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 (Symbol) Focus Groups – Phase III

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 (Symbol) Focus Groups - Phase III."

   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 exploring the development of 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 (hereafter called symbols) and its own systematic literature review, from which the Phase I focus groups were developed.

   The global literature take-aways are:

   - An 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);

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

- 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;
- Some manufacturers have reformulated products following the implementation of FOP nutrition symbols; there is some evidence of increased sales of products bearing an 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 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 seal, and others inspired by the MyPlate symbol. Each of these themes had four styles: "Healthy" alone on the symbol, 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.

The Phase I focus groups were analyzed using the transcripts 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 symbol but could easily see it when prompted;
- Participants expressed strong preference for circles or soft angles versus squares;
- Many suggested using the color green as symbolic of healthy;
- Most did not like vertical lettering;
- Many did not like redundancy, e.g., when "healthy" appeared twice;
- Participants preferred symbols identifying the sponsor.

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

Phase II "Healthy" Symbol Focus Group Results

OMB approved the Phase II Healthy Symbol Focus Groups on 9-10-19 (ICR Reference Number 201707-0910-018) and approved an additional symbol for testing in the Phase II groups on 10-22-19 (Same reference number).

The Phase II focus groups tested a set of professionally produced symbols that fell into 8 themes. Each theme had 3 or 4 stylistic variations (e.g., different colors, borders or no borders, placement of "FDA"). Phase II symbol themes are listed below:

1. Sunrise
2. Checkmark
3. Fresh
4. Checkmark/Fresh
5. Leaf
6. Food Groups
7. FDA Banner
8. USDA “My Wins”-inspired (added to the final two groups)

The goal of the Phase II focus group was to narrow down the professionally-produced designs from among those tested and help FDA gain a better understanding of how consumers might use a “healthy” FOP symbol in making healthier food choices.

Takeaways from the Phase II focus groups are that symbols without organizational attribution are largely ignored or seen as manufacturer marketing devices. The focus groups also revealed that it is difficult to invoke “nutritional health” with a symbol because: (1) recognizable imagery carries halos (e.g., a sunrise symbolizes morning, a leaf symbolizes “plant-based”); and (2) colors communicate beyond a symbol’s intention (e.g., green symbolizes the environment; red symbolizes “stop”). Researchers concluded from the Phase II focus groups that an eye-catching, high-contrast symbol – with organizational attribution – could work as a front-of-pack “Healthy” symbol.

In addition to helping to narrow down the group of potential FDA “Healthy” symbols, the Phase II focus group discussions raised further research questions – described in the next section.

Request for Phase III “Healthy” Symbol Focus Groups

It was clear following the Phase II focus groups that further qualitative research was necessary for testing symbol design modifications resulting from the Phase II groups and to explore new research questions before any quantitative study of “healthy” symbols is pursued.

For example, will a more complex or interesting font - versus a simple font - improve interest and contrast; does including a URL in the symbol help participants understand that there is a place (website) they can go to for information; do modifications away from using the color green and obvious leaves reduce references to “environmental health” and “plant-based”?

The set of 9 symbols to be tested in the Phase III focus groups (Appendix I) incorporate the information gained from the two previous sets of focus groups. This current set can be summarized according to the following themes:

Symbol #	Theme
1	USDA Organic-like
2,3	Leaf shape
4,7	Leaves inside
5,6	Waterdrop with wavy "Healthy"
8,9	Rounded square with check

In addition to the themes, the symbols also vary by the following characteristics: contrast, font (official FDA font; wavy, use of caps), and URL and participants will be asked to compare symbols based on these.

2. **Intended use of information:**

This package is requesting approval of eight (8) online focus groups for a third phase of "Healthy Symbol" focus groups. As in Phases I and II, Phase III focus groups will be used to explore and test draft "healthy" symbols that would graphically indicate the nutrient content claim "Healthy" and will be available to manufacturers for voluntary usage on the label. FDA continues to work with the professional communications firm that used the findings from Phase I to produce the set of symbols tested in the Phase II groups.

As identified above, the Phase III focus groups will be used to test symbol design modifications resulting from the Phase II groups and explore new research questions arising from the Phase II groups. The intention is that the results of the Phase III focus group will inform quantitative studies to more systematically test symbol effects. Following the Phase III focus groups, a reduced number of symbols will be subject to two sets of online market research surveys and an online experiment. The body of research involved in the exploration of a "healthy" symbol will help FDA assess the potential for a "healthy" symbol to help consumers make food choices. A separate information collection request will be submitted for the quantitative 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 6 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. By holding the focus groups online, the study will enroll participants from locales across the United States.

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 receive the web-link to participate in the groups from their preferred locations. Facilities will conduct recruitment and ensure that the needed number of participants appear for their scheduled time slot. The facilities will send confirmation and reminder correspondences to the recruited participants to help ensure participation.

   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 with 6 participants each will be conducted.

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

   To prepare for these focus groups, we consulted with facilities and recruitment vendors that host and recruit online focus groups to determine incentive rates. Based on these consultations, we propose an incentive amount of $75 as a token of appreciation, to be dispersed after the discussion has ended. The incentives will ensure that we are able to attract participants who meet our screening requirements to participate in the online focus groups and improve the likelihood that they will show for the discussion.

   The proposed incentive amount is below market rate for focus groups, whether online or in-person. Recruiting firms and researchers determine market rates for research participation based on what other comparable studies in the field are offering and what rate will incentivize the required population to participate in the research. Vendors

estimate that studies conducted with similar populations and levels of effort in this market at this time pay incentives of $100-$150. Our proposed incentive is based on participants spending approximately two hours of their time on this effort, which includes time spent for online and phone screening (5 minutes), time for testing the platform (10 minutes), time to participate in the focus group (90 minutes), and the request to log in 15 minutes early to confirm technical operation. The Bureau of Labor Statistics (BLS) calculated that the average hourly wage of employees on private nonfarm payrolls in June 2020 is $29.37 (Bureau of Labor Statistics, 2020)[2]. At that hourly rate, compensation for two hours is approximately $60. Additional factors contributing to the cost of our proposed incentive include:

- Participants are required to join the group from a quiet location where there are no distractions, which may require childcare or special accommodations during that time. BLS calculated in May 2018 that the average hourly wage of childcare workers is $11.83, making the average cost of two hours of childcare $24 (Bureau of Labor Statistics, 2018)[3]

- The focus groups will be conducted online, and participants must have a computer and broadband Internet to participate in the groups; participating will use approximately two hours of data on their Internet plans.

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.[4] 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.[5] 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 the effort they expend to participate.[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, FMG.

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[2]Bureau of Labor Statistics, U.S. Department of Labor, Economic News Release, on the Internet at https://www.bls.gov/news.release/empsit.t19.htm (visited July 6, 2020).
[3]Bureau of Labor Statistics, U.S. Department of Labor, Occupation Employment Statistics, on the Internet at https://www.bls.gov/oes/2018/may/oes399011.htm (visited July 6, 2020).
[4]Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.
[5]Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79.
[6]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.
[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.

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 access the web portal where the groups will take place on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants participate during 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 6 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	72	5	6
Testing Platform and logging into system	48	25	20
Focus group discussion	48	90	72
Total			98

List of all attachments:

a. Appendix I: "Healthy" Symbols
b. Appendix II: Participant Screener
c. Appendix III: Moderators Guide
d. Appendix IV: Phase III Healthy Symbols Information Piece
e. Appendix V: Confirmation and Reminder Letters

REQUESTED APPROVAL DATE: July, 2020

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