United States Food and Drug Administration

Quantitative Research on
Front of Package Labeling on Packaged Foods

OMB Control No. or 0910-NEW

SUPPORTING STATEMENT

Part B. Statistical Methods

1. Respondent Universe and Sampling Methods

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.

The current target sample size for the experimental study is 9,000. Participants will be segmented by higher and lower nutrition literacy, assessed through a screener, and randomly assigned by literacy levels to each study condition such that 50% of each condition will be higher literacy and 50% will be lower literacy. Otherwise, demographic distributions of the sample will be matched to those of the U.S. population, and the percentage of the population living in rural areas (15%) will also be reflected.

The U.S. Food and Drug Administration (FDA, we, or the agency) will test hypotheses related to between-label differences. 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 2-way interactions of a medium size (see Appendix B for detailed power analysis).

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 on 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 lies 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

Panel members will be invited by email (see Appendix C for an example invitation) to a contractor website to complete the study online in one session. After screening (see Appendix D for study screener) and a brief introduction to the study, each participant will see three nutrient profiles (most healthful, middle, least healthful) of a single front of package (FOP) scheme and will be asked to identify the most and least healthful profile. Participants will complete that task three times, each time with a different, randomly assigned scheme. Within scheme, healthfulness profiles will also be shown in random order; sometimes the most healthful profile will be on the left, sometimes in the middle, and sometimes at the far right. In another section of the study, participants 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. All participants will see questions about the food product but only participants in the FOP scheme conditions will be asked questions about the scheme (See Appendix E for questionnaire and Appendix F for schemes and mock-up product labels). The instrument will also collect information from participants about their history of purchasing or consuming similar products; nutrition knowledge; dietary interests; motivation regarding label use; health status; and demographic characteristics. We estimate that it will take participants about 15 minutes to complete the full study.

Scheme Type
1. Guideline Daily Amount
2. Nutrition Info - Black and White
3. Nutrition Info - Black and White with Magnifying Glass
4. Nutrition Info - Color
5. Nutrition Info with Daily Value - Black and White
6. Nutrition Info with Daily Value - Color
7. High In
8. High In with Daily Value

Nine cognitive interviews with English-speaking adults will be conducted, to identify potential response error caused by the questionnaire and study materials. Two pre-tests with 200 adults each will also be conducted prior to administering the experimental study. It is expected that there will be minor adjustments to the study materials following the cognitive interviews and the pretests.

The design for this section is: 3 (products: breakfast cereal, frozen meal, canned soup) x 3 (nutrient profiles: most healthful, middle healthfulness, least healthful) x 10 (scheme conditions).

Scheme Conditions
1. Guideline Daily Amount

2. Nutrition Info - Black and White
3. Nutrition Info - Black and White with Magnifying Glass
4. Nutrition Info - Black and White - Placement (lower right)
5. Nutrition Info - Color
6. Nutrition Info with Daily Value - Black and White
7. Nutrition Info with Daily Value - Color
8. High In
9. High In with Daily Value
10. No scheme – Control

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

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

FDA plans to perform tests to minimize collection burden on participants and improve quality of collected information.

For the experimental study, the first test consists of nine 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 pretest focusing more on the length of the questionnaire and participant burden. The contractor will administer two waves of the full questionnaire to 200 (each wave) adult members of the Prodege 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 pre-tests, but substantive changes are not expected. This proposed information collection requests OMB approval for the pre-tests in combination with the main collection of information. We will inform OMB of any substantive changes to the survey procedures or data collection instrument with a final version before actual data collection begins.

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

The contractor, Westat, will collect the information on behalf of the Agency. Stephanie Fowler is the Senior Study Director. She was consulted on the statistics and study design.

Dr. Linda Verrill, FDA Social Scientist, is the FDA Principal Investigator and will oversee all aspects of the data collection. She is assisted on the project by Jessica Behm (social scientist), Dr. Fanfan Wu (social scientist), Kristi Meadows (social scientist), and Martine Ferguson (statistician). The FDA research team will conduct the data analysis and information dissemination.