

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: Food Allergen Advisory Labeling 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 of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, “Food Allergen Advisory Labeling Focus Groups.”

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282, Title II) is an amendment to the Federal Food, Drug, and Cosmetic Act that requires that the label of a food containing an ingredient that is or contains a protein from a “major food allergen” declare the presence of the allergen in the manner described by the law. It was meant to improve food labeling for millions of consumers who suffer from food allergies. However, FALCPA does not cover the unintentional or unavoidable presence of allergens due to situations such as cross contact, e.g., through shared equipment. Allergen advisory statements are often used voluntarily by manufacturers on food packages to inform consumers of the possible presence of allergens in foods, however, these advisory statements have no specific or uniform criteria or conditions under which the statements should be used. Research suggests that consumers view the statements differently and take different actions based on the specific language of the statement¹ and therefore, potentially put themselves at risk of adverse reactions. FDA’s position is that these statements may not be used in lieu of current Good Manufacturing Practices (cGMPs). However, until recently, as explained below, FDA did not have cGMPs specific to the handling of allergens.

One of the directives of FALCPA was to prepare a report that described:

- the various types of advisory labeling (such as labeling that uses the words “may contain”) used by food products
- the conditions of manufacture of food that are associated with the various types of advisory labeling; and

¹ Verrill, L and C. Choiniere. 2009. Are Food Allergen Advisory Statements Really Warnings? Variation in Consumer Preferences and Consumption Decisions. *Journal of Food Products Marketing*. 15:139-151.

- the extent to which advisory labels are being used on food products

In 2008 FDA published a notice of public hearing and a request for comment that solicited comments and information to assist the agency in determining how manufacturers currently use advisory labeling, how consumers interpret different advisory labeling statements, and what wording was likely to be most effective in communicating to consumers the likelihood that an allergen may be present in a food. The agency was also interested in receiving comments about whether consumers found advisory labeling helpful for making food purchasing decisions. Later in 2008 FDA held a public hearing to discuss the questions. The comment summary was compiled by the agency at the same time that the Food Safety Modernization Act (FSMA) had directed the agency to update the cGMPs regulation. One of the updates included the addition of an allergen control plan which would affect the development of an allergen advisory labeling strategy, because FDA now has criteria for cGMPs for allergen control and handling.

Currently FDA is in the process of completing a long-term strategy to assist manufacturers in using allergen advisory labeling that is truthful and not misleading, conveys a clear and uniform message and adequately informs food-allergic consumers and their caretakers. The focus groups will help inform a long-term strategy for use of advisory labeling on prepackaged food that clearly communicates to the allergic consumer and their caregivers' necessary information about the potential presence of food allergens. The focus group results will also help FDA to gain a better understanding of how food allergic consumers and their caregivers currently use the advisory labels, what information they are looking for as far as advisory labels, and what specific wording may influence their purchasing decisions.

2. **Intended use of information:**

The qualitative information collected from this study will provide important information about consumers' perceptions and reactions to potential food allergen advisory statements.

3. **Description of respondents:**

Groups will include only adults (18+) and will be segmented by a) food allergic individuals and b) parents/caregivers to children with a food allergy.

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 I, 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 of 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 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 II) and mock food labels (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 as a token of our appreciation 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 \$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 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 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.

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.

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

8. Questions of a Sensitive Nature:

None.

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 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 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: May 7, 2019

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Research Methods Section; Alexandria, VA: 1992. pp. 393-398.