



Memorandum

Date January 29, 2009

From PRA Specialist, Paperwork Reduction and Records Management Staff
Office of Information Management

Subject Request for Approval of FDA Focus Group, "Gluten-Free Labeling of Food Products Focus Groups"; OMB Control No. 0910-0497

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer _____

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, is seeking OMB approval under the generic clearance 0910-0497 to conduct a set of four focus groups entitled, "Gluten-Free Labeling of Food Focus Groups." The purpose of the focus groups is to explore issues related food product labels with respect to gluten content and gluten-free claims in order to help inform the development of an experimental study on the same topic.

The focus groups will explore characteristics related to claims of "gluten-free" and allowed variants (e.g., "free of gluten," "without gluten," "no gluten"), in addition to other types of statements (e.g., "made in a gluten-free facility" or "not made in a facility that processes gluten-containing foods") on the food label. The focus groups will also assess consumer understanding of "gluten-free" claims on foods that are naturally free of gluten, and gauge consumer reaction to a product carrying a gluten claim concurrently with a statement about the amount of gluten the product contains.

A respondent screener and moderator's guide (see Appendices I and II) prepared by CFSAN will be used by the Contractor (RTI, Inc.) to recruit participants and facilitate the guided discussion.

A total of four focus groups will be conducted at two different locations: Washington, DC, and North Carolina. Individuals participating in the groups must be adults, at least 18 years old and must meet the criteria listed in the respondent screener. Of note, participants must have medically diagnosed Celiac disease or a gluten intolerance (both self-reported) and must be following a gluten-free food diet and eat packaged, processed foods. Participants may also be individuals who regularly purchase or prepare foods for individuals with medically diagnosed celiac disease or a gluten intolerance.

The Contractor will recruit 12 individuals for each focus group discussion, expecting to have 10 to 12 participants per group, with a minimum of 8 participants. No more than 12 individuals will participate in a group. Drawing from the American Celiac Disease Association's membership list, the Contractor will contact potential respondents by telephone and screen them for eligibility. To maximize response rate, recruiters will contact each sample unit at least five times to screen for eligibility and recruit for participation.

Additionally, respondents will receive a reminder call and confirmation letter before the groups convene and a \$75.00 incentive for their participation.

For focus groups employing similar respondent selection criteria, the incidence of a successful completed telephone screening is between 30-40%. The recruiter will require approximately five minutes to complete the screening interview for a selected participant, and will require less time to disqualify a potential respondent.

The time required for screening and participation will be 2.1 hours per participant. There will be a total of no more than 48 participants in four groups, producing a total estimated respondent burden of 100.8 hours.

Table 1. Estimated Annual Reporting Burden for Selected Respondents^a

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
48	1	48	2.1	100.8

^aThere are no capital costs or operating and maintenance costs associated with this collection of information.

CFSAN would like to begin the focus group study in March, 2009.

The data from these focus groups will be used to help inform the design of an experimental study on gluten and gluten-free labeling of food products.

If you have any questions, please contact Jonna Capezzuto on 301.796.3794.

Attachments

