

**Experimental Study of Consumer Response to Health Claims and Disclaimers
About the Relationship between Selenium and Risk of Various Cancers**

**Draft Questionnaire
As of June 2012**

*Form Approved: OMB No. 0910-xxxx
Expiration Date: xx/xx/201x*

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Department of Health and Human Services
Food and Drug Administration
CFSAN/PRA Comments/HFS-24
5100 Paint Branch Parkway
College Park, MD 20740-3835.

[DISABLE “PREVIOUS” OR “BACK” FUNCTIONALITY]
[DISABLE PROGRESS INDICATOR]

Study Introduction:

Thank you for agreeing to participate. The following questions are about dietary supplements and the labels you might see on these products.

Dietary supplements include vitamins, minerals, and other less familiar substances such as herbals, botanicals, amino acids, enzymes, and animal extracts. Dietary supplements are often sold in the form of tablets, capsules, softgels, and gencaps.

It usually takes about 10 minutes to answer all the questions in this survey. The information you provide will be kept strictly confidential.

Please click the “NEXT” button to begin the study.

SECTION A. QUESTIONS TO ESTABLISH ELIGIBILITY FOR STUDY INCLUSION

Before you start the main part of the survey, we’d like to ask a few questions about you.

1. Please think about dietary supplements such as vitamins, minerals, herbs, and other dietary supplements that you may take in addition to your regular diet. Some examples include garlic pills, Echinacea, selenium, ginkgo, glucosamine, fish oil, and calcium.

Have you ever taken a multi-vitamin, mineral, or other dietary supplement?

- Yes
- No [Go to question 2 if female. Go to question 3 if male unless quota is filled.]

- 1a. [If yes] Have you ever taken any of the single-ingredient supplements listed below?

	Yes	No
Iron		
Selenium		
Zinc		

[All male participants who say YES to selenium go to question 3. If male + NO to selenium, go to question 3 unless quota is filled.]

2. [If female] Are you currently married?

- Yes
- No [Thank and end if NO to selenium in question 1a.]

- 2a. [If yes] Has your spouse ever taken a single-ingredient selenium supplement?

- Yes
- No
- Don't know

SECTION B. LABEL RESPONSES, INTENTIONS TO USE SELENIUM SUPPLEMENTS, AND OTHER PERCEPTIONS

Please take a moment to look at this label for a selenium product. Selenium is a mineral used in some dietary supplements. Please note that the label information you see in this study may or may not be the same as you would see on an actual product. [Each participant is randomly assigned to a label condition.]

3. Based on what you see on the label, how likely is it that this product would improve your general health?

Not at all likely				Very likely	Don't know
1	2	3	4	5	

4. Does the label mention or suggest that this product may help lower the risk of any of these health problems? [Randomize list, except for last item.]

	Yes	No	Don't know
Diabetes			
Cancer			
Hypertension or high blood pressure			
Heart disease			
Other health problems not on this list			

[Randomize questions 5 and 6.]

5. Does the label mention or suggest that this product may **treat** any of these health problems? [Randomize list, except for last item.]

	Yes	No	Don't know
Diabetes			
Cancer			
Hypertension or high blood pressure			
Heart disease			
Other health problems not on this list			

6. Does the label mention or suggest that this product may **completely prevent** any of these health problems? [Randomize list, except for last item.]

	Yes	No	Don't know
Diabetes			
Cancer			
Hypertension or high blood pressure			
Heart disease			
Other health problems not on this list			

7. [If yes to cancer in questions 4, 5, or 6] If you were shopping for a dietary supplement and saw a product with this label, how likely is it that you would do the following?

How likely is it that you would...	Not at all likely 1	2	3	4	Very likely 5	Don't know
Use a lot of this product to get more benefits from it?						
Use this product if you were worried about getting cancer?						
Use this product if you had						

How likely is it that you would...	Not at all likely 1	2	3	4	Very likely 5	Don't know
any kind of cancer?						

8. [If yes to cancer in questions 4, 5, or 6] Suppose you are shopping for a dietary supplement and see a product with this label.

If you needed medical treatment, how likely is it that you would...	Not at all likely 1	2	3	4	Very likely 5	Don't know
Use this product instead of using prescription drugs?						
Use this product instead of a drug or other treatment recommended by your healthcare provider?						
Use this product in addition to a drug or other treatment recommended by your healthcare provider?						

9. [If yes to cancer in questions 4, 5, or 6] Based on the information shown on this label, how much would you agree or disagree with the following statements?

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Don't know
This product helps reduce the risk of developing any kind of cancer.						
This product helps people with cancer live longer.						
If you take this product, you will not get any kind of cancer.						
This product helps cure cancer.						
This product helps reduce the risk of some kinds of cancer, but not all.						
This product treats cancer symptoms.						
This product prevents tumor growth.						
This product reduces the risk of developing bladder cancer.						
This product reduces the risk of developing skin cancer.						

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Don't know
Once cancer has gone away, this product will keep it from coming back.						
If you take this product, you will not get thyroid cancer.						

10. [If yes to cancer in question 4] Does the label mention or suggest that this product may lower the risk of: [Randomize list, except for last item.]

	Yes	No	Don't know
Bladder cancer?			
Bone cancer?			
Breast cancer?			
Colon cancer?			
Liver cancer?			
Lung cancer?			
Prostate cancer?			
Rectal cancer?			
Skin cancer?			
Thyroid cancer?			
Cancer in general?			

OR Alternate Question 10:

[If don't know to cancer in question 4] You indicated that you don't know if the label mentions or suggests that this product may help lower the risk of cancer. Please describe the reason for your answer in the space below.

When answering the next two questions, please focus on the part of the label that is highlighted. [Image will highlight the health claim language plus disclaimer, if any. Skip if assigned to no-claim condition.]

11. In general, how hard or easy is it to understand this information?

Very hard to understand				Very easy to understand	Don't know
1	2	3	4	5	

12. In your opinion, how trustworthy is this information?

Not at all trustworthy				Very trustworthy	Don't know
1	2	3	4	5	

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SECTION C. BELIEFS, KNOWLEDGE, AND PERCEPTIONS ABOUT CANCER

[All participants]

The next section of the survey includes general questions. These questions are **not** about the label you saw in the previous questions. [Start next question on a new screen.]

How much do you agree or disagree with each of the following statements? [Rotate statements]

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Don't know
13. All kinds of cancer have the same causes.						
14. Every kind of cancer can be prevented in the same way.						
15. Every kind of cancer can be treated in the same way.						
16. Every kind of cancer can be cured in the same way.						
17. A person can completely prevent any cancer by eating a healthy diet.						
18. A person can completely prevent any cancer by taking dietary supplements.						

19. How much control do you think you have over whether you will get cancer?

1 2 3 4 5 6 7

No control Complete control

- Prefer not to answer
- Don't know

20. Compared to other people your age, how would you rate your overall chance of getting any type of cancer?

- Much less likely than average
- Somewhat less likely than average
- About the same as other people's chance
- Somewhat more likely than average
- Much more likely than average
- Prefer not to answer
- Don't know

21. How often do you worry about getting cancer of any kind?

- Never
- Rarely
- Sometimes
- Often
- All the time
- Prefer not to answer
- Don't know

SECTION D. PERCEPTIONS OF DIETARY SUPPLEMENTS

[Only participants who answered "Yes" to question 1]

22. Please think about the labels on vitamin and mineral products. Do you yourself use these labels to find out any of the following?

Do you use vitamin/mineral labels to find out...	Yes	No	Information is not on the label
What the product is for?			
If there are side effects or drug interactions from using the product?			
If anyone should avoid the product?			
What ingredients are in the product?			
Health benefits of the product?			

For each of the following, please mark how much you agree or disagree with the statement.

[Rotate statements]

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Don't know
23. A good reason for me to take vitamin or mineral supplements is to prevent illnesses.						
24. A good reason for me to take vitamin or mineral supplement is to treat illness.						
25. It is important to educate myself about vitamin and mineral supplements before I try them.						

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Don't know
26. I try to pay attention to possible side effects or drug interactions when I take vitamin or mineral supplements.						

SECTION E. EXPERIENCE WITH DIETARY SUPPLEMENTS

27. [If yes to selenium in question 1a] When was the last time that you took a single-ingredient selenium supplement?
- Within the last month
 - Within the last 6 months
 - Within the last year
 - Over a year ago
 - Never [included to identify potentially inconsistent responders; skip next question]
28. [If yes to selenium in question 1a] What reasons did you have for taking a single-ingredient selenium supplement? Please provide a brief description of your reason(s).
29. [If yes to question 1] In the past 12 months, have you experienced any health problem that you thought might be related to ANY dietary supplements you took?
- Yes
 - No
30. [If yes] What supplement(s) were you taking at the time you experienced your health problem(s)?

SECTION F. KNOWLEDGE ABOUT DIETARY SUPPLEMENTS AND HOW THEY ARE REGULATED

[All participants]

31. As far as you know, does the government regulate the manufacturing of vitamin and mineral supplements?
- Yes
 - No
32. As far as you know, does the government approve vitamin and mineral supplements before they are sold to consumers?
- Yes

- No

SECTION G. DEMOGRAPHICS, HEALTH STATUS, AND OTHER COVARIATES

We have one final set of questions about you and your health. It is not required that you answer these questions. We use this information for analysis purposes and to better understand the information obtained in this study as a whole. All answers to this survey will be kept strictly confidential.

33. In what year were you born?

Year: _____

- Prefer not to answer

34. Do you work either full- or part-time for a dietary supplement manufacturer, distributor, or retailer?

- Yes
- No
- Prefer not to answer

35. What is the highest degree or level of school you have COMPLETED? Please select one.

- Less than 9th grade
- 9th grade to 12th grade, No Diploma
- High school graduate - Diploma or GED
- Some college or Associate degree
- Bachelor's degree
- Graduate or professional degree
- Prefer not to answer

36. Are you of Hispanic or Latino origin?

- Yes
- No
- Prefer not to answer

37. What race do you consider yourself to be? Please select one or more.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Other
- Prefer not to answer

38. Would you say your health in general is:

- Excellent
- Very good
- Good
- Fair
- Poor
- Don't know
- Prefer not to answer

39. Have you ever been told by a doctor or other healthcare professional that you have cancer?

- Yes
- No
- Prefer not to answer

40. [If yes] What type of cancer did you have?

Please specify:

- Prefer not to answer

41. Which of the following categories includes your total household income in [*previous calendar year*] before taxes?

- Less than \$25,000
- \$25,000 to \$49,999
- \$50,000 to \$74,999
- \$75,000 to \$99,999
- \$100,000 and over
- Prefer not to answer

You have reached the end of the survey. Thank you very much for your participation. We appreciate your taking time to provide this information.

If there is anything you would like to tell us about this survey, please feel free to type your comments in the space provided below.

If you would like further information about dietary supplements, please refer to:
<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm109760.htm>

You can also find more information at the Food and Drug Administration's website:
<http://www.fda.gov/>

If you would like further information about cancer prevention or treatment, please refer to:
<http://www.webmd.com/cancer/default.htm>

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