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: Safety Alert and Outbreak Advisory Templates Testing Focus Group

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, "Safety Alert and Outbreak Advisory Template Testing Focus Group".

   It is estimated that about 1 in 6 Americans (48 million people) get sick each year due to foodborne diseases, among which 128,000 are hospitalized, and 3,000 die[1]. As such, mislabeled or contaminated food products may pose a serious threat to public health. To reduce or prevent adverse health impacts associated with potentially mislabeled or contaminated food products, it is crucial to identify the source of the issue, as well as to effectively inform and communicate with the public.

   As the government agency responsible for protecting the public health by ensuring the safety of our nation's food supply and cosmetics, FDA Center for Food Safety and Applied Nutrition (CFSAN) uses safety alerts and outbreak advisories to inform the public when an FDA/CFSAN-regulated product (i.e. food and beverages, dietary supplements, infant formula, and cosmetics) is mislabeled, presents a health risk because of contamination, or has caused an outbreak of illness. These messages are posted on the FDA website, and are designed to reach the public, industry, retailers, as well as other stakeholders.

   To further improve FDA's communication and messaging, FDA is planning to conduct focus groups to better understand how consumers understand and react to safety alerts on food and cosmetic products, as well as outbreak advisories posted on FDA website. The goal of this study is, by testing different safety alert and outbreak advisory templates with consumers, to better understand consumer preferences toward different ways of formatting FDA safety alert and outbreak advisory messages. Specifically, the research is designed to explore how to best frame the FDA safety alerts and outbreak advisories so the public can be informed and be able to take actions to protect themselves during such public health emergencies.

[1] U.S. Centers for Disease Control and Prevention. Food Safety Homepage, https://www.cdc.gov/foodsafety/foodborne-germs.html.

For the purpose of this message testing effort, FDA is planning to show focus group participants different safety alerts and outbreak advisories (with selected products and templates), using three real cases that happened in the past. Each case has three message templates (see Appendix I, Message Templates):

1. Safety alert for infant formula:
    - Template 1
    - Template 2
    - Template 3
2. Safety alert for tattoo ink:
    - Template 1
    - Template 2
    - Template 3
3. Outbreak advisory for romaine lettuce:
    - Template 1
    - Template 2
    - Template 3

2. **Intended use of information:**

The qualitative information collected from this study will provide findings on how to best frame FDA/CFSAN safety alert and outbreak advisory messages, thus provide valuable feedback to FDA/CFSAN stakeholders on how to further enhance FDA/CFSAN's messaging and communication on food and cosmetic safety issues.

3. **Description of respondents:**

FDA has contracted with RTI International to conduct a total of 12 in-person focus groups.

Groups will include only adult individuals (18+). Groups will be segmented by: (1) infant formula usage (half of the participants will be infant formula users/parents of young children and half will be tattoo ink users and potential users); (2) education level (half of participants with some university level courses and higher and half with a community college degree and lower); and (3) device type (half of the participants will read the testing messages on a laptop and half will read the messages on a cell phone).

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):**

Given the ongoing COVID-19 pandemic, the groups will be conducted after receipt of OMB approval and when it is safe to do so.

The focus groups will be conducted in the Washington, DC metro area; St. Louis, MO; and Phoenix, AZ. The selected locations offer suitable focus group facilities and

recruitment capabilities that will enable us to recruit 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

An RTI International staff member will serve as moderator 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 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 12 focus groups with 6 participants in each will be conducted.

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

To prepare for these focus groups, we consulted with facilities that recruit and host focus groups to determine appropriate amounts as tokens of appreciation for participants' time. Based on these consultations, we propose offering $75 for 90 minutes as a token of our appreciation to ensure that we are able to 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 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 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 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.

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[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 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):**

   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	300	5	25
Focus group discussion	72	90	108
Total			133

REQUESTED APPROVAL DATE: March 30, 2020

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila S. Mizrachi (PRA Analyst)
Ila.Mizrachi@fda.hhs.gov
301-796-7726

Fanfan Wu (Program Contact)
Fanfan.Wu@fda.hhs.gov
240-402-1808

FDA CENTER: Center for Food Safety and Applied Nutrition (CFSAN)