GLUTEN-FREE LABELING OF FOOD PRODUCTS EXPERIMENTAL STUDY

OMB No. 0910-NEW

SUPPORTING STATEMENT

PART B

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The universe for the study are (1) adults with celiac disease or adults who purchase groceries or prepare foods for individuals with celiac disease, (2) adults with a gluten intolerance or adults who purchase groceries or prepare foods for individuals with gluten intolerance, (3) adults who do not have either of these conditions but follow a gluten-free diet, and (4) adults for whom gluten poses no adverse health effects to themselves or the people for whom they prepare food, and who do not follow a gluten-free diet.

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

2. Procedures for the Collection of Information

2.1 Statistical methodology for collection and sample selection

The estimated prevalence of diagnosed celiac disease in the United States is less than 1% of the population. Therefore, FDA will employ a convenience sampling method to procure a sample of groups 1-3 above.

FDA will solicit the assistance of major celiac disease and research centers across the United States to procure the study sample of groups 1-3 above. FDA will ask the centers to forward an invitation to participate in the study to their respective patients by e-mail and to post a paper flyer about the study at their respective centers. Both the e-mail and the flyer will include a web address where respondents will find the screener and questionnaire and a telephone number where potential respondents can call and request a paper questionnaire. Respondents that access the questionnaire using the web address will be randomly assigned to an experimental condition. Respondents that request a paper copy will be mailed a questionnaire chosen randomly from among the experimental conditions.

FDA will obtain the sample for group 4 (consumer for whom gluten poses no adverse health effects for themselves or the people for whom they prepare food) from a proprietary web-based consumer panel.

2.2 Estimation Procedure

The study will employ an experimental design. Generalized Linear Modeling procedures will be employed to test for statistically significant differences in mean scores on measures of helpfulness, believability, and utility between conditions. The unbalanced design conditions include five mock food-product labels (onion soup, chocolate bar, millet, milk, and eggs), 17 gluten-free labeling claims and four health status groups (adults with celiac disease or the caregivers, adults with gluten-intolerance or the caregivers, adults who follow gluten-free diet but do not have gluten-intolerance or their caregivers, and a control group).

Since not all possible combinations of gluten-free labels and product type are meaningful (e.g. FDA will not test the naturally gluten-free claims on bread since most people understand that bread is not naturally gluten-free), we end up with 27 experimental conditions (see attached). Each individual is randomly assigned to these 27 experimental conditions which results in 108 cells.

2.3 Degree of accuracy needed for the purpose described in the justification

The key experimental hypotheses concern the effects of the gluten-free claims on different groups of respondents. We estimate that 50 subjects per cell (N= 5,400 respondents) will provide adequate power to identify moderate detectable contrasts or the size effects around .5 for all main effects and first order interactions with power well in excess of .70 at the .05 significance level.

2.4 Use of specialized sampling procedures

Because of the small size of the respondent universe and because many of those currently diagnosed with celiac disease or gluten-intolerance are over age 50, FDA will offer a paper questionnaire to those who do not want to participate online. The e-mails and flyers distributed to the Celiac Disease and Research Centers will include, along with a web address for accessing the screener and questionnaire, a telephone number where potential respondents can call to request a paper version of the questionnaire. These callers will be screened over the telephone. The contractor will assign a questionnaire packet at random to the screened respondent and mail it to them, including a stamped, self-addressed return envelope

FDA does not anticipate any differences in measurement bias between the web and paper/pencil modes of the survey as these modes share a great deal of characteristics in common (e.g., visual presentation, self-administration, allow time for review, etc.); in addition, we are not aware of any published evidence showing measurement differences between web and paper/pencil modes of administration. However, to combat any potential differences that might occur between the web and paper/pencil survey, the two instruments will be designed to be very similar in the way questions are presented in both modes; some minor accommodations will be made to the web survey to make it function optimally in an Internet environment (e.g., reduce the number of questions on a page, use standard radio buttons/response boxes, prompts for skipped questions, etc.). We believe that these efforts will ensure that responses by respondents in the survey will be equivalent across the two modes.

2.5 Use of periodic data collection cycles to reduce burden

This is a one-time data collection.

3. Methods to Maximize Response Rates

In an effort to increase cooperation by prospective respondents, the agency plans to take the following measures:

- Enlist the help of major celiac disease and research centers across the United States to procure a sample
- Perform cognitive interviews to ensure survey instruments and collection procedures are appropriate
- Use a Web-based consumer panel whose members have agreed to participate to procure a control group sample
- In the invitation, carefully explain the importance of participating in the survey
- Offer respondents the option to participate on paper
- Craft a survey that is easy to understand and compelling

4. Tests of Procedures or Methods

FDA plans to perform two tests to minimize collection burden on respondents and improve quality of collected information. The first test is the cognitive interview; the primary purpose of these interviews is to understand the thinking processes that respondents use to answer survey questions. Seven adults with celiac disease or gluten intolerance will complete a draft questionnaire and will be probed on the thinking processes they went through in providing the answers. The focus of analysis will be on (1) comprehension of the meaning of certain questions or words, and (2) strategies used to recall information and to arrive at an answer.

The second test is field pretests focusing more on the length of the questionnaire and respondent burden. The contractor who is responsible for the data collection will administer the full questionnaire to 140 adult members of a web-based consumer panel shortly after OMB approval of the collection of information. This is the same web-based consumer panel from which the control group will be selected. Because the Agency will have only one opportunity to invite individuals with celiac disease and gluten intolerances to participate in the study, we reserve this invitation for the full and final data collection.

5. Individuals Involved in Statistical Consultation and Information Collection

The contractor, Research Triangle Institute (RTI) will collect the information on behalf of the Agency. Kathy Kosa is the project lead at RTI. RTI will subcontract to Synovate, Inc. to use their proprietary consumer panel for part of the data collection. Analysis of the information will be conducted primarily by the FDA Project Officer, Linda Verrill, Ph.D., telephone 301-436-1765.