

Draft Questionnaire
Experimental Study on Consumer Responses
to Nutrient Content Claims on Fortified Foods
2/25/14

[MUST SHOW ON FIRST PAGE]

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PUBLIC Disclosure Burden Statement

Public reporting burden for this collection of information is estimated to average 15 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. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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

- [1. INFORMATION IN ALL CAPS IN BRACKETS IS NOT DISPLAYED; SOME ARE INSERTION DIRECTIONS;**
- 2. RESPONSE OPTION CODES ARE NOT DISPLAYED;**
- 3. IF NO “GO TO” INSTRUCTIONS, PROCEED TO NEXT QUESTION;**
- 4. SHOW “MISSED QUESTION” NOTIFICATION IF RESPONDENT SKIPS A QUESTION, BUT LET THEM PROCEED AFTER THAT WITHOUT ANSWERING;**
- 5. PLEASE ADD AN OPTION FOR “DON’T KNOW” TO EVERY QUESTION;**
- 6. MAKE SURE TO CLEARLY SEPARATE “DON’T KNOW” VISUALLY FROM THE OTHER RESPONSE OPTIONS;**
- 7. CODE ALL “DON’T KNOW” AS “8” UNLESS “8” IS ALREADY BEING USED. THEN USE “88”;**
- 7. FOR SECTIONS D AND E, ENSURE THE LABEL IS VIEWABLE AT ALL TIMES;**
- 8. PLEASE ENSURE NO SCROLLING IS NEEDED TO ANSWER ANY QUESTIONS ON A 13” MONITOR.]**

[INTRODUCTION –SECTION HEADINGS IN LIGHT BLUE ARE FOR FDA]

Thank you for agreeing to participate. We are interested in your views about certain food products. Please read each question carefully and then select the answer that best suits you. It usually takes about 15 minutes to answer all the questions. The information you provide will be kept strictly confidential.

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

[SECTION A: CHOICE TASKS]

[CHOICE 1. PARTICIPANTS ARE ASKED TO SELECT ONE OF TWO PRODUCTS. USE PRODUCT PAIRING FROM SPREADSHEET COLUMN LABELED “CHOICE TASKS”; RANDOM ASSIGNMENT; RANDOMIZE HORIZONTAL DISPLAY (LEFT/RIGHT POSITION)]

Please look at these two food labels and answer the questions below based on what you can see on the labels shown on your screen.

[A1a.] If you wanted to buy some cookies] and only had these two to choose from, which one would you pick?

- Product A.....1
- Product B.....2
- Other8

[A2a] Please look at these two food labels again. If you wanted to buy the healthier product, which of these two products would you pick?

- Product A is healthier **[GO to B1]**.....1
- Product B is healthier**[GO to B1]**.....2
- Other8

[A2a1]

In the previous question, you selected “other.” Which of the following best describes why you selected “other”?

- Both seem equally unhealthy.....1
 - Both seem equally healthy.....2
 - Don’t know.....8
 - Other.....3
- Please specify: **[ALLOW FOR 300 CHARACTERS]**

[SECTION B: PRODUCT USE/CONSUMPTION]

These next questions are about food you eat in the morning. They assume that you go to bed sometime in the evening and wake up sometime in the morning. If your sleep schedule is different, please answer the questions according to when you wake up after your daily long stretch of sleep.

[B2] On average, how often do you have something to eat or drink in the morning?

1 day a week.....	1
2 days a week.....	2
3 days a week.....	3
4 days a week.....	4
5 days a week.....	5
6 days a week.....	6
7 days a week.....	7
I never eat or drink anything in the morning.....	0 [GO TO B5]
Don't know.....	8

[ROTATE B3 OPTIONS]

[B3] When you eat or drink something in the morning, about how many days of the week do you include something...?

- [B3a]**Healthy
- [B3b]**Nutritious
- [B3c]**Low in calories
- [B3d]**High in certain vitamins or minerals
- [B3e]**Convenient
- [B3f]**Portable (easy to take with you)

1 day a week.....	1
2 days a week.....	2
3 days a week.....	3
4 days a week.....	4
5 days a week.....	5
6 days a week.....	6
7 days a week.....	7
I never include this.....	0
Don't know.....	8

[B4] On average, how often do you eat/drink the following food products **IN THE MORNING?** **[ROTATE ITEMS]**

- [B4a]**Hot beverage (such as coffee or tea)
- [B4b]**Juice or milk (cow's milk, soy milk, etc.)
- [B4c]**Carbonated soft drink, diet (Diet Soda, Diet Pop)
- [B4d]**Carbonated soft drink, regular (Soda, Pop)
- [B4e]**Donuts, sweet rolls, muffins, cake, sweetened breads (such as banana bread)
- [B4f]**Cookies
- [B4g]**Cereal bar,protein bar, granola bar, breakfast bar
- [B4h]** Candy

- [B4i]** Oatmeal or other hot cereal
- [B4j]** Energy drink
- [B4k]** Meal replacement drinks, shake, or smoothie

Daily.....	6
A few times a week.....	5
Once a week.....	4
Once or twice a month.....	3
About once or twice every six months.....	2
Less than once every six months.....	1
Never	0
Don't know.....	8

[B5] On average, how often do you eat/drink the following food products (any time of day) ?
[ROTATE ITEMS]

- [B5a]** Hot beverage (such as coffee or tea)
- [B5b]** Juice or milk (cow's milk, soy milk, etc.)
- [B5c]** Carbonated soft drink, diet (Diet Soda, Diet Pop)
- [B5d]** Carbonated soft drink, regular (Soda, Pop)
- [B5e]** Donuts, sweet rolls, muffins, cake, sweetened breads (such as banana bread)
- [B5f]** Cookies
- [B5g]** Cereal bar, protein bar, granola bar, breakfast bar
- [B5h]** Candy
- [B5i]** Oatmeal or other hot cereal
- [B5j]** Energy drink
- [B5k]** Meal replacement drinks, shake, or smoothie

Daily.....	6
A few times a week.....	5
Once a week.....	4
Once or twice a month.....	3
About once or twice every six months.....	2
Less than once every six months.....	1
Never	0
Don't know.....	8

[SECTION C: SELF HEALTH]

[C2] Compared to other people your age, would you say your health is...?

Excellent.....	5
Very good.....	4

- Good.....3
- Fair.....2
- Poor.....1
- Don't know.....8
- Prefer not to answer.....9

[C3] Have your doctors/health care providers told you that you have the following health conditions or do you believe you are at risk for any of the following health conditions? Please select an answer for each of the health conditions. **[ACCEPT ONE RESPONSE PER ROW – SEE RESPONSE OPTIONS BELOW.] [ROTATE HEALTH CONDITIONS]**

- [C3a]** Diabetes
- [C3b]** Heart disease
- [C3c]** Hypertension or high blood pressure
- [C3f]** Osteoporosis (brittle bones)

[RESPONSE OPTIONS FOR C3a-f]

- I currently have this health condition.....3
- I believe I am at risk for this health condition.....2
- I do not have, nor believe I am at risk for, this health condition.....1
- Don't Know.....8
- Prefer not to answer9**[SITUATE NEXT TO DON'T KNOW, VISUALLY**

SEPARATE FROM OTHER OPTIONS

[C4.] How tall are you without shoes? Please enter a number in both “feet” and “inches” or select “prefer not to answer.” If you are not sure, make your best guess.

- a. Feet _ **[ONE SPACE]** b. Inches _ _ **[TWO SPACES, range of 1-11]**
- c. Don't know.....8
- d. Prefer not to answer.....9

[C5] How much do you weigh without shoes? Please enter the number of pounds (round up or down to the closest whole number). If you are not sure, make your best guess.

- a. Pounds _ _ _ **[THREE SPACES]**
- b. Don't know.....8
- c. Prefer not to answer9

[SECTION D: RANDOM ASSIGNMENT 1]

[SINGLE PRODUCT EVALUATION; PARTICIPANTS ARE ASKED TO RESPOND TO QUESTIONS ABOUT A SINGLE PRODUCT; SELECT FROM SPREADSHEET COLUMN “RANDOM ASSIGNMENT”; ENSURE RESPONDENTS DO NOT GET THE SAME CLAIM AS CHOICE TASK]

Please take a moment to look at this food product. Feel free to click on the link provided below to see the Nutrition Facts Label more clearly. The Nutrition Facts Label provides nutrition information about this product.

[PERCEPTIONS OF PRODUCT HEALTHFULNESS AND HEALTH BENEFITS]

[D3] On a scale from 1 to 6, where 1 is strongly disagree and 6 is strongly agree, how much do you disagree or agree with the following statements?

[ROTATE ITEMS D3a to D3j; PUT ONLY 2 OR 3 ITEMS ON A SINGLE TABLE GRID TO REDUCE THE NEED FOR SCROLLING; INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=STRONGLY DISAGREE AND 6=STRONGLY AGREE; PROVIDE A SELECTION BOX FOR INDICATING “DON’T KNOW.”]

[FOR VITAMIN FILL: INSERT “CALCIUM” FOR COOKIE AND CHOCOLATE CANDY AND “VITAMIN C” FOR JELLY/VITA BEANS AND SODA].

[D3a] Including this product as part of my diet may lower my risk of coronary heart disease.

[D3b] The more of this product I consume the healthier I will be.

[D3c] This product is good for my health.

[D3d] I consider this product to be a healthy food.

[D3e] Including this product as part of my diet will improve my overall diet.

[D3f] I consider this product to have some positive health qualities.

[D3g] Regularly consuming this product would help me manage my weight.

[D3h] I think it would be alright to get all of my **[VITAMIN]** from eating this product.

[D3i] Regularly consuming this product would help someone have more energy for sports.

[D3j] I consider this product to be a nutritious source of energy.

[D4] How low or high is this product in the following nutrients? Please use a scale from 1 to 6, where 1 means “none or very low” and 6 means “very high”.

[ROTATE ITEMS. INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=NONE OR VERY LOW AND 6=VERY HIGH; PROVIDE A SELECTION BOX FOR INDICATING “DON’T KNOW.”]

[D4a]Calories

[D4b]Fiber

- [D4c] Vitamin D
- [D4d] Calcium
- [D4e] Sugar
- [D4f] Saturated Fat
- [D4g] Vitamin C
- [D4h] Potassium

[CONSUMPTION AND SUBSTITUTION]

Please read all the response options before answering the question.

[D5a] I would have this product for breakfast

- Three or more times a week in place of my usual breakfast.....5
- Twice a week in place of my usual breakfast.....4
- Once a week in place of my usual breakfast.....3
- Once or twice a month in place of my usual breakfast...2
- Less than once a month in place of my usual breakfast..1
- Never0
- Don't know....8

[D5b] I would have this product for a snack

- Three or more times a week in place of another snack.....5
- Twice a week in place of another snack4
- Once a week in place of another snack3
- Once or twice a month in place of another snack2
- Less than once a month in place of another snack..1
- Never0
- Don't know....8

[D5b] I would serve this product to school-aged children for breakfast

- Three or more times a week in place of their usual breakfast.....5
- Twice a week in place of their usual breakfast.....4
- Once a week in place of their usual breakfast.....3
- Once or twice a month in place of their usual breakfast...2
- Less than once a month in place of their usual breakfast..1
- Never0
- Don't know....8

[D5b] I would serve this product to school-aged children for a snack
Three or more times a week in place of another snack.....5
Twice a week in place of another snack4
Once a week in place of another snack3
Once or twice a month in place of another snack2
Less than once a month in place of another snack..1
Never0
Don't know....8

[D5c] I would [**“EAT” FOR COOKIES AND CANDY; “DRINK” FOR SODA**] this product to help me get enough of my daily [**FILL VITAMIN: “CALCIUM” FOR COOKIE AND CHOCOLATE CANDIES AND “VITAMIN C” FOR JELLY/VITA BEANS AND SODAS**].

Three or more times a week in place of other sources of [VITAMIN].
.....5
Twice a week in place of other sources of [VITAMIN].
.....4
Once a week in place of other sources of [VITAMIN].
.....3
Once or twice a month in place of other sources of [VITAMIN].
....2
Less than once a month in place of other sources of [VITAMIN].
..1
Never0
Don't know....8

FILL: “EAT” FOR COOKIES AND CANDY; “DRINK” FOR SODA.

[D6] [INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=STRONGLY DISAGREE AND 6=STRONGLY AGREE; PROVIDE A SELECTION BOX FOR INDICATING “ DON’T KNOW” AND “NOT APPLICABLE”]

Assuming that the calories for the following foods are equal, having this product would be as healthy as having a

[D6a] bowl of oatmeal.

[D6b] serving of fresh fruit.

[D6c] serving of wheat toast.

[D6d] some raisins.

[D6e] small handful of nuts

[PERCEPTIONS OF PRODUCT ATTRIBUTE]

[D7] On a scale from 1 to 6 where 1 is strongly disagree and 6 is strongly agree, now much do you disagree or agree with the following statements.

[ROTATE ITEMS. INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=STRONGLY DISAGREE AND 6=STRONGLY AGREE; PROVIDE A SEPARATED SELECTION BOX FOR INDICATING “ DON’T KNOW.”]

[D7a] This product looks like it would be tasty for breakfast.

FILL: “EAT” FOR COOKIES AND CANDY; “DRINK” FOR SODA.

[D7d] This product would be a convenient option for breakfast.

[D7e] This product would be a healthy option for breakfast.

[D7f] This product would be a healthy option for dessert.

[D7g] This product would be a healthy option for a snack.

[BELTRAMINI BELIEVABILITY SCALE]

D8. The labels says **[INSERT CLAIM FROM PACKAGE FRONT]**. Please rate this using the following scale

D8A. Unbelievable-----Believable

1 2 3 4 5

D8B. Untrustworthy -----Trustworthy

D8C. Not Convincing -----Convincing

D8D. Not Credible-----Credible
D8E. Unreasonable-----Reasonable

D9. What is your attitude toward this product?

Very Negative-----Very Positive
Vitamins are natural-----Vitamins are added
1 2 3 4 5

[SECTION F: DIETARY INTERESTS] [NO LABEL VIEWING FROM THIS POINT FORWARD.]

[F1] For each of the following statements, please indicate how strongly you agree or disagree.

1. Strongly disagree
2. Somewhat disagree
3. Neither agree nor disagree
4. Somewhat agree
5. Strongly agree

[F1a] What I eat or drink can make a big difference in my chance of getting a disease, like heart disease.

[F1b] I am confident that I know how to choose a healthy diet.

[F1c] I am confident that I know how to get enough vitamins or minerals from the foods that I eat.

[F1d] Eating foods fortified with vitamins and minerals will help to prevent illness.

[F1e] Eating foods fortified with vitamins and minerals can help to treat illness..

[F2] From the list below, which nutrients have you ever tried to limit from your diet?

[ROTATE ITEMS; PROVIDE A SEPARATED SELECTION BOX FOR INDICATING “DON’T KNOW FOR EACH ITEM.]

I have tried to limit . . .

[F2a] Fat

[F2b] Carbs or carbohydrate

[F2c] Salt or sodium

[F2d] Calories

[F2e] Sugar

Yes.....1

No.....0

Don't know.....8

[F3] From the list below, which nutrients have you ever tried to get enough of?

[ROTATE ITEMS; PROVIDE A SEPARATED SELECTION BOX FOR INDICATING “DON’T KNOW FOR EACH ITEM.]

I have tried to get enough of . . .

[F3a] Fiber

[F3b] Vitamin C

[F3c] Calcium

[F3d] Iron

Yes.....1

No.....0

Don’t know.....8

[F4] When available, I choose foods that are fortified with vitamins and minderals over those that are not.

[SECTION G: FOOD LABEL SELF-EFFICACY]

[G1 - ROTATE ITEMS. INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=STRONGLY DISAGREE AND 6=STRONGLY AGREE. PROVIDE SELECTION BOX INDICATING ‘DON’T KNOW’ FOR EACH ITEM.]

[G1] On a scale from 1 to 6, where 1 is strongly disagree and 6 is strongly agree, now much do you disagree or agree with the following statements?

[G1a] I feel confident that I know how to use food labels to choose a nutritious diet.

[G1b] Reading food labels takes more time than I can spare.

[G1c] The nutrition information on food labels is useful to me.

[G1d] Reading food labels makes it easier to choose foods.

[SECTION I(eye): BELIEFS ABOUT PRODUCT CATEGORY HEALTHFULNESS]

[I1] In general, how healthy do you think are each of these types of foods, on a scale of 1 to 6, where 1 is “not at all healthy” and 6 is “very healthy”? (Nutritious?)

[ROTATE ITEMS IN I. INSERT RESPONSE OPTION SCALE 1 THROUGH 6 ANCHORED BY 1=NOT AT ALL HEALTHY AND 6=VERY HEALTHY. PROVIDE SEPARATED OPTION FOR 8=DON'T KNOW.]

- [I1a]Cookies
- [I1b]Whole milk, unflavored
- [I1c]Carbonated soft drink, diet (Diet Soda, Diet Pop)
- [I1d]Carbonated soft drink, regular (Soda, Pop)
- [I1e]Candy
- [I1f]Chocolate

[SECTION J: FOOD SHOPPING AND LABEL READING]

Now we have some questions about your food shopping habits.

[J1] How much of your household’s food shopping do you do?

- All of the food shopping.....5
-
- Most of it.....4
- About half of it.....3
- Only a little of it.....2
- None of it.....1
- Don’t know.....8

[J2] When you buy foods for the first time, how often do you read the nutrition facts label to compare how healthy or nutritious different foods are?

- Always.....5
- Most of the time.....4
- Sometimes.....3
- Rarely.....2
- Never.....1
- Don’t know.....8

[J3] When you buy a food product for the first time, how often do you read the label to find out how much it has of things like calories, fat, sodium, or vitamins?

- Always.....5
- Most of the time.....4
- Sometimes.....3

Rarely.....2
 Never.....1
 Don't know.....8

[SECTION K: HEALTH STATUS AND DEMOGRAPHICS]

The next few questions may seem a bit personal, but we need this information because this survey is about health and nutrition.

[PROGRAMMER: ROTATE K1A-K1E. NOTE THAT K1F SHOULD ALWAYS BE AT THE END OF THE TABLE GRID.]

[K1]Have you taken any vitamin or mineral dietary supplements in the past 3 months, that is, since **[FILL MONTH]** 2013? (Yes/No)

[K1a]Multi-vitamin or multi-mineral supplement, such as One-A-Day, Mega-Vitamin, Centrum A-to-Z.

[K1b]Calcium supplement Please do not include calcium added to foods or beverages, for example, calcium in milk.

[K1c] Vitamin D supplement. Please do not include Vitamin D added to foods or beverages.

[K1d] Potassium supplement. Please do not include potassium added to foods or beverages.

[K1e] Vitamin C supplement. Please do not include Vitamin C added to foods or beverages.

[K1f] Other vitamin or mineral supplements. Please do not include Vitamins or minerals added to foods or beverages.

Yes.....1
 No.....0
 Don't know.....8

[K2]What is the highest grade or level of school you have completed? Please select one answer.

1. Less than 9th grade
2. 9th to 12th grade, NO DIPLOMA
3. High school graduate – DIPLOMA or GED
4. Some college or Associate degree
5. Bachelor's degree
6. Graduate or professional degree
7. Don't know
8. Prefer not to answer

[K3] What year were you born?

19 __ _ **[TWO SPACES]**

[K4] Are you (please select one)

Female.....1

Male.....0

[K5] Are you of Hispanic or Latino origin? Please select one.

Yes.....1

No.....0

[K6] What is your race? You may choose one or more categories as they apply.

[K6a] White

[K6b] Black or African American

[K6c] Asian

[K6d] Native Hawaiian or other Pacific Islander

[K6e] American Indian or Alaska Native

[K6f] Some other race

[K7] How many children live in your household at least half-time who are 17 years of age or younger? _____

[If K7 > 0]

[K8]. Starting with the youngest child, please list the ages (in years) of the children in your household. If child is less than a year old, enter 0.

[K8a] Child 1	[K8b] Child 2	[K8c] Child 3	[K8d] Child 4	[K8e] Child 5	[K8f] Child 6

[K9– OPEN ENDED]

Please provide any comment you wish.

Thank you very much.