



## Memorandum

Date November 30, 2009

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

Subject Request for Approval of FDA Focus Group, "Make Your Calories Count Focus Group Study";  
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 (CFSAN)/Office of Regulations, Policy and Social Sciences is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group, "Make Your Calories Count Focus Group Study," to collect information about consumer behaviors related to maintaining a healthy lifestyle and managing a healthful diet. AS TERMS OF CLEARANCE BY OMB, THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION WILL NOT DEPLOY THIS FOCUS GROUP STUDY UNTIL AFTER THE CENSUS FOOD BLACKOUT PERIOD ENDS ON AUGUST 31, 2010.

In March 2004, FDA issued "Calories Count: Report of the Working Group on Obesity." This report emphasizes the importance of public information and education aimed at helping consumers better manage their weight by making healthier food choices. One of the recommendations from the "Calories Count" report encourages FDA to focus its educational strategy on influencing behavior in the context of healthy choices for consumers. As a follow-up action to this recommendation, FDA developed the "Make Your Calories Count" (MYCC) interactive Web-based program (<http://www.fda.gov/Food/LabelingNutrition/ConsumerInformation/ucm114022.htm>).

The main goal of this focus group research is to collect information that may help us improve the usefulness of the MYCC Website. In the focus groups, participants will be discussing how they manage their diets and how they use the Nutrition Facts label.

Particularly, we will explore behavior domains such as:

- participants' daily habits related to maintaining a healthy lifestyle and managing their diet;
- what motivates (and prevents) participants with respect to paying attention to the Nutrition Facts label;
- what messages would motivate participants to use the Nutrition Facts label in order to maintain a healthy lifestyle and diet;
- what factors affect participants' interest in serving sizes/portion sizes; and
- what participants' responses are regarding current messages at the FDA "Make Your Calories Count" Website.

Eight focus groups will be conducted; four in Washington, DC and the other four in Memphis, TN. The groups will consist of women, the primary food purchasers and preparers in many households, and be segmented by race and age. Four groups will be conducted with African American women, two at each location, and the other four with Caucasian women, two at each location. Within each of the race segment, one group will consist of younger participants and the other group older participants. In order to build sufficient rapport between the moderator and participants, groups with African American women will be conducted by an African American moderator and groups with Caucasian women will be conducted by a Caucasian moderator. The current funding does not allow including women of other racial/ethnic groups in the study.

We will recruit 12 women for each group, expecting to have 8 to 10 participants per group. No more than 12 women will participate in a group.

The Contractor will contact prospective participants by telephone and screen them for eligibility. To maximize participation rate, recruiters will contact each potential participant at least five times to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene. Each respondent will also receive a \$75.00 cash incentive for their time and participation.

The time required for screening and participation will be 2.1 hours per participant. There will be a total of no more than 96 participants in eight groups, producing a total estimated respondent burden of 202 hours.

A participant screener, a moderator's guide, and stimuli ( Appendix III) to be used for the study are attached.

If you have any questions, please contact Denver Presley Jr. on 301.796.3793.

#### Attachments

Appendix I. Participant Screener

Appendix II. Moderator's Guide

Appendix III. Stimuli (Printouts of the FDA's "Make Your Calories Count" Website)