Experimental Study on Consumer Responses to Nutrient Content Claims on Fortified Foods

OMB Control No. 0910-NEW

SUPPORTING STATEMENT Part B

B. Statistical Methods (used for collection of information employing statistical methods)

1. Participant Universe and Sampling Methods

The participant universe for this study is U.S. residents who are 18 or older of Research Now's online Consumer Panel. Consumers are invited to join the Panel through an affiliate marketing program where Research Now partners with select "brick and mortar" firms with large customer databases to promote Panel membership through targeted email campaigns. Currently, Research Now's Panel has about 2.5 million U.S. participants and more than 6 million worldwide.

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. The interviews will be conducted prior to OMB approval. (see Appendix A and B for cognitive interview invitation and screener).

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 D 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.

As discussed in Section A2, we will test hypotheses related to between-label claim differences as well as interactions among label claim condition, food category, nutrition profile, and the effects of disclaimers/disclosures with respect to perceived healthfulness of product and other product perceptions such as consumption and substitution intentions. We also test hypotheses related to the likelihood of product selection in a comparison task. The target sample size will yield approximately 42 observations for each of 120 experimental conditions. We expect that this will provide adequate power to detect small 2-way interaction effects.

The agency does not intend to generate nationally representative results or precise estimates of population parameters from the experimental studies. The studies will use a convenience sample rather than a probability sample. 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

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.

The contractor, RTI, will utilize an online consumer panel owned by Research Now to select study participants. Panel members will be invited by email (Appendix D) to an RTI website to complete the study online in one session.

After a brief introduction, each participant will begin the study with a product selection task . Participants will be shown a single product type (a chip) under two claim conditions (claim versus no claim) and are asked to select the product they would purchase if they were shopping for this kind of product and only had these two to choose from. Participants will select between two different kinds of chips; a healthier chip and a less healthy chipThen, from the same product pairing, they will be asked to select the product from the pair they think is healthier. After some distractor questions about food purchase and consumption behavior, they will be assigned to a product evaluation task (with products and claims not seen earlier). In this section, participants will be randomly assigned to a single product and will be asked to evaluate the product based on perceived healthfulness, consumption intentions and substitution, and other product attributes (See Appendix E for questionnaire and Appendix F for mock-up labels). We estimate that it will take participants about 15 minutes to complete the full study.

The study employs a fractional factorial design (not all study conditions are crossed) (See Appendix G for spreadsheet visual display of conditions). Task A employs a 12 (labeling conditions) x 4 (nutrition profile/product type) design. The single-product evaluation task is a are 12x 1 designs. See Appendix G for a complete list of all claims and claim conditions tested in the study.

The products in the study are: Two kinds of chips and two kinds of cookies with a rotating nutrition profiles ("healthy" and "less healthy") Two Jelly Bean candies with same nutrition profile (plain Jelly Beans and "VitaBeans"); a plain bite-sized chocolate candy and a "vita" chocolate candy; a regular carbonated soft drink and a "vita" soft drink.

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

Questionnaire Section	Topic
A	**Product choice task**. Participants are shown a pair of products and asked to select the one they would purchase if shopping for this type of productThen participants are shown the same product pairing and are asked to select the healthier product in each pairing.
B	Covariates: Product consumption behaviors
C	Covariates: Self-rated health
D	Single-product evaluation; random assignment to label condition. Measures are 1) perception of product healthfulness and health benefits, 2) consumption and substitution beliefs and intentions, 3) perceptions of product attributes.
F	Covariates: Dietary interests
G	Covariates: Food label self-efficacy
H	Covariates: Food label numeracy
I	Covariates: Beliefs about product category healthfulness
J	Covariates: Food shopping and label reading
K	Covariates: Health status and demographics

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

Our experience with online experimental studies suggests that about 25% 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 (see Appendix D for invitation); (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 two tests to minimize collection burden on participants and improve quality of collected information. 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 field pretests focusing on the length and the programming of the questionnaire. The contractor, who is responsible for the data collection, will conduct two sets of pre-tests. In each, the contractor will administer the full questionnaire to 200 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 or the pretests, but substantive changes are not expected. This proposed information collection requests OMB approval for the pretests 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

The contractor, RTI, will collect the information on behalf of the Agency. Sheryl C. Cates is the Senior Study Director and project lead at RTI. Jonathan Blitstein, Research Psychologist at RTI, was consulted on the study design. Data analysis and dissemination will be led by Linda Verrill, Ph.D., Consumer Science Specialist at FDA, telephone 240-402-1765.