

Appendix I

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Focus Groups on Bioactives in Infant Formula Screener – Phase I

Recruiting Goals

- The target audience for these focus groups is primary purchasers of formula for infants (newborn to 12 months of age).
- Twenty-four (24) virtual focus groups will be conducted, and segmented as follows:

Group	Time Zone	Education	Language, Race/Ethnicity
Phase 1			
Mock*	TBD	TBD	English-Speaking, All Races/Ethnicities
Grp 1	Eastern	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 2	Eastern	Lower Edu	Spanish-Speaking Hispanics
Grp 3	Eastern	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 4	Eastern	Higher Edu	Spanish-Speaking Hispanics
Grp 5	Central/Mountain	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 6	Central/Mountain	Lower Edu	Spanish-Speaking Hispanics
Grp 7	Central/Mountain	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 8	Central/Mountain	Higher Edu	Spanish-Speaking Hispanics
Grp 9	Pacific	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 10	Pacific	Lower Edu	Spanish-Speaking Hispanics
Grp 11	Pacific	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 12	Pacific	Higher Edu	Spanish-Speaking Hispanics
Phase 2			
Mock*	TBD	TBD	TBD
Grp 13	Eastern	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 14	Eastern	Lower Edu	Spanish-Speaking Hispanics
Grp 15	Eastern	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 16	Eastern	Higher Edu	Spanish-Speaking Hispanics
Grp 17	Central/Mountain	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 18	Central/Mountain	Lower Edu	Spanish-Speaking Hispanics
Grp 19	Central/Mountain	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 20	Central/Mountain	Higher Edu	Spanish-Speaking Hispanics
Grp 21	Pacific	Lower Edu	English-Speaking, All Races/Ethnicities
Grp 22	Pacific	Lower Edu	Spanish-Speaking Hispanics
Grp 23	Pacific	Higher Edu	English-Speaking, All Races/Ethnicities
Grp 24	Pacific	Higher Edu	Spanish-Speaking Hispanics

*Data collected from mock focus group will not be included in analysis; South region will be captured in Eastern and Midwest

- The groups will include people who are at least 18 years of age and who are primarily responsible for choosing and buying infant formula for infants (newborn -12 months).
- If possible, would encourage recruiting in any group a participant whose infant is enrolled in WIC¹
- All participants must be able to read, understand, and speak the language of the group: English for English-speaking groups and Spanish for Spanish-speaking groups.
- Participants cannot have participated in a focus group or a similar study in the past six months. Participation in phone surveys is allowed.
- Participants will need to have access to adequate internet, hardware, and software to participate virtually (see screener questions for specifications).
- Sufficient recruits will be invited in order to achieve a target of 4-6 participants for virtual/online groups.
- Each participant will receive a \$75 as a token of appreciation for participating in the focus group.

Study Protocol

- Each focus group will last approximately 90 minutes (excluding time needed for signing in before the group starts and signing out after the group ends).
- Groups will be audio- and video-recorded and also video-streamed and archived via a password-protected website.
- Westat will request a waiver of documentation of informed consent from the Westat IRB. Participants will receive a copy of the informed consent form when they are sent the details about the group (e.g., date, time, web link), but will not be required to sign the form and return it. Moderators will review the elements of informed consent prior to beginning the formal discussion.
- The identity of the participants will be kept secure d to the extent permitted by law.
- Groups will be observed by a research team including staff from FDA.
- Participants do not have to answer any questions that they do not want to, but will be encouraged to participate.

PARTICIPANT SCREENER SCRIPT

Hello Mr./Mrs./Ms. _____. My name is _____ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration. We are looking for individuals to take part in upcoming online focus group discussions about infant formula.

[INTERVIEWER: IF EXPLANATION IS NEEDED: A FOCUS GROUP IS A WHEN A SMALL GROUP OF INDIVIDUALS COME TOGETHER TO TALK ABOUT A CERTAIN TOPIC.]

1. **If you are interested in participating, could you answer a few questions? This will only take a few minutes of your time.**
 - Yes
 - No → ELIMINATE [THANK RESPONDENT POLITELY]
2. **Do you live with and care for an infant?**

¹ See Questions 14 and 15

- Yes
- No →

ELIMINATE [THANK RESPONDENT POLITELY]

3. How many months old is your infant? _____

[If older than 12 months, → ELIMINATE [THANK RESPONDENT POLITELY]]

4. How often do you give your infant formula?

- No, never or almost never → ELIMINATE [THANK RESPONDENT POLITELY]
- Occasionally
- Often
- Always or almost always

5a. Are you the person who usually decides what infant formula you use?

- Yes → SKIP TO Q6
- No, never or almost never

5b. Is the person who usually decides what infant formula to use available and interested in participating in this focus group discussion instead?

- Yes → SEE DIALOG BOX (BELOW)
- No, never or almost never → ELIMINATE [THANK RESPONDENT POLITELY]

- Hello Mr./Mrs./Ms. _____. My name is _____ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration. We are looking for individuals to take part in upcoming online focus group discussions about infant formula.

[INTERVIEWER: IF EXPLANATION IS NEEDED: A FOCUS GROUP IS A WHEN A SMALL GROUP OF INDIVIDUALS COME TOGETHER TO TALK ABOUT A CERTAIN TOPIC.]

5bi. If you are interested in participating, could you answer a few questions? This will only take a few minutes of your time.

- Yes
 No ELIMINATE [THANK RESPONDENT POLITELY]

5bii. Are you the person who usually decides what infant formula you use?

- Yes
 No, never or almost never ELIMINATE [THANK RESPONDENT POLITELY]

5biii. The person I was previously speaking with said that you all live with and care for an infant. How many months old is your infant? _____

[If older than 12 months, ELIMINATE [THANK RESPONDENT POLITELY]]

1.

2. **5biv. How often do you give your infant formula?**

- No, never or almost never ELIMINATE [THANK RESPONDENT POLITELY]
 Occasionally
 Often
 Always or almost always

6. Have you participated in a focus group within the past 6 months?

[Interviewer: participation in online or telephone surveys is allowed. If explanation is needed: A focus group is a when a small group of individuals come together to talk about a certain topic.]

- Yes ELIMINATE [THANK RESPONDENT POLITELY]
 No

7. Do you or someone from your immediate family work for any of the following:

- A Market Research Firm ELIMINATE [THANK RESPONDENT POLITELY]
 Nutritionist or Dietitian ELIMINATE [THANK RESPONDENT POLITELY]
 Food Industry, Restaurant or Food Retailer ELIMINATE [THANK RESPONDENT POLITELY]
 A Public Health Organization ELIMINATE [THANK RESPONDENT POLITELY]
 State or Local Food Agency ELIMINATE [THANK RESPONDENT POLITELY]
 U.S. Department of Agriculture ELIMINATE [THANK RESPONDENT POLITELY]
 U.S. Food and Drug Administration ELIMINATE [THANK RESPONDENT POLITELY]

8. Are you of Hispanic or Latino origin?

- No
 Yes SKIP TO Q10

Prefer not to answer ELIMINATE [THANK RESPONDENT POLITELY]

9. What is your race? I am going to read several categories of race. You may choose one or more categories. Are you...?

- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- Prefer not to answer

10. What language do you feel most comfortable reading? _____

- Spanish RECRUIT TO SPANISH LANGUAGE GROUP
- English RECRUIT TO ENGLISH LANGUAGE GROUP
- Either or Both English or Spanish CONTINUE
- Neither English nor Spanish ELIMINATE [THANK RESPONDENT POLITELY]

11. What language do you feel most comfortable speaking in a group? _____

- Spanish RECRUIT TO SPANISH LANGUAGE GROUP
- English RECRUIT TO ENGLISH LANGUAGE GROUP
- Either or Both English or Spanish RECRUIT TO SPANISH LANGUAGE GROUP
- Neither English nor Spanish ELIMINATE [THANK RESPONDENT POLITELY]

12. I am going to read some age categories, could you please tell me in which category your age falls?

- Under 18 years old ELIMINATE [THANK RESPONDENT POLITELY]
- 18-30
- 31-40
- 41-50
- 51-60
- 61 and over

13. What is your yearly household income? Your best guess is fine: _____

14. Are you, or is anyone in your household, currently receiving benefits from WIC—that is, the Special Supplemental Nutrition Program for Women, Infants, and Children?²

[For Recruiter: WIC is short for the Special Supplemental Nutrition Program for Women, Infants, and Children. This program provides food assistance, nutrition education including breastfeeding

² <https://www.fns.usda.gov/wic/frequently-asked-questions-about-wic>

support, and nutritional screening to low-income pregnant and postpartum women and their infants, as well as to low-income children up to age 5.]

- Yes
- No

15. Is the infant you live with and care for currently receiving benefits from WIC?³

[For Recruiter: WIC is short for the Special Supplemental Nutrition Program for Women, Infants, and Children. This program provides food assistance, nutrition education including breastfeeding support, and nutritional screening to low-income pregnant and postpartum women and their infants, as well as to low-income children up to age 5.]

- Yes TRY TO RECRUIT AT LEAST 1 FOR EACH GROUP, PRIORITIZING LOWER EDUCATION GROUPS
- No

16. What is your gender? _____

[Recruit no more than two men/males per group]

17. What is the highest level of education that you have completed?

- Less than high school → RECRUIT TO LOWER EDUCATION GROUP
- High school graduate or GED → RECRUIT TO LOWER EDUCATION GROUP
- Technical/vocational school → RECRUIT TO LOWER EDUCATION GROUP
- Community college → RECRUIT TO HIGHER EDUCATION GROUP
- Some college (1-3 yrs towards Bachelor's) → RECRUIT TO HIGHER EDUCATION GROUP
- College (Bachelor's degree) → RECRUIT TO HIGHER EDUCATION GROUP
- Advanced degree (postgraduate degree) RECRUIT TO HIGHER EDUCATION GROUP; NO MORE THAN 2 PER GROUP

18. For this discussion, you would be required to use your computer's webcam and your computer audio to participate. Do you have a computer (laptop or desktop) with a webcam and audio that you can use to participate?

- No → ELIMINATE [THANK RESPONDENT POLITELY]
- Yes → CONTINUE

19. Do you have access to high-speed (in other words, not dial-up) internet?

- No → ELIMINATE [THANK RESPONDENT POLITELY]
- Yes → CONTINUE

³ Wording for WIC participation adapted from NHANES: https://wwwn.cdc.gov/nchs/data/nhanes/2011-2012/questionnaires/rhq_capi.pdf

20. Do you have a quiet place where you can access high-speed internet and participate in the focus group without interruption?

- No → ELIMINATE [THANK RESPONDENT POLITELY]
- Yes → CONTINUE

21. Can you login to the Internet on your own?

- No → ASK:
Is there someone at home who can help you?
 - No → ELIMINATE [THANK RESPONDENT POLITELY]
 - Yes → CONTINUE
- Yes → CONTINUE
-

Elimination Script for Ineligible Participants:

Thank you for answering all of my questions. Unfortunately, you are not eligible to participate in this project. There are many possible reasons that people may not be eligible. These reasons were decided earlier by the research team. We value your interest in the focus groups. Thank you for being willing to help us.

Invitation Script for Eligible Participants:

Thank you for answering these questions. We would like to invite you to participate in a focus group to discuss infant formula. The discussion will last about 90 minutes. The discussion will be video- and audio-taped, and also observed by members of a research team. Your participation and everything you say during the discussion will remain secure to the extent permitted by law, and your personal identifying information will not be included in any reports. At the end of the focus group, you will receive \$75 as a token of appreciation for your participation.

Are you interested in participating in this focus group?

- Yes
 No [\[THANK THE PERSON FOR HIS/HER TIME\]](#)

I'm glad that you are interested! The online focus group will take place on (Day), (Date), at [X:00 or X:00 p.m.] at [website/streaming application].

Will you be available to participate at this time?

- Yes
 No [\[THANK THE PERSON FOR HIS/HER TIME\]](#)

I would like to send you a confirmation email or letter containing log-on instructions. In order to do so, could you please tell me the best way to reach you (e.g., email and/or a phone number)?

Name: _____

Address (if needed to reach participant):

City: _____

State: _____ Zip: _____

Email (if needed to reach participant):

Phone (if needed to reach participant):

Date of focus group: _____ Time: _____

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen. We look forward to seeing you on [date] at [time]. Please have any aids (hearing aids, reading glasses) with you to participate in the focus group.