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

Focus groups do not yield quantitative findings. They can provide public input, but they do not yield data about public opinion that can be statistically 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 Icon Focus Groups – Phase II

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, "Healthy Icon Focus Groups - Phase II."

On January 11, 2018, the FDA issued a Strategic Policy Roadmap[1] outlining key priorities the agency intended to pursue to advance its public health mission. As part of the Roadmap, the FDA outlined a Nutrition Action Plan aimed at reducing preventable death and disease caused by poor nutrition by ensuring that consumers have access to accurate, useful information to make healthy food choices. One of the steps under this Action Plan involves leveraging dietary information to reduce the burden of disease through nutrition and encouraging the development of more healthful food options. As one of the methods for achieving this step of the Action Plan, the FDA is developing a graphic symbol to help consumers identify packaged food products that would meet an FDA definition for "healthy." The symbol would be voluntary, allowing packaged food companies to place it on their products if the products meet the FDA definition of "healthy."

On April 4, 2019, OMB approved without change, Phase I of this focus group project (ICR Reference Number 201707-0910-018). In the Phase I request, FDA described the extant literature on front-of-pack (FoP) icons and its own systematic literature review, from which the Phase I focus groups were developed.

The global literature take-aways are:

- A FOP rating system or symbol can help consumers identify and select healthy foods;
- Consumers generally prefer simple labels (such as the ones using a summary system);
- There is limited research on: (1) which type of summary system works best and; (2) whether consumers' use of summary systems result in healthier diets;

[1] Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap. https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm. Accessed 11-27-18.

- Some manufacturers have reformulated products following the implementation of FOP nutrition symbols; there is some evidence of increased sales of products bearing a FOP symbol; and
- Institutional endorsement of logos may be related to greater confidence in the label.

Phase I Focus Group Results

The FDA/CFSAN Graphics Department had developed some "healthy" symbols or icons for testing in the Phase I focus groups. The intention was to get participant feedback on thematic and stylistic differences. Themes included testing a graphic inspired by the Nutrition Facts Label, graphics that were circular and square, one inspired by the UDSA organic icon, and others inspired by the MyPlate symbol. Each of these themes had four styles: "Healthy" alone on the icon, including "FDA," an explanation for why the product is deemed healthy, and a version showing the food groups that might render the product "healthy' by FDA standards.

Data from the Phase I focus groups were analyzed using the topline summaries from each group and noting general responses to each of the early prototype themes and styles. The major top-line findings are:

- Many participants did not automatically recognize the NFL-inspired icon but could easily see it when prompted;
- Participants expressed strong preference for circles or soft lines versus squares;
- Many suggested using the color green as symbolic of healthy;
- Most did not like vertical lettering;
- Many did not like redundancy; when "healthy" appeared twice;
- Participants preferred icons identifying the sponsor.

Results from the Phase I focus group testing of early icon prototypes —wherein FDA explored icon themes and styles using a wide variety of in-house developed icons— will guide (but not limit) the development of more icon prototypes for further testing.

Phase II "Healthy" Icon Focus Groups

The Phase II focus groups will be a follow-on of the Phase I focus groups, wherein the results from Phase I have informed a set of professionally produced icons for focus group testing (see Phase II icons in Appendix I).

These professionally-developed icons fall into 7 themes. Each theme has 3 or 4 stylistic variations (e.g., different colors, borders or no borders, placement of "FDA"). Phase II Icon themes are listed below:

1. Sunrise
2. Checkmark
3. Fresh
4. Checkmark/Fresh
5. Leaf
6. Food Groups
7. FDA Banner

The Phase II focus group results will help FDA narrow down the designs, from among those tested, that may best resonate with consumers, and help FDA gain a better understanding of how consumers might use symbols in making healthier food choices. The focus group results will also help FDA in developing future quantitative research that might be used for providing guidance or regulations for a voluntary symbol for "healthy" for use on the food label.

2. **Intended use of information:**

The eight (8) focus groups requested in this package are the second phase of the planned two (2) phases of focus groups (Phase I groups were approved on 4-4-2019). A professional communications firm with experience in developing logos consulted with FDA on the first set of focus groups and used the findings from Phase I to produce a new set of icons for testing.

The results of the Phase II focus group will inform future quantitative studies to more systematically test icon effects. A reduced number of icon prototypes will be subject to two sets of online market research surveys and an online experiment. The information gathered from the overall research plan will help FDA assess the potential for a "healthy" icon to help consumers make healthier food choices. A separate information collection request will be submitted for the quantitative part of the research.

3. **Description of respondents:**

Groups will include only adults (18+) and will be segmented by level of nutrition motivation (high and low nutrition motivation), assessed using two questions that will gauge participants use of the Nutrition Facts Label. Segmenting by nutrition motivation will help FDA clarify differences between levels of motivation and learn how best to convey "healthy" in a way that appeals to individuals not already motivated to making healthy food choices.

Groups will also be segmented by education level with half the groups being comprised of individuals with some university level courses and higher and half with a community college degree and lower. The groups will have a mix of ages, race/ethnicities, and genders. No more than 10 participants will participate in a group (see Appendix II, Participant Screener).

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

Focus groups will be conducted approximately one month from the date of OMB approval. The study will enroll participants who reside in the Washington, DC metro area, the Midwest, and the Southwest US. The selected locations offer suitable focus group facilities and recruitment capabilities that will enable us to recruit groups 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 II). 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 show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

The moderator will use the attached moderator guide (Appendix III) 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.

6. **Number of focus groups:**

A total of 8 focus groups of 8 to 10 participants will be conducted.

7. **Amount and justification for any proposed incentive:**

Facilities that recruit and host focus groups have shared with us the amounts for tokens of appreciation for participants' time. We propose $75 for 90 minutes to ensure that we can attract a reasonable cross-section of participants.

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 must reschedule their participation in the focus group.

Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the 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 $48[2]; (2) an estimated cost for an average driving commute to and from the facility of approximately $18[3]; 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 is comparable to what has been the level of reimbursement for the target audiences in similar government-funded activities. Parents of young children are often more difficult to recruit than more 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 minimal levels of 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] When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation and treats them justly and with respect by recognizing and acknowledging

[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.

[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.

the effort they expend to participate.[7] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[8] and internal proprietary research conducted by our contractor, FMG.

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 Contractor will contact prospective participants by telephone and screen them for eligibility to participate (Appendix II). 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 show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

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

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

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	300	5	25
Focus group discussion	80	120	160
Total			185

REQUESTED APPROVAL DATE: September, 2019

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[7] Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*, *164*(7), 801-803.

[8] 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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