

Appendix II

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Focus Groups on Bioactives in Infant Formula Phase I Moderator’s Guide

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) online focus groups will be conducted, and segmented as follows:

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

*Data collected from mock focus group will not be included in analysis; South region split between Eastern and Midwest time zones

Purpose

The purpose of this focus group study is to better understand the perceptions of primary shoppers for infant formula about bioactive ingredients and associated label claims on infant formula products, and how this information may influence purchasing behaviors. The findings from these groups will add to the repository of information on this topic and also inform an experimental study on this topic.

NOTES TO REVIEWER:

This focus group guide is not a script and should not be read verbatim. The moderator will use these questions as a roadmap and probe as needed to maintain the natural flow of conversation.

Research Questions/Aims of the Study

1. What influences consumers' decision to purchase or obtain a specific infant formula?
 - a. HCP's recommendation
 - b. Baby's preference/tolerance,
 - c. Brand, price, claims
 - d. For WIC enrollees: How, if at all, does enrollment in WIC influence their infant formula purchasing decisions?
2. What, if anything, do consumers look at on an infant formula product label?
 - a. What on the package catches their attention? – ingredients, claims
 - b. What on the package do they find helpful?
 - c. What on the package do they find confusing?
3. What are consumers' perceptions of claims around ingredients being similar to those found in human breast milk?
 - a. How do product labels that mention these claims of similarity to breast milk impact these purchasers' perceptions of the healthfulness of infant formulas?
 - b. How do disclaimers such as "Not from human milk" impact the reading of these claims?
4. What are consumers' perceptions of "bioactives"?
 - a. How, if at all, do product labels that mention bioactives impact these purchasers' perceptions of infant formulas?
 - b. How do the claims, whether or not consumers understand what bioactives are, impact the desirability of the product?

Introduction, Walkthrough, and Warm-Up (15 min.)

Thank you for joining us today. I'm _____, and I'm from Westat, a research firm in Rockville, MD. We are conducting research on behalf of the U.S. Food and Drug Administration, or "FDA". Today I am going to be asking about your beliefs, attitudes and feelings about what you look for when deciding on an infant formula and how these influence you to purchase and/or use these products. You all are the experts on this, so I'm here to learn from you and hear what you have to say. Our discussion today is going to help FDA better understand how caregivers of infants think about and make decisions about infant formula. What you have to say is very important to us and your time today is appreciated. We will have about 90 minutes for our discussion.

Before we begin, I want to review a few ground rules for our discussion.

- First, your participation is voluntary. If you decide you would rather not be in the group, you can leave and there's no penalty for doing so. And while I'd like to hear from everybody over the course of the discussion, you don't have to answer any questions that you're not comfortable with. Just let me know and I'll ask someone else.
- Just so you are aware, there are project staff from FDA and Westat [if appropriate] in [an observation "room" that is a separate section of this online focus group format]. They will be observing today's discussion and may have additional questions for me to ask you at the end of our group today. So I'll be checking in with them towards the end of the discussion.
- We are audio and video recording this conversation so that I can give you my full attention and not have to take a lot of notes. We will be using the audio file to make a written transcript of our discussion. When I go to do my analysis, I'll use this and transcripts from other groups like this that we are running.
- When writing up our findings, we will not include any information that could identify you. We are interested in what is being said, not who is saying it. Also, as I mentioned, we are running several groups on this topic, so I'll be looking for themes that are similar across the different discussions. Nothing you say will be tied to you directly.
- Your name or contact information will not be given to anyone, and no one will contact you about this research after this group is over. This information will be kept secure to the fullest extent of the law.
- There are no right or wrong answers to any of the questions I ask you all today, so it is OK to disagree with each other.
- Also, I am not an expert on this topic. You may have questions as we go along that I can't answer, but please ask them anyway. We have FDA observers and they will be interested in the questions consumers like yourselves may have about these products.

- Please speak up loudly and please speak one at the time so we can hear all the responses—no side conversations.
- Please set your cell phones to “do not disturb” and turn off anything else that may make it difficult to concentrate.
- If you need to step away for a minute, please mute your microphone before you do so. If you have a question, please raise your hand so I can see it on camera.
- Finally, please keep an open mind and remain respectful of your fellow participants. I’d ask that you don’t share what we discuss with others after the group.
- Do you have any questions before we begin?

Warm-Up. Thanks again for being here. Let’s warm up by going around the room and tell us your name, what state you live in (if online groups), and something about yourself – a hobby, a favorite food or book, etc.

Choosing Infant Formula (12-15 min.)

1. Where do you usually get your infant formula from?
2. Do you get the same infant formula every time?
IF NO: What are some of the reasons you might select a different formula?
3. What is important to you in deciding to use a certain infant formula?
 - a. Probe for baby’s acceptance/tolerance, brand, price/coupons, ingredients/claims, HCP or others’ recommendations, their own research
 - b. How do you find information about different infant formulas?
 - c. ASK ONLY IN SPANISH GROUPS: What are the languages of these resources?
4. Where on the package do you look to find information that is important to you?
 - Label, claims, etc.
 - ASK ONLY IN SPANISH GROUPS: What is the language(s) of the infant formula labels?

Mock Package Exercise – 3 labels/iterations max (60 min.)

I'm going to show you some sample infant formulas now and get your reactions to them. These are not real products, but might be similar to something you might see that is real.

Mock Package 1: [HMO]

1. What are your first impressions of this product?
2. What jumps out at you and catches your attention on this label? Why?
3. What questions do you have after seeing this label?
4. Let's talk about your reactions to "has Human Milk Oligosaccharides." Have you heard of it? If so, what do you think of it?
 - a. Based on this label, do you think this ingredient is from human breast milk? Why or why not?
 - b. [IF NEEDED] What are your thoughts on the disclaimer right below it that says, "not from human milk"?
 - i. What does this say to you about this product?
 - c. After seeing this, what questions do you have about Human Milk Oligosaccharides?
5. What are your reactions to "2'FL-HMO" [READ AS "TWO PRIME F L"]?
 - a. [OPTIONAL PROBE] Have you heard of 2'FL-HMO?
6. What are your thoughts on the phrase "2'FL-HMO for immune support"?
 - a. How important is this statement to you?
 - b. How believable is this statement to you?
7. What do you think is the relationship, if any, between Human Milk Oligosaccharides and "2'FL-HMO for immune support"? Explain.
8. How might this label influence your decision to use this product?

Mock Package 2: [MFGM]

1. What are your first impressions of this product?

2. What questions do you have after seeing this label?
3. What jumps out at you and catches your attention on this label? Why?
[PROBE on what jumps out]
4. What do you think of the phrase, “has MFGM Components”?
 - a. Have you ever heard of “MFGM”? If so, what have you heard?
 - i. [MODERATOR: Point out asterisk on MFGM that leads to footnote]
Probe: Have you ever heard of the term “Milk Fat Globule Membrane”? If so, what have you heard?
 - b. Based on this label, do you think this ingredient is from human breast milk? Why or why not?
 - c. [IF NEEDED] What was your reaction to reading “inspired by breast milk”?
5. What are your thoughts on the phrase “helps support brain development”?
 - a. How important is this statement to you?
 - b. How believable is this statement to you?
 - i. [PROBE]Why do you think this product does/does not help support brain development?
6. How might this label influence your decision to use this product?

Mock Package 3: [Lactoferrin]

1. What are your first impressions of this product?
2. What questions do you have after seeing this label?
3. Have you ever heard of the term “lactoferrin”? If so, what have you heard?
 - a. Based on the label, do you think lactoferrin in this product is from human breast milk? Why or why not?
 - b. [PROBE IF NEEDED] If you’ve heard of colostrum, what have you heard?
 - c. What are your thoughts on “modeled after breast milk”?
4. What do you think of “lactoferrin helps support immune health”?
 - a. How important is this statement to you?

- b. How believable is this statement to you?
5. How might this label influence your decision to use this product?

False Close

1. Is there anything that caught your attention on these labels that we didn't get to talk about?

If you will excuse me for just a moment, I would like to check with my team to see if there are any follow-up questions for you.

□ *Moderator goes to back room to see if there are any new questions.*

Close

Great, I believe we are all done here. Thank you so much for your time!

□ *Moderator stops recording and directs participants to the assistant who will administer incentives and obtain receipts.*