

OMB Control Number 0910-0891
 Dietary Supplement Claims One-on-one In-depth Interview Study
 Attachment 1 – Recruitment screener

OMB No: 0910-0891 Expiration Date: 8/31/2023

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0891. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

Recruitment Goal: Recruits within each of the three clusters below shall be diverse in age (40-65 years old vs 66 years or older), education (with vs without a college education), race/ethnicity (non-Hispanic white vs other), and gender (male, female, or non-binary).

Cluster	User status*	Purpose of use**	Time zone	Number of interviews
N/A	(Mock interview #1) Non-user	Not applicable	TBD	1
N/A	(Mock interview #2) User	Non-specified	TBD	1
1	Non-users	Not applicable	All 3 zones	20
2	Users	For one or more of the listed health condition(s)	All 3 zones	20
3	Users	NOT for any of the listed health conditions	All 3 zones	20
Total				62

* “User” is defined as an individual who has used one or more dietary supplements in the twelve (12) months prior to the date of recruitment.

** Purpose of use: Whether any supplements are used for one or more of the following health conditions: high blood pressure/hypertension, high blood sugar/diabetes, high cholesterol, cardiovascular diseases/heart disease/stroke, and cancer.

My name is () and I'm calling about a consumer research study we are conducting on behalf of the U.S. Food and Drug Administration (FDA). The study is to help FDA gather information from consumers to provide accurate and useful product labels to help you make informed choices about food products. We will conduct video calls with individual consumers online in the coming weeks, and we will audio and video record the call for analysis purposes. As a token of appreciation, we will provide \$60.00 after the approximately 1-hour interview.

1. Would you be interested in participating in the study?

yes
no [*TERMINATE*]

Great! Could you please answer the following questions to help us determine whether to invite you to participate? This should take an average of 5 minutes.

[IF ONLINE RECRUITING IS USED, (1) DO NOT OFFER THE “BACK” FUNCTIONALITY, (2) PROVIDE PROMPTS AT Q2-Q6 TO FORCE ANSWERS]

2. Please check the age group that you are in.

17 years and below [*TERMINATE*]
18 – 39 years [*TERMINATE*]
40 – 64 years
65 years and above

3. Please check ALL the products that you have consumed or used in the past 12 months.

drugs (prescription or over-the-counter) [*SKIP TO Q5*]
dietary supplements – vitamins, minerals, herbs such as One-A-Day, Centrum, vitamin C tablets, calcium plus vitamin D caplets, garlic softgels, ginger powder, Metamucil, or fish oil capsules [*GO TO Q4*]
cosmetics or beauty products [*SKIP TO Q5*]

[IF ‘DIETARY SUPPLEMENT’ IS CHECKED]

4. You said you have consumed or used dietary supplements in the past 12 months. Is or was any of the use related to ANY of these health conditions: [*CHECK ALL THAT APPLY*]

high blood pressure (hypertension)
high blood sugar (diabetes)
high cholesterol
cardiovascular diseases, heart disease, stroke

cancer

5. Have you ever been told by a doctor or other healthcare professional that you have any of the following health conditions? [*CHECK ALL THAT APPLY*]

high blood pressure (hypertension)
high blood sugar (diabetes)
high cholesterol
cardiovascular diseases, heart disease, stroke
cancer

6. Have you ever worked in the marketing, sale, development, or manufacturing of dietary supplements?

yes
no

7. Do you own or have access to EACH of the following?

	yes	no
A laptop, iPad, or desktop		
Broadband or highspeed Internet		
A webcam		
A separate and quiet place where you can participate in a video call		

[*TERMINATE IF "NO" IN ANY ITEM*]

8. Would you be comfortable logging in to a Zoom meeting on your computer, either by yourself or if you had someone who can help you?

yes
no [*TERMINATE*]

9. Are you? [*CHECK ALL THAT APPLY*]

male
female
Transgender, non-binary, or another gender

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

high school graduate, GED, or less than high school
some college education or an associate/Bachelor's degree
some graduate education or an advanced degree

11. Are you of Hispanic or Latino?

yes

no

12. What is your race? [*CHECK ONE OR MORE*]

White

Black or African American

American Indian or Alaska Native

Asian

Native Hawaiian or other Pacific Islander

[*READ IF INELIGIBLE*] 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 these interviews. Thank you for being willing to help us.

[*READ IF ELIGIBLE*] You are eligible to participate in the study. The video call will be held on [DATE] at [TIME] and will last about an hour. We provide a check of \$60 at the end of the call.

13. Would you like to participate in the study at [TIME] on [DATE]?

yes

no [*TERMINATE*]

Great! May I please have your phone number and e-mail address to send you a confirmation with instructions? [*Repeat email address and phone number.*]

Thank you. That's all the questions I have today. Before your interview, you will receive an email with a link to join the interview using Zoom. Please connect to the link at least 10 minutes before the start of the interview to ensure you have time to sign in. If you have any questions or find that you are unable to attend, please call [*Insert facility's phone number*] as soon as possible.

Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].

[*Read if necessary*]

If you have any questions about the study, you may contact Cynthia Robins of Westat at (240)367-4753 or cynthiarobins@westat.com. If you have concerns about how participants are being treated in the study, you may contact the Westat Human Subjects Protections office at (888) 920-7631.