

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: Nutrition Facts Label Campaign Focus Groups (Formative Research and Stimulus Testing)

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 Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, “Nutrition Facts label Campaign Focus Groups (Formative Research and Stimulus Testing).”

On May 27, 2016, the FDA published a final rule in the Federal Register revising the format and appearance of the Nutrition Facts label (NFL) for packaged foods. The newly redesigned label provides consumers with access to information to help them make informed decisions about the foods they eat. The final rule states that FDA intends “to update our existing educational materials and create new educational opportunities to explain how to use the label to help consumers make healthy dietary choices, with an emphasis on each of the new changes of the label.”¹ This focus group study will assist FDA in this effort by collecting qualitative information to help develop educational messages about FDA’s newly redesigned NFL. The study will be split up into two phases: Phase 1 will test draft consumer awareness concepts, and Phase 2 will test draft educational messages.

This OMB submission covers Phase 1 of the study—Concept Testing. This study will explore participants’ reactions to draft consumer awareness concepts designed to attract consumers’ attention and invite them to look for the newly redesigned NFL in the marketplace and seek information on it.

FDA plans to complete all focus groups for this first phase by November 2018. FDA will use the findings to inform development of consumer education and outreach materials about the NFL, which we plan to test in Spring 2019 (Phase 2). We intend to have final materials ready prior to the NFL implementation date of January 1, 2020.

2. Intended use of information:

This information collection request involves qualitative research that will be used to inform development of consumer awareness concepts to encourage consumers to look for the newly redesigned NFL in the marketplace and seek information on it.

¹ Food Labeling: Revision of the Nutrition and Supplement Facts Labels. 81 FR 33741 (2016).

3. Description of respondents:

All groups will include primary shoppers ages 35-50 years, of households consisting of at least 2 individuals, including the participant. The study will enroll participants who make most of the decisions about food purchases for their households, and purchase most of their household's food in person (as opposed to online). The groups will be segmented by education (lower education; higher education). Within these groups, there will be a mix of genders, ages, and races/ethnicities. No more than 10 participants will participate in a group (see Appendix I, Participant Screener). We will recruit 12 participants for each group, and expect to have 8 to 10 participants per group. FDA has contracted with RTI International to conduct these in-person focus groups.

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 regions of the United States: Mid-Atlantic, West Coast, and Mid-West. These regions were chosen to represent consumers from a range of geographic locations and population size and diversity. The selected regions offer suitable focus group facilities and recruitment capabilities that will enable us to recruit the desired participants, who meet the criteria described in section 3 above.

5. How the Information is being collected:

Recruitment Information

Staff from the focus group facilities will use their in-house databases to recruit participants via telephone using the participant screener (Appendix I). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants are present for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

RTI staff members will serve as moderators for all focus groups. FDA staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology.

The moderator will use the attached moderator guide (Appendix II) to ensure that all relevant topic areas are addressed. The focus group facilities will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

Appendix III - NFL Concepts presentation, Appendix IV - old-to-new label presentation, and Appendix V - consent form are included in this individual generic submission.

6. Number of focus groups:

A total of 6 focus groups are planned for this phase.

7. Amount and justification for any proposed incentive:

In preparation for these focus groups, RTI consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of \$75 for 90 minutes to ensure that we are able to attract a reasonable cross section of participants who earn household incomes within our preferred range.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the 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 amount will help ensure that respondents honor their commitment of participating in the focus group focus groups. Our incentive was chosen based on: (1) an estimated cost 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 \$48²; (2) an estimated cost for an average driving commute to and from the facility of approximately \$18³; 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.⁴ The proposed amount of \$75 is comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. Caregivers of young children are often more difficult to recruit than more

² Assumes an hourly rate of \$16 per hour for a professional babysitter

³ Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf

⁴ 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.

general audiences and the incentive needs to be enough to help the participants cover outside childcare costs if needed. As noted above, we expect that lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

The importance of monetary compensation for focus group participation has been discussed by Krueger and Casey (2014), who indicate that offering monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.⁵ Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups.⁶ Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)⁷ and internal proprietary research conducted by our contractor, RTI.

8. Questions of a Sensitive Nature:

None.

9. Description of statistical methods (i.e., sample size & method of selection):

This study employs qualitative methods and does not entail the use of any statistical methods.

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

Table 1 shows the estimated annual reporting burden for the groups, assuming 10 participants per group.

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	480	5	40
Focus group discussion	60	90	90
Total			130

REQUESTED APPROVAL DATE: August 24, 2018

⁵ Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

⁶ Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79.

⁷ Berlin, M., L. Mohadjer, J. Waksberg, A. Kolstad, I. Kirsch, D. Rock, & K. Yamamoto. An experiment in monetary incentives. American Statistical Association, Proceedings of Survey Research Methods Section; Alexandria, VA: 1992. pp. 393-398.

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