are two-tailed). Accordingly, the target sample size (160) is projected to provide adequate power ($\alpha = 0.05$ and $\beta = 0.2$) to identify main label effects of a medium size for both sample proportions and sample means.

We do not intend to generate nationally representative results or precise estimates of population parameters from the study. Being an experimental study, the strength of the eye tracking study lies in its internal validity, on which meaningful estimates of differences across experimental conditions can be produced and generalized.

Procedures for the Collection of Information

Cognitive Interviews for experimental study

The recruitment will target for diversity in respondents' gender, age, race and education. Eligible respondents will complete the draft study questions on a personal computer by herself/himself. Then, a moderator will debrief the participant about how she/he interpreted certain questions and the process by which she selected her/his responses. Refinements will be made to the study questionnaire based on the respondents' input.

Experimental Study

Members of the contractor's online consumer panel will be invited by email to complete the study online in one session. Each respondent will view a Nutrition Facts label and answer questions about the product based on the label information. They will be presented with a set of two Nutrition Facts labels for products in the same product category (for example, two different frozen meals) and asked to make choices about which product is healthier and which product they would like to buy. We will also ask respondents questions about their health and general questions about how often they use Nutrition Facts labels when shopping. We estimate that it will take respondents about 15 minutes to complete the study.

Eye-tracking Study

At each of the four locations, all participants will be brought to a central location. After signing in and having completed the informed consent, they will be asked to look at the Nutrition Facts labels on a computer screen and state their reactions to the label on a questionnaire shown on the computer. The computer will be equipped with an eye tracker to record participants' eye movements during the entire experimental session. Each data collection session is expected to last 10 minutes.

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

For both the experimental study and the eye-tracking study, we will conduct pretests to help improve usability of the questionnaire, to reduce participant burden, and to enhance interview administration. In addition, the contractor will (1) provide an email address and a toll-free number for prospective participants to inquire about the authenticity of the interview and other questions; and (2) monitor all interviews and sample assignment and solve any problems daily throughout the course of the data collection.

3. Test of Procedures or Methods to be Undertaken

In the study, 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 participant burden.

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

   The Agency has consulted with statisticians and operation experts at its contractors, Ipsos. Amy Lando at the FDA will lead data analyses.