FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Sodium Reduction Education; OMB Control Number 0910-0497

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), is seeking OMB approval under the generic clearance 0910-0497 to conduct a set of focus groups, "Sodium Reduction Education," to collect information for a consumer education campaign on sodium reduction. On April 21, 2010, the Institute of Medicine of the National Academies (IOM), tasked with recommending ways to reduce Americans' intake of sodium to levels consistent with the Dietary Guidelines for Americans, issued a report, STRATEGIES TO REDUCE SODIUM INTAKE IN THE UNITED STATES. The report called for government action to reduce the overall sodium content of the food supply. The IOM further called for an education program to: (1) increase consumer understanding of the importance of elevated blood pressure as a public health problem; (2) increase consumer understanding of the ubiquitous nature of sodium in the food supply and the importance of supporting government and industry activities to reduce sodium in foods; (3) change consumer attitudes toward and perceptions of lower-sodium foods; and (4) facilitate consumer understanding of the role of sodium reduction as part of an overall healthy diet. The IOM recommended consumer research to enhance current understanding of factors that impact consumer awareness and behavior relative to sodium reduction and to inform message development for a consumer education program.

2. **Intended use of information:**
   Based on IOM's recommendations, FDA/CFSAN is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, "Sodium Reduction Education." The objective of the study is to collect information on the following topics to inform the agency's development of a consumer education program:

   1) How do participants perceive their personal health risk from sodium?
   2) What kinds of messages will persuade participants to reduce their dietary intake of sodium?
   3) What kinds of strategies are participants likely to follow for reducing sodium in their diets?
   4) What are the participants' reactions to the new voluntary sodium reduction program in processed foods?

3. **Description of respondents:**
   The groups will consist of general population participants. Each focus group will include a mix of both women and men. These focus groups will be segmented based on socio-economic status (education and income) and age. Half of the groups will be conducted

with higher education/higher income participants and half with lower education/lower income participants. Additionally, half of the groups will be conducted with participants between ages of 18 to 45 and half ages 46 and over. We will recruit 12 participants for each group, and expect to have 8 to 10 participants per group. No more than 12 participants will participate in a group.

4. **Date(s) to be conducted and location(s):**
   The focus group research will begin by the end of January 2011 and be completed by April 2011. The focus groups will be conducted in four locations: Washington, DC; New York, NY; Kansas City, KA; and Seattle, WA.

5. **How the Information is being collected:**
   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.

   With the aid of a moderator's guide, a moderator will guide the group discussions.

6. **Number of focus groups:**
   There will be eight focus groups.

7. **Amount and justification for any proposed incentive:**
   The amount of the proposed incentive is $75 per participant. The justification for this incentive is to compensate them for their time and participation, and to ensure that there will be between 8 and 10 participants who show up for each group.

8. **Questions of a Sensitive Nature:**
   There are no questions of a sensitive nature in this study.

9. **Description of Statistical Methods (I.E. Sample Size & Method of Selection):**
   This study uses a qualitative research methodology and collects information from a convenience sample. The study does not plan to use any statistical methods to analyze or report the information.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Higher education/income and 18-45 years old	24	2.1	50.4
Higher education/income and 46+ years old	24	2.1	50.4

Lower education/income and 18-45 years old	24	2.1	50.4
Lower education/income and 46+ years old	24	2.1	50.4
Total	96		201.6

REQUESTED APPROVAL DATE: January 20, 2011

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FDA CENTER: Center for Food Safety and Applied Nutrition (FDA/CFSAN)