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**Focus Groups to Support Education on Dietary Supplements:
Older Adults, Phase 1
Appendix III: Moderator’s Guide**

The target audience for these focus groups is adults 55-80 years old.

Recruiting Goals

- Eight (8) focus groups will be conducted, and segmented as follows:

Group No.	Location	Age Bracket (years)	Education Level
Mock*	Mid-Atlantic (Local)	55-80	N/A
Group 1	Mid Atlantic (Local)	55-64	Lower Edu
Group 2	Mid Atlantic (Local)	55-64	Higher Edu
Group 3	Mid Atlantic (Local)	65-80	Lower Edu
Group 4	Mid Atlantic (Local)	65-80	Higher Edu
Group 5	West Coast	55-64	Lower Edu
Group 6	West Coast	55-64	Higher Edu
Group 7	West Coast	65-80	Lower Edu
Group 8	West Coast	65-80	Higher Edu

*Data collected from mock focus group will not be included in analysis

Purpose of Phase 1:

To better understand perceptions, behaviors, and motivations surrounding dietary supplement use, including:

- Attitudes on interactions between dietary supplements and prescription meds
- Where do older adults go for information on dietary supplements? Are they talking to their medical professional about them?
- Are older adults using dietary supplements in place of or delaying recommended treatment? (Reasons why -- Cost factor or don't like taking medication, are supplement natural)
- Do they know where to report Adverse Events?
- What do they know about how dietary supplements are regulated?
- Claims that these products make – speak to medical professional

Introduction (5 minutes)

MAKE SURE RECORDING IS ON

Thanks for joining us today. I'm _____, and I'm from Westat. We're a non-profit research organization based in Maryland. We are conducting these discussions on behalf of the U.S. Food and Drug Administration (also known as FDA). We are holding discussions around the country with folks just like yourselves on dietary supplements. Your opinions are 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 things with you. First, did everyone receive a form when you were in the waiting room that you read and signed? I want to go through the key points of that form and see if you have any questions.

- Your participation is voluntary. You can leave at any point in the discussion. There's no penalty to you for doing so. In addition, if at any point you feel uncomfortable with my questions, simply let me know that you prefer not to answer.
- As I mentioned, this is a study being conducted for the FDA. The findings from these groups will help them better understand how older Americans [think about/use/?] dietary supplements.
- We will be writing up our findings from all of the groups in a report for FDA. When we do this, we may use a quote from someone, but we will never include your name or any identifying information about you. The facility has your contact information, but I do not, nor do the project staff at FDA. After this group, no one will contact you about this discussion.
- However, I will not be able to guarantee your information will be secure when the discussion is finished because we will be discussing information as a group. While I request that everyone keeps what is said in the room, if you would feel uncomfortable with any of your statements being shared with others in or outside the group, please do not share them today.
- As mentioned on the consent form, 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 have transcripts made of the audio recordings to make sure when we do our analyses that we are accurate. FDA will receive a copy of the transcripts, but any identifying information will be removed by myself or other Westat project staff before we send them to FDA.
- You can see that there is a one-way mirror behind me. There is an observation room back there from which a couple of my project colleagues are watching the groups. They may have additional questions for you, so towards the end of our discussion I'll go back and check in with them.
- We are also livestreaming this discussion for project staff who were not able to attend in person tonight. All the project staff are held to the same confidentiality procedures and your privacy is secure to the extent allowed by law.
- We ask that you only use first names when addressing others or referring to yourself or others in your life. Also, we ask that you respect each other's privacy and do not share what is said in the group once it is over.

Does anyone have any questions about what I just reviewed? [ANSWER ALL QUESTIONS]

Alright, now I just want to review a few ground rules for our discussion.

- There are no right or wrong answers in today's discussion and I'm not going to ask you any trick questions. We want to know your honest opinion so that we can improve the materials.

- I'd love to hear from everybody this evening, but don't feel like you have to jump in on each question that I ask. You also don't have to wait for me to call on you if you have something to say; I would ask that you speak one at a time, though, so that I can hear what each of you has to say
- We're also not looking for consensus here, so it is OK to disagree with each other.
- Please speak up (speak loudly).
- Please turn off your cell phones or anything else that may make it difficult to concentrate.
- And if you need to use the restroom, please feel free to step out [DESCRIBE WHERE RESTROOMS ARE LOCATED]. Please don't all step out at once!

Do you have any questions before we begin?

Warm-Up (5-8 min)

NOTE TO MODERATOR: KEEP WARM-UP BRIEF.

Thanks again for being here.

- To start, let's go around the room and say your first name and what you would be doing if you weren't here tonight.

Dietary Supplement Use and Purchasing Behaviors (15-20 min.)

Let's get started.

1. Tonight, we are going to be talking about dietary supplements. [TEST: What comes to mind when you hear the term, "dietary supplements?"]

For the purpose of our discussion, when we are talking about dietary supplements, we mean a product, taken by mouth, that is used to supplement your diet. Common dietary supplements include vitamins or minerals, but dietary supplements can also include ingredients such as herbs or botanicals, amino acids, and probiotics. These products are often marketed for purposes such as maintaining or improving health.

- a. Do you use any other terms for what we're calling dietary supplements?
2. HISTORY: Let's start by talking about what got you interested in taking dietary supplements? When did you first start taking a dietary supplement?
[NOTE TO MODERATOR: We are not interested in personal medical information. Try to keep the discussion as general as possible and not get into details about specific medical conditions or treatments.]
 - a. PROBE: Was it for preventive reasons?
 - b. PROBE: A recommendation? From who?
 - c. PROBE: Was it with or in place of a prescription drug (or other treatment; OTC?)
 - d. How did you learn about that dietary supplement? (PROBE: family, friends, health care professional, etc.)
 3. PRESENT: What dietary supplements are you taking now? (Probe for same reasons as above as needed.)

- a. PROBE: Have the reasons why you are taking dietary supplements you changed over time?
4. Use/Dose: How do you decide how much of a dietary supplement to use? If you don't benefit from the recommended dose, how likely are you to increase the amount you take?
5. Is anyone taking dietary supplement instead of a prescription or OTC medication? If you don't mind, and you don't need to mention your health condition, tell us about your choice to go with dietary supplement rather than an OTC drug or prescription drug.
 - a. For those who are not, what are your thoughts about taking dietary supplements in place of medications?
6. Among different brands of the same supplement, how do you choose which brand to buy?
 - a. Probe: Price, brand familiarly, information on the package, other?

Information about Dietary Supplements (10-15 min.)

1. What kinds of questions have you had – or do you have – about the dietary supplements you are currently taking?
 PROBE: **Concerns about drug interactions**, how you know how often and how much, awareness of potential adverse events.
2. What sources have you used – or would you use – to try to get those questions answered?
 FOR THOSE WHO HAVE USED RESOURCES: How well did those sources answer your questions?
 PROBE if needed: Has anyone talked with his/her health care professional? What kinds of questions did you ask him/her? How helpful was s/he in answering your questions?

Adverse Event Reporting and Oversight (15-20 min.)

1. What are your expectations for what your dietary supplements should do for your health?
 How do you know if the dietary supplement you're taking is working?
 IN THE ABSENCE OF EVIDENCE: Why do you think people continue to take dietary supplements if they're not sure that it's helping them?

 If anyone's had a dietary supplement that didn't seem to be working, what did you do?
 [PROBE: Stop taking; start taking more; take a different brand]
2. Have you ever had a bad experience after taking a dietary supplement? We are talking about things like nausea, dizziness, and/or shortness of breath.
 - a. Terminology check: What do you call these types of bad experiences? (Probe: adverse events, adverse effects, adverse reactions, other terms?) For the rest of the groups we are going to call them "adverse events."
 - b. How did you know they were from the supplements?

- c. What did you do when you had those experiences?
Probe: stop taking, talk to health care professional, report to manufacturer, gov. agency, poison control, switch brands or lower dose
- d. Have any of you had an adverse event that you reported? Tell me about that reporting process (e.g., Who did you contact? How did you know to contact that person/company/agency? What, if any, follow-up did you receive from the person/company/agency after you filed your report?)

IF NO ADVERSE EFFECTS or NO to item c: Would you report an adverse event or safety issue? To whom would you report it? What kinds of negative reaction would lead you to report it?

- e. Who, if anyone, provides oversight on the dietary supplements that you use to be sure that they are safe and effective? Is there any other government agency or organization that you think should be involved in the oversight process? If yes, what government agency and why?

Concept Testing (15 - 20 min.)

I'm going to pass around some materials on dietary supplements.

1. What do you think the main message(s) is in this piece?
2. What are your thoughts regarding the first section of the page— “Keep all healthcare professionals ‘in the know’”?
 - a. Probe: Is this something you do/can do?
 - b. Probe: Anything unclear or confusing about this section?
3. What are your thoughts about the second headline and the text below it— “Many factors play a role in deciding if a dietary supplement is right for you, including possible drug interactions and side effects”?
 - a. Probe: What does “unexpected consequences” mean to you?
 - b. Probe: Anything unclear or confusing about this section?
4. What about the third bulleted section -- “In case of Adverse Events: Alert your Doctor and FDA”?
 - a. Probe: what qualifies as adverse event?
 - b. Probe: Would you report to FDA? If so, where would you go to report this?
5. What would you do after reading this sheet?
 - a. Probe: would you visit the website listed at the bottom of this sheet?
 - b. Probe: Is any of this information new to you?
 - c. Probe: Any other feedback about this sheet?
6. Is there any information that you would like to see on a sheet like this that is currently missing? What?

7. What other information on dietary supplements would you like to know to help you make informed decisions?
8. How would you prefer to get this type of information? (print-out, pamphlet, brochure, flyer, website, social media (which platform), etc.)

False Close (5 minutes)

That's all the questions I have. I am going to check in with my colleagues to see if I missed anything. I'll be right back.

[MODERATOR: GO TO BACK ROOM TO SEE IF THERE ARE ANY NEW QUESTIONS.]

Close (2 minutes)

Do you have any questions for me or any additional feedback that you'd like to provide?
Thank you very much for your time today. Your feedback is very much appreciated.

[MODERATOR: STOP RECORDING. ADMINISTER INCENTIVES AND OBTAIN RECEIPTS.]