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: Dietary Supplement Education Focus Groups (Formative Research)

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, "Dietary Supplement Education Focus Groups (Formative Research)."

This request was originally approved by OMB on February 19, 2020. Due to the COVID-19 pandemic, FDA was only able to conduct approximately half (9 of 17) of the focus groups requested before the generic clearance timeframe expired on October 30, 2020. OMB No. 0910-0497 was reapproved on November 3, 2020 for a period of 3 years and now expires on November 30, 2023. This request is for OMB to approve the remaining burden hours needed to complete this project. The remaining 8 groups are planned for December 2020.

Dietary supplement use is common in the United States and is generally perceived by consumers as a healthy and low-risk behavior. However, dietary supplements often make unsubstantiated claims about purported health benefits and can pose health risks, including interactions with prescription medications. While the risks and benefits of dietary supplement use vary by population, consumers and even health professionals often lack awareness of these risks and how to determine or advise patients on appropriate dietary supplement use.[1,2,3]

The remainder of this focus group study will follow the protocol of the individual generic submission approved by OMB on February 19, 2020 and will collect qualitative information to help develop educational messages and materials about dietary supplements. The study comprises two phases: Phase 1 is formative research and will explore consumer attitudes, behavior, and knowledge about dietary supplements as well as test draft consumer education concepts, and Phase 2 will test draft educational

[1] Qato, DM, Wilder, J., Schumm, MA., et. al., Changes in Prescription and Over-the-Counter Medication and Dietary Supplement Use Among Older Adults in the United States, 2005 vs 2011., JAMA Intern Med. 2016; 176(4):473-482.
[2] Mintel. "Supplements - U.S., October 2019. Mintel Reports. FDA Library, College Park, MD., October 15, 2019.
[3] Bailey, R.L., Gahche, J.J., Miller, P.E., et al., Why U.S. Adults Use Dietary Supplements. JAMA Intern Med. 2013; 173(5):355-361.

messages. This OMB submission covers the completion of focus groups associated with Phase 1 of the study.

FDA plans to complete the remainder of all focus groups for this phase by December 31, 2020. FDA will use the findings to develop dietary supplement educational materials which will be tested in Phase 2 of the study.

2. **Intended use of information:**

This information collection request involves qualitative research that will be used to develop consumer education and outreach materials about dietary supplements.

3. **Description of respondents:**

FDA is planning on developing two sets of education materials for two distinct groups: 1. Older adults (ages 55 and older) and 2. Younger adults (ages 18 to 35). A total of 17 groups will be conducted: 8 groups will be with the older adults and 9 groups with the younger adults. All the groups will exclude those who work or have immediate family members who work in heath care or public health, market research, or for food related government agencies.

Within the older adult groups, half of the groups will be with those aged 55 to 64 and half will be aged 65 to 80. The older adult groups will also be segmented by education (lower education; higher education). There will be a mix of genders, and races/ethnicities in the groups.

Within the younger adult groups, 3 of the groups will be with 18 to 24-year-old college students, 3 groups with 25 to 35-year-old college graduates, and 3 groups with 25 to 35-year old's with less than a college degree. There will be a mix of genders, and races/ethnicities in the groups.

No more than 10 participants will participate in a group (see Appendices I (older adults) and II (younger adults), Participant Screeners). We will recruit 12 participants for each group and expect to have 8 to 10 participants per group. FDA has contracted with Westat to conduct these in-person focus groups.

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

The remainder of the focus groups will be conducted immediately upon the date of OMB approval. The focus groups will be conducted in three regions of the United States: Mid-Atlantic, West Coast, and South. These regions were chosen to represent consumers from a range of geographic locations and population size and diversity. The selected regions offer suitable focus group facilities and recruitment capabilities that will enable us to recruit the desired 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 screeners (Appendices I and 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 are present for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

Westat staff members will serve as moderators 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 guides (Appendices III (older adults) and IV (younger adults)) and test messages/fact sheets (Appendices V (older adults) and VI (younger adults)) 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 17 focus groups are planned for this phase.

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

In preparation for these focus groups, Westat consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, as a token of our appreciation to participants of these focus groups, we propose an incentive of $75 for 90 minutes to ensure that we are able to attract a reasonable cross section of participants who earn household incomes within our preferred range.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the 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); and
- 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 group. 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[4]; (2) an estimated cost for an average driving commute to and from the facility of approximately $18[5]; 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.[6] The proposed amount of $75 is comparable to what has been the level of monetary incentive for the target audiences in similar government-funded activities. 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 monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.[7] 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.[8] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[9].

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[4] Assumes an hourly rate of $16 per hour for a professional babysitter

[5] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf

[6] 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.

[7] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

[8] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79.

[9] 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	640	5	53
Focus group discussion	80	90	120
Total			173

REQUESTED APPROVAL DATE: November 23, 2020.

NAME OF PRA ANALYST & PROGRAM CONTACT:

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

Amy Lando (Program Contact)
Amy.Lando@fda.hhs.gov
240-402-1996

FDA CENTER: Center for Food Safety and Applied Nutrition