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 Icon Focus Groups – Phase I

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 1."

In January 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."

Scientific Support for a "Healthy" Icon

In Spring of 2018 (and continuing) FDA conducted a thorough review of the scientific literature on front-of-pack (FOP) symbols, noting that there had been several such reviews conducted in the recent past. The seminal pieces include a 2005 literature review on consumer understanding and use of nutrition labeling which summarized more than 100 studies[2]. The review concluded that that interpretational aids could contribute to consumers making healthy point-of-purchase choices and moreover, that these aids could help consumers interpret the contribution of the food to the overall diet.

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

[2] Cowburn and Stockley. 2005 Consumer Understanding and Use of nutrition labeling: a systematic review. Public health Nutrition 8(1):21-28.

The first large systematic review of FOP nutrition indicators was conducted by the National Academies of Science[3]. This groundbreaking report, requested by Congress, evaluated the international landscape on FOP nutrition symbols generated by manufacturers, supermarkets, organizations, and governments. The report discusses three types of FOP symbols: 1) Nutrient-Specific Systems; 2) Summary Indicator Systems; and 3) Food Group Information Systems. The overall conclusion was that a FOP rating system or symbol could help consumers identify and select healthy foods, that calories and serving size would be helpful to include in the symbol, and that further testing of consumer use and understanding of "nutrient-specific information" or a "summary indicator" would be necessary. The Institute of Medicine (IOM) report also concluded that a FOP symbol should be geared toward the general population.

The IOM produced a Phase II report[4], focused on consumers' use of FOP symbols. The Phase II report concluded that, for a FOP symbol to encourage healthier food choices, a simple summary symbol "…that serves as a signal or cue…" would be better than detailed information about nutrient content; the Phase II report recommended "…shifting from an informational approach to an interpretive one…," and asserted that a successful symbol system would encourage product reformulation or development of products that meet the criteria.

Meanwhile, FDA commissioned a literature review to update the Cowburn and Stockley (2005) literature review discussed above. The 2011 FDA review (published by Hersey, et al, 2013)[5] looked at scientific studies on FOP and Shelf Label Nutrition Systems - to learn which types of FOP systems are most effective for influencing healthy food choices. This literature review found that summary systems incorporating text and color worked better than those using only numeric information in attracting consumer attention and getting them to make healthier food choices.

In 2016, FDA commissioned an update to the 2011 literature review discussed in the previous paragraph. This update captured the scientific literature on FOP from 2010 to August 2016[6]. Similar to previous reviews, the Addendum reported that 1) the literature suggests that graphic elements help consumers with food purchase decisions; 2) consumers – especially diverse subpopulations - prefer simple labels over those that have numerical information; 3) color coding with some text leads to better understanding of the nutrition information; 4) there is not enough evidence to indicate exactly which type of FOP label most influences consumers behavior; and 5) there is some evidence that

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3 IOMa (Institute of Medicine). 2010 Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report. Washington, DC: The National Academies Press.

4 IOMb (Institute of Medicine). 2012. Front-of-Package Nutrition Ratings Systems and Symbols: Promoting Healthier Choices. Washington, DC: The National Academies Press.

5 Hersey, JC, KC Wohlgenant, JE Arsenault, KM Kosa, MK Muth. 2013. Effects of front-of-package and shelf nutrition labeling systems on consumers. Nutrition Reviews. 71(1):1-14.

6 Research Triangle Institute (RTI). 2016. Addendum to Policy Research for Front of Package Nutrition Labeling: Environmental Scan and Literature Review. Report prepared for U.S. Food and Drug Administration.

FOP labels influence sales but no evidence on whether they lead to decreasing consumption of nutrients to limit or increasing consumption of nutrients to get enough of.

FDA reviewed the scientific literature from August 2016 to present, using the same targeted database search algorithm and the analytical categories used in earlier reviews. Currently, 44 scientific articles on FOP have been analyzed. In a nutshell, the findings from the scientific literature are robust; the updated FDA review did not yield results different from what the literature has already revealed.

Although the scientific literature on FOP is nuanced, there are some global take-aways:

- 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.
- 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.
- Institutional endorsement of logos may be related to greater confidence in the label.

Prototype Icons for Eliciting Information from Consumers

For the purposes of initial consumer testing, FDA graphic designers developed a set of FOP "healthy" icons varying in style and text (See draft icons in Appendix I). These prototype icons will be used to elicit information from consumers about the various elements of the icons (e.g., imagery, text, color). The information will be used to develop a refined set of icons for additional consumer testing. FDA has contracted the services of a professional communications firm to design the refined set of icons. The prototypes fall into six themes:

1. NFL check
   These icons are designed to resemble the format of the Nutrition Facts Label.

2. Postage Stamp

3. Stylized text

4. USDA Organic-inspired
   These icons are designed to resemble the USDA Organic icon.

5. Circle icons

6. MyPlate-inspired
   These icons incorporate elements of the USDA/FSIS MyPlate logo.

These themes were selected to elicit responses from consumers about a variety of elements in the icons, such as shape or style (postage stamp, circle, stylized text), resemblance to other food related icons (USDA Organic, MyPlate), and the potential for implied government endorsement (NFL check, MyPlate).

Within each theme, the icons are characterized by subthemes related to the use of language or explicit references to FDA. The subthemes represent icons 1) without reference to FDA; 2) with "FDA" explicitly listed; 3) with the explanatory text "Meets FDA criteria for Healthy"; and 4) references to the food groups that make the product meet the FDA definition for "healthy."

The focus group results will help FDA gain a better understanding of the icon elements that are most useful to consumers, work best for gaining consumers' attention, and that will potentially influence purchasing decisions.

FDA is developing the "healthy" icons in consultation with the USDA Center for Nutrition Policy and Promotion (CNPP). CNPP is the USDA center responsible for the MyPlate initiative.

2. **Intended use of information:**

The eight (8) focus groups requested in this package will be the first set of a planned two (2) phases of focus groups (a separate data collection request will be submitted for the second phase). A professional communications firm with experience in developing logos and icons will be consulting with FDA on the first set of focus groups and will use the findings to refine FDA's prototype icon designs. The refined designs will be evaluated in the second phase of the focus groups. Ultimately, results from the two sets of focus group will inform studies to more systematically test icon effects. 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. Separate information collection requests will be submitted for each part of the research.

3. **Description of respondents:**

Groups will include only adults (18+) and will be segmented by level of nutrition motivation, assessed using two questions that will gauge participants engagement with - and commitment to good dietary practices. 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 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 $48[7]; 2) an estimated cost for an average driving commute to and from the facility of approximately $18[8]; 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.[9] 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.[10] 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.[11] 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.[12] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin

[7] Assumes an hourly rate of $16 per hour for a professional babysitter
[8] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf
[9] 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.
[10] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.
[11] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79.
[12] 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.

and colleagues (1992)[13] 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: April, 2019

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[13] 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.