FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

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: "Claims about Natural" Focus Group Study

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

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 study, "Claims about Natural," to collect qualitative information about how consumers understand claims using the word "natural" on food labels.

FDA does not have regulations defining the word "natural" or specifying how "natural" should used on food labels. Instead, it follows a 1993 policy that states: "[FDA] has not objected to the use of the term [natural] on food labels provided it is used in a manner that is truthful and not misleading and the product does not contain added color, artificial flavors or synthetic substances." Most food manufacturers abide by this policy. Recently, however, the agency has received complaints about certain food manufacturers labeling their products as "natural" when natural spices or other natural ingredients have been added for coloring. Under the "natural" policy, adding these types of natural colorants would disqualify a product from including the term "natural" or "all natural" on the food label. However, these types of products could still claim that they are "made with all natural ingredients." FDA is interested in learning how consumers understand these various claims.

2. Intended use of information:

FDA plans to use the study to explore consumers' understanding of the term "natural" on food labels. The agency will use the knowledge as background information to identify and develop further research needs that will help dietary choices.

3. Description of respondents:

The focus groups will consist of general population participants. The groups will be segmented based on education status of the participants; half of the groups will be conducted with higher-educated participants and half with lower-educated. The groups will be also segmented by gender (six groups will be conducted with women and two groups with men). All of the participants will be primary food purchasers in their households. Two out of eight focus groups will be conducted with participants who purchase organic food on regular basis to solicit opinions from consumers who are actively pursuing healthy lifestyles. Each focus group will include a mix of ages 18 years old 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. For more details, please see Appendix I.

4. Date(s) to be conducted and location(s):

We hope to have the groups conducted in June-July 2012, in Washington, DC; Philadelphia, PA, and Richmond, VA.

5. How the Information is being collected:
With the aid of a moderator's guide (see Appendix II), a moderator supplied by the independent contractor will guide the focus group discussions that will solicit information from the participants. Participants will be asked to view a sample of food labels (see separate files) and discuss their reactions to the labels. The discussion will be recorded and transcripts will be made from these recordings. Transcripts and notes taken by the project staff will be the bases for data analysis. The NVivo software will be used to analyze data.

6. Number of focus groups:
Eight.

7. Amount and justification for any proposed incentive:
We propose to provide each participant a $75.00 cash incentive. This amount is the standard market rate that the research industry has found necessary to recruit general population participants for focus groups of comparable length of time (90 minutes).

8. Questions of a Sensitive Nature:
There will be no questions of a sensitive nature asked of participants.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):
The study is a qualitative research and will not employ any statistical methods. The study uses a convenience sample.

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)
General population respondents	96	126	201.6

REQUESTED APPROVAL DATE: August 2012

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