DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date

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

Subject Request for Approval of FDA Focus Group, "Factors related to Listeriosis Prevention in Pregnant Women: a 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, "Factors related to Listeriosis Prevention in Pregnant Women: a Focus Group Study", to collect qualitative consumer data using focus group discussions to explore consumer knowledge and beliefs related to listeriosis, behaviors related to listeriosis, and reactions to changing advice related to listeriosis prevention.

Listeriosis is a bacterial infection caused by *Listeria monocytogenes. L monocytogenes* is the cause of only 0.02% of foodborne infections, but causes 27.6% of deaths from foodborne infections.[1,2] Pregnant women are twenty times more likely than other adults to become infected, with consequences such as miscarriage, stillbirth, or serious illness in newborns.[3] Consumer education is an important component of listeriosis prevention and should focus on those who are at most risk.[1,4]

A literature review conducted in the fall of 2008 revealed that while pregnant women actively seek pregnancy-related information, they have both limited knowledge of *L. monocytogenes* in general and limited awareness that pregnancy increases susceptibility.[3,5,6] Further, pregnant women have also reported eating foods associated with a high risk of listeriosis, including deli meats, hot dogs, pates, and soft cheeses.[3,7,8,9] Little research has explored pregnant women's beliefs related to listeriosis, but one study found that pregnant women reacted negatively to the listeriosis prevention guidelines.[5] An additional issue related to listeriosis prevention is that the FDA guideline related to soft cheese consumption was updated following a quantitative risk assessment conducted by the FDA, the USDA and the CDC in 2003.[10] No study has been done to examine the impact of changing advice regarding listeriosis prevention on consumer behavior, but studies in other health areas suggest that conflicting or contradictory information evoked negative emotions and was linked to the adoption of less healthful behaviors.[11,12,13]

The data in many of these studies were collected prior to 2003, i.e., before the guideline was changed, or were collected from pregnant women outside the United States, where food practices differ. The current incidence of listeriosis is lower than it was in 1996, but it is still higher than the government's Healthy People 2010 objective.[14] Further, the number of reported cases of listeriosis reached its lowest point in 2002 but has increased since then.[14] Thus, a need exists for a more current understanding of listeriosis prevention in pregnant women because understanding their perceptions is a critical component in developing effective risk-related communications.[15] Qualitative methods, such as focus

groups, play an essential part in understanding the actual food safety beliefs and concerns that consumers have.

The purpose of these focus groups is to provide a current understanding of pregnant women's knowledge of listeriosis, consumption behaviors related to listeriosis, and underlying beliefs that affect the adoption of listeriosis prevention behaviors. The focus groups will also be used to examine how pregnant women respond to changing health advice, such as that related to the updated soft cheese guideline. Findings from the focus groups will be used to identify strategies for presenting listeriosis prevention information to pregnant women.

A total of six focus groups will be conducted at three different locations around the United States: Washington, DC, Boston, MA, and Philadelphia, PA. Individuals participating in the groups must be pregnant women who are 18 years of age or older. They must also have reported eating at least one of the high-risk foods in the past year (hot dogs; luncheon meat or cold cuts; soft cheeses like Feta, Brie, and Camembert, "blue-veined cheeses," or "queso blanco," "queso fresco," or Panela; refrigerated pates or meat spreads; refrigerated smoked seafood or refrigerated fish labeled as "nova-style," "lox," "kippered," "smoked," or "jerky"; or raw or unpasteurized milk or foods that contain unpasteurized milk). As a quality assurance strategy, the Research Involving Human Subjects Committee (RIHSC) at the FDA has required that participants provide verification of pregnancy from their healthcare provider, so participants will only be included if they agree to provide verification of their pregnancy.

We will recruit 12 individuals for each focus group, expecting to have 8 to 10 participants per group. No more than 12 individuals will participate in a group. The Contractor will contact potential participants by telephone and/or newspaper advertisements 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 participant will also receive a $90.00 cash incentive for her time and participation.

The time required for screening and participation will be 2 hours per participant. There will be a total of no more than 72 participants in eight groups, producing a total estimated respondent burden of 144 hours.

The findings will serve as part of the input into any future CFSAN deliberation on the design of listeriosis prevention information to pregnant women.

FDA would like to begin the study immediately upon OMB approval. Currently, there is no plan for any future surveys on this subject.

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

Attachments
Appendix I. Participant Screener
Appendix II. Moderator's Guide
Appendix III. References