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The objective of this study is to obtain qualitative information on current and detailed consumer interpretation of labeling statements on dietary supplement products, particularly structure/function claims, and the relationship between the interpretation and personal background and other factors. The study is designed to use open-ended and semi-structured questions and other probes to elicit the information in one-on-one in-depth online interviews.

Section 1. Introduction (3-5 minutes)

Thanks for agreeing to participate today. I'm _____, and I'm from Westat. We're a research organization based in Maryland. We are conducting the interview on behalf of the U.S. Food and Drug Administration (also known as FDA). We will be talking about a product you may or may not have used – dietary supplements; I will explain later what we mean by dietary supplements. Your opinions are very important to the FDA and your time and help are appreciated. This interview will take approximately 60 minutes.

Before we begin, I want to let you know that your participation is completely voluntary, and your responses to our questions will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed, this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

I also want to review a few things with you. First, you should have received a copy of the informed consent form with the confirmation email to participate in this interview. I want to go through the key points of that form and see if you have any questions.

- [Voluntary Participation] 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.
- [Study is for FDA] The purpose of the study is to help FDA gather consumer inputs to provide accurate and useful product labels on dietary supplements to protect and promote of public health.
- [Risks/benefits] We believe the risks to you for participating are minimal. We're going to ask you some questions about supplements you use and then get your opinion on some supplement labels.

There are no particular benefits to you for participating, but you will be helping FDA to better understand how consumers understand the information on supplement labels.

- [Report findings] We will report our results in a summary report. We may quote what you say in our report, but we won't use your name. No information that can identify you will be given to FDA.
- [Audio Recording] We will be audio recording this interview so that I can give you my full attention and not have to take a lot of notes during the interview.
- [Observers] Some of our colleagues from Westat and FDA are observing the interview. They are also required to protect your privacy and confidentiality.

Do you have any questions about what I just reviewed? [ANSWER ALL QUESTIONS]

Now, may I have your permission to audio record this interview?

[IF YES, TURN ON RECORDER AND READ: "Today is _____ [DATE] and it is [TIME]. This is Participant [NUMBER]. _____ [name of participant], For the record, do you agree to participate in this interview? Do you agree to be recorded?"]

[IF NO, TERMINATE.]

Section 2. Introduction and personal background (3-4 minutes)

First, let me explain what we mean by dietary supplements in this study. Dietary supplements are taken by mouth and are intended to be taken **in addition to** the regular diet, but are not intended for use as a meal replacement. Dietary supplements may be in various forms, including a pill, tablet, caplet, capsule, gummy, liquid, and powder. Examples of dietary supplements are One A Day, Centrum, vitamin C tablets, calcium plus vitamin D caplets, garlic softgels, ginger powder, fiber supplements such as Metamucil, or fish oil capsules. For this study, dietary supplements are **not** prescribed by a health care provider (e.g., physician, nurse practitioner, physician assistant, dentist), but could have been recommended by a health care provider. Please keep this definition in mind or ask me during the interview.

[GO TO 'USER SEGMENTS' OR 'NON-USER SEGMENT' DEPENDING ON SCREENER RESULT]

[**User segments** – allow reclassification to be a Non-user if the participant says they did NOT take supplements in the past 12 months, though reported as a user in the screener, and skip to Questions 2b]

1a. We understand you've taken dietary supplements in the past 12 months. Can you tell me what supplements have you taken?

2a. For how long have you been taking any dietary supplements?

2a1. [IF 2a is longer than 12 months] Are there supplements that you have taken earlier in your life but are not included in the supplements you just mentioned for the past 12 months?

2a2. [IF 2a1=YES] What were they, if you still remember?

[**Non-user segment** - allow reclassification to be a User if the participant says they have taken supplements in the past 12 months, though reported as a non-user in the screener, and go to Questions 1a and 2a]

2b. We understand you've **not** taken dietary supplements in the past 12 months. Have you taken any supplements previously? What were they, if you still remember?

Section 3. Claim interpretation (45-50 minutes)

Now, I'd like to ask you to look at some dietary supplement labels and tell me what you think the labels say the product is for. These labels may look similar to or different from supplement labels you've seen before.

Sub-section 3.1. Claims related to sugar/glucose (or hypertension) depending on participant assignment

3. (*Show Slide 1*) Imagine you see this product label in the store. Please take a few moments to look at the label [for reviewer only - e.g., Image 1A1] and tell me who you think the product is for and why you think so. [*If necessary, probe (1) what does the label say the product is for? (2) who do you think may be interested in using this product? (3) are there any particular parts of the label that you think say that? (4) please tell me more.*]

4. (*Show Slide 2*) The next label is very similar to the last one you saw, except this one has a different brand name [*mention the name*]. Again, please tell me who you think the product is for. [*use probes in #3 as needed.*]

5. (*Show Slide 3*) Now, let's look at a pair of labels; the one on the top is what you just saw on the last slide. Please take a few moments to look at each of the labels and tell me who you think each product is for, and why. [*If necessary, please tell me more*]

6. (*Show Slide 4*) Here is another pair of labels. Again, tell me what you think each of them says, if they say similar or different things, and why. [*If necessary, please tell me more*]

7. (*Show Slide 5*) Next, let's do something different. I'd like to look at these statements on the screen [e.g., *card sorting claims – sugar/glucose or hypertension depending on participant assignment*] and put them into different groups as you see appropriate. There is no limit on how many groups you create. All that matters is that the grouping makes sense to you. After you put the statements into groups, give a name to each group that you think best describes what the group represents; name can be one word or a few words. Also, feel free to talk out loud as you put the statements into groups. Let's take about 10 minutes for this exercise.

8. (*Show Slide 5*) How easy or difficult was it for you to group these statements? Please explain.

9. (*Show Slide 5*) Did you feel that some of the statements could be put into more than one group? [If yes] can you give me an example?

Sub-section 3.2. Claims related to hypertension (or sugar/glucose) depending on participant assignment

10. Thank you for sharing your thoughts. (*Show Slide 6*) Let's do the grouping exercise for a different list of statements [e.g., *card sorting claims – hypertension or sugar/glucose depending on participant assignment*]. Please put them into different groups as you see appropriate. There is no limit on how many groups you come up with. All it matters is that you think the grouping makes sense to you. You

have up to 10 minutes for this exercise. Again, please feel free to talk aloud as you are going through this exercise.

11. *(Show Slide 7)* Please take a few moments to look at this label and then tell me who you think the product is for. *[If necessary, probe (1) what does the label say the product is for? (2) are there any particular parts of the label that you think says that? (3) please tell me more.]*

12. *(Show Slide 8)* The next label is very similar to the last one you saw, except this one has a different brand name *[mention the name]*. Again, please tell me who you think the product is for.

13. *(Show Slide 9)* Now, let's look at a pair of labels; the one on the top is what you just saw on the last slide. Please take a few moments to look at each of them and tell me what you think each of them says, if they say similar or different things, and why. *[If necessary, please tell me more.]*

14. *(Show Slide 10)* Here is another pair of labels. Again, tell me what you think each of them says, if they say similar or different things, and why. *[If necessary, please tell me more.]*

15. *(Show Slide 10)* You may have noticed the box containing two statements *[read the disclaimer "These statements ..."]* on the upper label but not on the lower label. Why do you think the upper label has the statements while the lower label does not? *[If necessary, probe (1) please tell me more, (2) what does the statement tell you?]*

16. *(Show Slide 10)* *[user segments only]* Have you seen these statements when you were selecting a supplement? If yes, did the statements affect your decision to buy the supplement? *[If necessary, probe "please tell me more."]*

17. *(Show Slide 10)* If you were interested in buying such a dietary supplement product, would the statements affect your decision to buy the supplement? *[If necessary, probe "please tell me more."]*

18. We really appreciate you sharing your opinions with us. I just have a few more questions. *[IF diabetes/high blood sugar or hypertension/high blood pressure has **not** been mentioned, ask "do you remember any statements or words that made you think of a health condition?" and/or "can you remember any of the health conditions you might have thought of?"]*

19. *(Show Slide 11)* Now, this is my final question about labels. Please tell me about your thoughts on the following two statements. Do you think they are saying the same thing or something different?

- *[IF SAME]* Would you want to purchase either product? Please explain. *[Interviewer – get explanation for why one and why not the other.]*
- *[IF DIFFERENT]* If you could, in your own words, tell me what you think each one is saying. Would you want to purchase either product? Explain. *[Interviewer – get explanation for why one and why not the other.]*

Section 4. Details on supplement use (3-5 minutes)

[User segments]

20a. You said earlier that you have taken (*INSERT SUPPLEMENTS MENTIONED IN 1a*) in the past 12 months. What led you to take them? [*If necessary, “In other words, how did you decide on the products you’ve taken?”*]

20b. [IF any supplement taken is related to chronic diseases (hypertension, diabetes, high cholesterol, cardiovascular diseases, heart disease, stroke, cancer)]

20b1. Did a healthcare provider prescribe or recommend the supplement?

20b2. Did you use any prescription drug together with the supplement for your health condition?

20b3. Did you take any prescription drugs for the health condition before using the supplement?

20b4. Did you substitute the supplement for a prescription drug? If yes, why?

[Non-user segment]

20c. Do you know anyone, like relatives, friends, or colleagues, who are or have been taking dietary supplements?

20d. [IF YES TO 20c - know anyone, like relatives, friends, or colleagues, who are or have been taking dietary supplements] What dietary supplements are they taking or have taken?

20d1. [IF ONE OR MORE SUPPLEMENTS ARE NAMED] What do they say about why they take the supplements?

20e. Do you plan to take any supplements in the future?

20e1. [IF 20e=YES] What supplements do you have in mind and for what purposes?

Section 5. Closing (2-4 minutes)

21. Before we wrap up today’s interview, let me check if my colleagues have any other questions for you.

- [*Ask additional questions, if any*].

- [*Terminate interview ,if none*].

This concludes the interview. Thank you again for your time and participation.

[Westat to add the appropriate closure] xxx will provide you with your incentive as a thank you for your time.