

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE FOR QUALITATIVE DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH FOR FOOD, DIETARY SUPPLEMENTS, COSMETICS, AND ANIMAL FOOD AND FEED (0910-0891)

Qualitative methods generally yield data that are not statistically generalizable. As such, they are useful for testing and refining ideas, and for developing hypotheses that can be further explored using quantitative methods, which is the preferred method for informing important policy and resource allocation decisions.

TITLE OF INFORMATION COLLECTION: Focus Groups on Bioactives in Infant Formula - Phase 1

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Type of Collection:**

[Check all that apply.]

- In-depth, one-on-one interviews
- Small groups
- Focus groups
- Observations

2. **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 0910-0891 for the focus group project, “Focus Groups on Bioactives in Infant Formula (Formative Research).”

The Food and Drug Administration (FDA) develops education initiatives aimed at helping consumers interpret and incorporate nutrition information in the context of their daily lives. This study is part of the agency’s continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Furthermore, the research aligns with FDA’s Center for Food Safety and Applied Nutrition (CFSAN) strategic goal to “advance diet and health research that contributes to the development of science-based policies and communication strategies.” This research may be used to highlight or identify gaps in current communication strategies and assist with formulating effective educational materials.

This focus group study will collect qualitative information to help FDA better understand consumer perceptions of bioactives in infant formula. The study comprises two phases: Phase 1 will collect formative research to explore consumer attitudes, behavior, and motivations about bioactives in infant formula, and Phase 2 will further build on what is learned in Phase 1. This OMB individual generic submission covers the 12 focus groups comprising Phase 1 of this study.

3. **Description of study participants:**

Phase 1 focus groups will consist of U.S. adults who make the primary decisions regarding which infant formula to purchase for their household. All the groups will

exclude those who work or have immediate family members who work in healthcare or public health, market research, or for food related government agencies. The groups will be segmented by time zone (Eastern, Pacific, and Central-Mountain), education (lower education, higher education), and primary language spoken at home and race/ethnicity (English, all races/ethnicities; Spanish, Hispanics).

These focus groups will be conducted online. No more than 6 participants will participate in a group (see Appendix I, Participant Screener). We will recruit 8-10 participants for each group and expect to have 4 to 6 participants per group. FDA has contracted with Westat, a social science research firm, to conduct these focus groups.

4. Date(s) to be conducted:

Focus groups will be conducted approximately one month from the date of OMB approval. FDA plans to complete all focus groups for Phase 1 by January 2022.

The focus groups will be conducted online within three regions of the United States: Eastern, Pacific, and Central-Mountain. 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 with 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 recruit participants via telephone using the participant screeners (Appendix I). The facilities' staff will provide all necessary information and instructions to ensure participants log in to the online platform 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 remotely using streaming technology.

The moderator will use the attached moderator guides (Appendix II) and test mock infant formula labels (Appendix III) to ensure that all relevant topic areas are addressed. Westat 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. 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 to be offered as a token of our appreciation. Based on these consultations, we propose an incentive of \$75 as a token of our appreciation to participants. All focus group participants will receive their tokens of appreciation after all focus groups have been completed. This ensures 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 log on and participate in the discussion.

The proposed incentive amount is considered to be 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 in 2020-2021 provide 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)¹. 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 2020 that the average hourly wage of childcare workers is \$12.24, making the average cost of two hours of childcare \$26 (Bureau of Labor Statistics, 2020)²
- The focus groups will be conducted online, and participants must have a computer or tablet and broadband Internet to participate in the groups; participating will consume approximately two hours of data usage on their Internet plans. Computer or tablet usage could also be a factor if participants were to rent this equipment for 2 hours.

In Westat and their vendors' experiences, offering lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and may result in longer recruiting time as well as higher overall project costs to the government (for which additional

¹Bureau 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).

²Bureau of Labor Statistics, U.S. Department of Labor, Occupation Employment Statistics, on the Internet at <https://www.bls.gov/ooh/personal-care-and-service/childcare-workers.htm#:~:text=and%20Wage%20Statistics-,The%20median%20hourly%20wage%20for%20childcare%20workers%20was%20%2412.24%20in,percent%20earned%20more%20than%20%2418.13.> (visited June 17, 2021).

funding is not available). Lower or nonmonetary incentives generally produce participation rates no better than the complete absence of any incentives.³ The consequences of offering an insufficient incentive include the following:

- Increased time and cost of recruitment due to lower response and enrollment levels, and/or the need to schedule additional groups to achieve the overall number of participants.
- Increased likelihood of “no-shows” (which may result in methodologically unsound focus groups with small numbers of participants).
- Skewed participant demographics, with increased representation of participants with lower incomes and lower education levels.
- 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. This incurs additional costs and places additional burden on the recruited participants who have to reschedule their participation in the focus group.

7. Questions of a sensitive nature:

There will be no questions of a sensitive nature asked of participants.

BURDEN HOUR COMPUTATION

No. of Participants: Provide an estimate of the number of participants.

Participation Time: Provide an estimate of the amount of time required for participation.

(Number of participants X estimated response or participation time in minutes (/60) = annual burden hours):

Activity	No. of Participants	Participation Time (minutes)	Burden (hours)
Focus Group/ Small Group Participant Screening	960	5	80
Focus Group/ Small Group Discussion	120	100	200
TOTAL			280

REQUESTED APPROVAL DATE: June 30, 2021

NAME OF PRA ANALYST & PROGRAM CONTACT:

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³See: 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.

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Appendices:

Appendix I – Recruitment screener

Appendix II – Moderator guide

Appendix III – Mock infant formula labels

FDA CENTER: Center for Food Safety and Applied Nutrition