United States Food and Drug Administration

Quantitative Research on a Voluntary Symbol
Depicting the Nutrient Content Claim "Healthy" on Packaged Foods

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part B. Statistical Methods

1. Respondent Universe and Sampling Methods

Survey. FDA proposes the use of an online (i.e., web-based) panel to conduct the consumer survey (see Appendix F for survey). The online survey will seek a panel-based (non-probability) sample of 1,000 U.S. adults ages 18+ that self-identify as primary food shoppers (i.e., they report they are responsible for at least 50% or more of the grocery shopping in their household). The contractor has demographic information for all panel members and will use this pre-existing data to select participants for this study based on the eligibility criteria. A reasonable degree of diversity in key demographic characteristics such as age, gender, education, and race/ethnicity is expected.

The sample of individuals invited to participate in the survey will be balanced to the U.S. population, based on demographic information (age, gender, educational attainment, geographic region, etc.) collected by the U.S. Census Bureau through the Current Population Survey. Once the data are collected, the sample will be weighted on the same demographic variables to adjust the sample to U.S. adult population and correct any potential differential responses by demographic groups. While the results will be weighted to the U.S. adult population, FDA does not intend to generalize the results to the overall population or produce precise estimates of population parameters using the survey.

To support implementation of the consumer online survey, FDA and its contractor will retain Ipsos, a vendor that maintains a preexisting representative national panel.

The overall sampling frame for the online consumer survey is the Ipsos Online Panel. The Panel is an actively managed research access panel that uses multi-source recruitment to maintain a representative base of respondents. It includes individuals who have volunteered to take part in market research and is extensively profiled to efficiently target respondents.

Ipsos employs a survey router (brand name is Cortex) to manage a sample so that it can be balanced to the US population. Ipsos follows best-in-class principles to measure and report any selection bias that arises from the use of a router, including:

- Designated team to manage and monitor the router, made up of Ipsos sampling and methodology experts;

- Router management team has final authority over which studies are in the router and any prioritization decisions;
- Restricted impact of highly-targeted studies;
- Random and priority reallocation is balanced;
- Respondents allowed to opt-out of the screening process with no penalty;
- Diverse, large number of studies maintained in the router;
- Limited number of custom screening questions allowed;
- All router studies are reviewed by the router team and removed from the router if necessary;
- Key metrics monitored multiple times daily to identify potential performance issues;
- Supplier traffic is monitored daily to ensure consistency; and
- Representativeness and consistency of the router population to the general population is monitored.

Experimental Study. Experimental study participants will be drawn from a panel maintained by Prodege. Consumers are invited to join the Panel directly through Prodege's network of portal sites and complete a double opt-in registration process with multiple verification steps including CAPTCHA, IP Address verification, and mobile device reputation check. Currently, Prodege's Panel has over 100 million participants worldwide.

The participant universe for this study is U.S. residents who are 18 or older of Prodege's online Consumer Panel.

Participants in the cognitive interviews will be recruited from a commercial database of residents in the Washington, D.C. metropolitan area. We will recruit approximately 15 to 20 participants to make sure at least 9 of them will show up for the interviews (see Appendix A for cognitive interview screener and guide).

The current target sample size for the experimental study 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, education, and race/ethnicity, i.e., outbound-balanced (see Appendix B for e-mail invitation to panel members). The planned balancing categories are: (a) gender: female and male, (b) age: 18-34, 35-54, and 55+, (c) education: high-school graduate or less and one year or more college education, and (d) race/ethnicity: non-Hispanic white and other.

We will test hypotheses related to between-label differences (see Appendix C for study design). We will impose no a priori direction of differences, if any (i.e., we assume all tests are two-tailed). The target sample size will yield enough observations to provide adequate power to identify 4-way interactions of a medium size (see Appendix D for experimental study instrument and Appendix E for mock food labels).

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental studies. The studies will not utilize probability sampling. Despite the attempt to match between the study's sample and the participant universe

in four demographic characteristics, matching is used solely to produce a sample with a reasonable degree of diversity in key demographic characteristics.

- The strength of experimental studies lay in their internal validity. 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 participants and conditions, counterbalancing condition assignments within the sample, and use of comparison conditions and relevant covariates.

2. Procedures for the Collection of Information

Survey and Experimental Study. For the cognitive interviews, the contractors will use a telephone invitation to recruit participants (Appendix A). The recruitment will target for diversity in participants' gender, age, race and education. Eligible participants will complete the draft questionnaire on a personal computer. Then, a moderator will debrief the participant about how certain questions were interpreted and the process by which responses were selected.

Survey. The survey will be administered online to a proprietary consumer panel. Through the sampling process, panelists are pre-selected to answer a certain survey; the surveys are not "open access" (i.e., respondents are not self-selected), and respondents do not know the survey content.

Panelists receive an invitation email with the following information:

- Survey information (end date, survey number, survey duration, number of incentive points)
- A unique URL that provides access to the questionnaire
- Physical address for Ipsos
- Member support email address
- Link to privacy policy
- Opt-out information

To ensure high quality, data will be subjected to validation techniques, such as disallowing out-of-range values.

Experimental Study. The contractor will utilize an online consumer panel owned by Research Now to select study participants. Panel members will be invited by email (Appendix B) to a contractor website to complete the study online in one session. After a brief introduction to the study, each participant will be shown a single product label and will be asked to evaluate the product based on measures of effectiveness such as perceived healthiness, contributions to a healthy diet, believability, and trustworthiness (See Appendix D for questionnaire and Appendix E for mock-up labels). We estimate that it will take participants about 15 minutes to complete the full study.

The study employs a full factorial design (See Appendix C for spreadsheet visual display of conditions).

The food labels in the study resemble those of real foods but are mock-ups developed for study purposes; these are: a breakfast cereal, a frozen meal, and a can of soup.

Table 3. Structure of experimental study (See Appendix D for questionnaire)

Questionnaire Section	Topic
A	Covariates: Affect, Past Label-reading, Behavior, self-reported literacy, self-reported health
B	Single Product/Symbol Evaluation (Random assignments to a label image; respond to measures of symbol effectiveness): Healthfulness perceptions; believability; label perceptions; symbol perceptions; effects perceptions; purchase intention; manipulation check
C	Covariates: Dietary interests/nutrition motivation-self-efficacy
D	Beliefs about product category healthfulness
E	Food Shopping and Label reading
F	Demographics

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

Survey. Methods for maximizing response rates includes the following:

- Targeted recruitment through various "wide net" methodologies (e.g., email campaigns, affiliate networks, banner ads, text ads, search engine, co-registration, ..offline-to-online, specialized websites);
- Use of a point system to incentivize panelists, along with sweepstakes draws. ..Points systems are recognized as being the best in class in online market research, ..as they are a neutral system which does not skew the participation of specific ..groups of people;
- Continuously testing new recruitment sources and methods; and
- Use of an internal data quality process that incorporates data quality checks at the ..survey level to reduce or eliminate random responding, illogical or inconsistent ..responding, overuse of item non-response, and too rapid survey completion.

We anticipate a 75% completion rate for the survey. We do not anticipate challenges with non-response, given the broadly defined eligibility criteria for the survey. However, in the event of non-response challenges, we will send reminders to non-respondents, and monitor and correct any potential non-response biases.

Experiment. Our experience with online experimental studies suggests that about 15% of those who are sent invitations will complete a study. The agency will implement several procedures to maximize participation. We will conduct cognitive interviews and pretests to help improve

understandability of the questionnaire, to reduce participant burden, and to enhance interview administration.

In addition, the contractors will: (1) identify FDA as the sponsor of the study and state the purpose of the study in their invitation and reminder to encourage participation; (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

For both the survey and the experiment, FDA plans to perform tests to minimize collection burden on participants and improve quality of collected information. Before the online survey is implemented, a contractor will pilot test the instrument(s) and method of data collection. Lessons from the pilot test will be identified, and changes as necessary will be incorporated into the instrument and method. All survey pilot tests will involve no more than nine individuals.

For the experimental study, the first test consists of cognitive interviews; the primary purpose of these interviews is to understand the thinking processes that participants use to answer the survey questions.

The second test is a field pretest focusing more on the length of the questionnaire and participant burden. The contractor will administer the full questionnaire to 180 adult members of the Research Now web-based consumer panel shortly after satisfactory revisions following the cognitive interviews.

Some fine-tuning of the data collection activity may result from the cognitive interviews and/or the pretest, but substantive changes are not expected. This proposed information collection requests OMB approval for the pretest in combination with the main collection of information. We will inform OMB of any changes to the survey procedures or data collection instruments with a final version before actual data collection begins.

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

Survey. Christina Nicols, MPH, MS, MS
Senior Vice President, Strategic Planning, Research & Evaluation
Hager Sharp

Experiment. The contractor, Fors Marsh, will collect the information on behalf of the Agency. Panne Burke is the Senior Study Director and Miriam Eisenberg Colman, the Senior Researcher at Fors Marsh, is the project lead. Ron Vega, Senior Scientist at Fors Marsh, was consulted on the statistics and study design.

Drs Linda Verrill and Fanfan Wu, FDA Social Scientists, are the FDA PI's and will oversee all aspects of the data collection. They will also conduct the data analysis and information dissemination.