

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 0910-0497. The time required to complete this screening document 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.

**Focus Groups to Support Education on Dietary Supplements:
Young Adults, Phase 1
Appendix II: Recruitment Screener**

The target audience for these focus groups is U.S. adults 18-35 years old.

Recruiting Goals

- Nine (9) focus groups will be conducted. The groups will be segmented, as follows:

Group No.	Location	Age Bracket (years)	Education Level
Mock*	Mid-Atlantic (Local)	18-35	N/A
Group 1	Mid Atlantic (Local)	18-24	Current student
Group 2	Mid Atlantic (Local)	25-35	Lower Education
Group 3	Mid Atlantic (Local)	25-35	Higher Education
Group 4	West Coast	18-24	Current student
Group 5	West Coast	25-35	Lower Education
Group 6	West Coast	25-35	Higher Education
Group 7	South	18-24	Current student
Group 8	South	25-35	Lower Education
Group 9	South	25-35	Higher Education

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

PARTICIPANT SCREENER SCRIPT: 18-24 year-old students

Hello Ms./Mr. _____, my name is _____ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration in your area. We are looking for adults to take part in upcoming focus group discussions about dietary supplements.

Are you interested in participating?

- Yes → continue
- No → eliminate [thank respondent politely]

Great. I'm just going to ask you a few questions to see if you are eligible for the group.

Q1. What is your age? _____ years

- Under 18 → eliminate [thank respondent politely]
- 18-24 → continue
- 25-35 → eliminate [thank respondent politely]
- 36 and over → eliminate [thank respondent politely]

Q2. Who makes most of the decisions regarding your health?

- Other (e.g., spouse/partner, family member, advocate) → eliminate [thank respondent politely]
- Me → continue

Q3. Over the past 12 months, have you regularly taken a *single-ingredient* vitamin or mineral supplement? This could be a tablet of vitamin C or E, an iron or calcium pill, or even a B complex vitamin. [NOTE: Please exclude if participant ONLY takes vitamin-fortified foods or beverages (e.g., milk fortified with vitamin D).]

[IF ANSWER IS NOT CLEARLY A SUPPLEMENT AND SOUNDS LIKE IT MAY BE AN INGREDIENT IN FOOD, ASK “is that in your food or is it taken separately as a supplement?” If taken as a food ingredient only, mark “No.”]

- No → continue
- Yes → continue
- ONLY take multi-vitamins → continue [recruit MAX 1 per group]

Q4. Over the past 12 months, have you regularly taken any dietary supplements *other than* vitamins, such as herbs or botanicals? We are talking about things such as garlic pills, Echinacea, ginkgo, glucosamine, St. John's wort, amino acids, fish oil, or melatonin.

[INTERVIEWER: IF ANSWER IS NOT CLEARLY A SUPPLEMENT AND SOUNDS LIKE IT MAY BE AN INGREDIENT IN FOOD, ASK “Is that in your food or is it taken separately as a supplement?” EXCLUDE fresh garlic, fresh ginseng, ginseng root, and herbs used to flavor foods in cooking such as garlic for spaghetti sauce or peppermint for tea; supplements that are not taken by mouth, such as vitamin E or aloe used on skin. If taken as a food ingredient or topical application only, mark “No.”]

- No → See DECISION BOX, BELOW
- Yes → CONTINUE

DECISION BOX

If respondent said YES to Q3 but NO to Q4, recruit no more than 2 participants to any focus group.
 If respondent said NO to Q3 **and** Q4, respondent is ineligible. Thank politely.

Q5. The focus group will be conducted in English, and will need people in the group to read some text. Are you comfortable understanding, speaking and reading English?

- Yes → continue
- No → eliminate [thank respondent politely]

Q6. Have you or someone from your immediate family worked for or as any of the following:

- A Market Research Firm → eliminate [thank respondent politely]
- Nutritionist or Dietitian → eliminate [thank respondent politely]
- Nurse/Nurse Practitioner, Doctor, Pharmacist → eliminate [thank respondent politely]
- A Public Health Organization → eliminate [thank respondent politely]
- Microbiologist, toxicologist, or chemist → eliminate [thank respondent politely]
- State or local food agency,
U.S. Department of Agriculture, or
U.S. Food and Drug Administration → eliminate [thank respondent politely]

Q7. Have you participated in a focus group within the past 6 months? [Interviewer: participation in telephone or online 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 → continue

Q8. Are you currently in school?

- No → eliminate [thank respondent politely]
- Yes → continue to 8a

Q8a. If so, what degree are you currently pursuing?

- High school graduate or GED → eliminate [thank respondent politely]
- Technical/vocational school → eliminate [thank respondent politely]
- Associate's degree → eliminate [thank respondent politely]
- Bachelor's degree → continue
- Advanced degree (postgraduate degree) → eliminate [thank respondent politely]

Q9. Are you of Hispanic or Latino origin? [RECRUIT A MIX]

- Yes
- No

Q10. What is your race? I am going to read several categories of race to choose from. You may choose one or more categories. Are you...? [RECRUIT A MIX]

- White

- Black or African American
- Asian
- Native Hawaiian or Other Pacific Islander
- American Indian or Alaska Native

Q11. What is your gender?

- Female
- Male [RECRUIT NO MORE THAN 4 MALES PER GROUP]
- Prefer not to answer

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 issues relating to dietary supplements with about 8 other participants. 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 provided 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 focus group will take place on (Day), (Date), at [X:00 or X:00 p.m.] at [site location].

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 directions to the facility. 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: _____

or

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]. If you use reading glasses, please bring them with you to the focus group.

PARTICIPANT SCREENER SCRIPT: 25-35 year-old adults

Hello Ms./Mr. _____, my name is _____ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration in your area. We are looking for adults to take part in upcoming focus group discussions about dietary supplements.

Are you interested in participating?

- Yes → continue
- No → eliminate [thank respondent politely]

Great. I'm just going to ask you a few questions to see if you are eligible for the group.

Q1. What is your age? _____ years

- Under 18 → eliminate [thank respondent politely]
- 18-24 → eliminate [thank respondent politely]
- 25-35 → continue
- 36 and over → eliminate [thank respondent politely]

Q2. Who makes most of the decisions regarding your health?

- Other (e.g., spouse/partner, family member, advocate) → eliminate [thank respondent politely]
- Me → continue

Q3. Over the past 12 months, have you regularly taken a *single-ingredient* vitamin or mineral supplement? This could be a tablet of vitamin C or E, an iron or calcium pill, or even a B complex vitamin. Please exclude if participant ONLY takes vitamin-fortified foods or beverages (e.g., milk fortified with vitamin D).

[IF ANSWER IS NOT CLEARLY A SUPPLEMENT AND SOUNDS LIKE IT MAY BE AN INGREDIENT IN FOOD, ASK "is that in your food or is it taken separately as a supplement?" If taken as a food ingredient only, mark "No."]

- No → continue
- Yes → continue
- ONLY take multi-vitamins → continue [recruit MAX 1 per group]

Q4. Over the past 12 months, have you regularly taken any dietary supplements *other than* vitamins, such as herbs or botanicals? We are talking about things such as garlic pills, Echinacea, ginkgo, glucosamine, St. John's wort, amino acids, fish oil, or melatonin.

[INTERVIEWER: IF ANSWER IS NOT CLEARLY A SUPPLEMENT AND SOUNDS LIKE IT MAY BE AN INGREDIENT IN FOOD, ASK "Is that in your food or is it taken separately as a supplement?" EXCLUDE fresh garlic, fresh ginseng, ginseng root, and herbs used to flavor foods in cooking such as garlic for spaghetti sauce or peppermint for tea; supplements that are not taken by mouth, such as vitamin E or aloe used on skin. If taken as a food ingredient or topical application only, mark "No."]

- No
- Yes

→ See DECISION BOX, BELOW
 → CONTINUE

DECISION BOX

If respondent said YES to Q3 but NO to Q4, recruit no more than 2 participants to any focus group.
 If respondent said NO to Q3 **and** Q4, respondent is ineligible. Thank politely.

- Q5. Have you or someone from your immediate family worked for or as any of the following:
- A Market Research Firm → eliminate [thank respondent politely]
 - Nutritionist or Dietitian → eliminate [thank respondent politely]
 - Nurse/Nurse Practitioner, Doctor, Pharmacist → eliminate [thank respondent politely]
 - Microbiologist, toxicologist, or chemist → eliminate [thank respondent politely]
 - A Public Health Organization → eliminate [thank respondent politely]
 - State or local food agency,
U.S. Department of Agriculture, or
U.S. Food and Drug Administration → eliminate [thank respondent politely]
- Q6. Have you participated in a focus group within the past 6 months? [Interviewer: participation in telephone or online 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 → continue
- Q7. What is the highest level of education that you have completed?
- Less than high school → recruit to lower ed group
 - High school graduate or GED → recruit to lower ed group
 - Technical/vocational school → recruit to lower ed group
 - Some college (1-3 years towards Bachelor’s degree) → recruit to higher ed group
 - College (Bachelor’s degree) → continue to 7a
 - Advanced degree (postgraduate degree) → recruit to higher ed group
- Q7a. Are you currently in school?
- No → recruit to higher ed group
 - Yes → continue to 7b
- Q7b. Are you currently in any of the following postgraduate programs?
- Medical school → eliminate [thank respondent politely]
 - Pharmacy school → eliminate [thank respondent politely]
 - Nursing school → eliminate [thank respondent politely]
 - Registered Dietitian → eliminate [thank respondent politely]
 - None of the above → recruit to higher ed group
- Q8. I am going to read some annual income categories; please let me know which one best applies to your household?
- Less than \$40,000
 - \$40,000 to less than \$65,000
 - \$65,000 to less than \$90,000
 - \$90,000 to less than \$125,000

- \$125,000 and over
- Prefer not to answer

Q9. Are you of Hispanic or Latino origin? [RECRUIT A MIX]

- Yes
- No

Q10. What is your race? I am going to read several categories of race to choose from. You may choose one or more categories. Are you...? [RECRUIT A MIX]

- White
- Black or African American
- Asian
- Native Hawaiian or Other Pacific Islander
- American Indian or Alaska Native

Q11. What is your gender?

- Female
- Male [RECRUIT NO MORE THAN 4 MALES PER GROUP]
- Prefer not to answer

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 issues relating to dietary supplements with about 8 other participants. 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 provided 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 focus group will take place on (Day), (Date), at [X:00 or X:00 p.m.] at [site location].

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 directions to the facility. 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: _____

or

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]. If you use reading glasses, please bring them with you to the focus group.