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: "Healthy Claims" Focus Groups

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, "'Healthy Claims Focus Groups", to collect qualitative information to explore consumers' interpretation of the term "healthy" on the food label. The purpose of these focus group studies is to explore participants' attitudes, beliefs, motivations, and reported behaviors related to foods that use a "healthy" claim. The results from this study will assist with internal discussions about consumers' understanding and use of the term "healthy" on the food label.

2. Intended use of information:

Studies show that Nutrient Content Claims (NCC's) have an effect on consumers' beliefs about product healthfulness and can influence purchase and consumption decisions. Some NCC's make explicit reference to a nutrient (e.g., free of fat). Other NCC's imply that the food helps consumers maintain healthy dietary practices. The implied NCC "healthy" has specific requirements for its use on the food label. The food is required to have certain minimal levels of total fat, saturated fat, carbohydrate, and sodium and contain certain levels of vitamins, minerals, protein, and fiber. Recently, however, developments in nutrition science about the role of some of these nutrients in promoting or maintaining people's health have led to interest in reconsidering the requirements for allowing the use of "healthy" and related terms (e.g., "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") on the food label. The focus groups will explore consumers' current understanding of "healthy" and the potential for misunderstanding if some of the regulatory requirements change.

3. Description of respondents:

A total of 12 focus groups are planned. Groups will include only adults (18+) of various racial/ethnic backgrounds, segmented by education; 6 of the focus groups will be held with those with 2 years or more of college or higher educational attainment and 6 groups will be held with those with less than two years of college. (See Appendix I)

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

Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted in three locations: Northeast/Mid-Atlantic/South, West Coast, and Mid-West.

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. The focus group 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. Transcripts and notes will be used to analyze data.

6. Number of focus groups:
Twelve focus groups of 8 to 10 participants in each group will be conducted.

7. Amount and justification for any proposed incentive:
To prepare for these focus groups, we consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of $75 to show a token of our appreciation to participants. The incentives will ensure that we are able to attract a reasonable cross section of participants who meet our screening requirements to participate in the focus groups.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs, but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

Our proposed incentive amounts will help ensure that respondents honor their commitment of participating in the focus groups. Incentives are based on 1) estimated costs related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately $48[1]; 2) an estimated cost for an average driving commute to and from the facility of approximately $18[2]; and 3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[3] The proposed amounts are comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. As noted above, we expect that lower or nonmonetary

[1] Assumes an hourly rate of $16 per hour for a professional babysitter
[2] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf, accessed 7/1/2016.
[3] See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, *16*(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

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):
This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix II). Sufficient recruits will be screened in order to achieve a target of 8-10 participants per group. To maximize participation rates, recruiters will make at least 5 attempts to contact each potential participant to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	600	5	50
Adult 18+	144	120	288
Total			338

REQUESTED APPROVAL DATE: April 7, 2017.

Ila S. Mizrachi (PRA Analyst)
Ila.Mizrachi@fda.hhs.gov
301-796-7726

Linda Verrill (Program Contact)
Linda.Verrill@fda.hhs.gov
240-402-1765

FDA CENTER: Center for Food Safety and Applied Nutrition