**OMB Approval Number: 0910-XXXX**

**OMB Expiration Date: XX/XX/XXX**

**Gluten-Free Labeling of Food Products**

**Experimental Study**

**Draft Paper Questionnaire**

**10-14-09**

**Introduction**

Thank you for participating in this important study on food labeling. Your responses are valuable to us. Please be assured that all your responses will be kept completely confidential. You can skip any of the questions and quit at any time. The whole questionnaire will take about twenty minutes to complete.

Thank you very much for your time.

1. Do you have medically diagnosed celiac disease or a gluten intolerance, or do you regularly purchase groceries or prepare food for someone with a medically diagnosed celiac disease or a gluten intolerance? Please choose the response that most closely matches your circumstances.

* YES, I have medically diagnosed *celiac disease*
* YES, I purchase groceries or prepare food for someone with medically diagnosed celiac disease
* YES, I have medically diagnosed *gluten intolerance*
* YES, I purchase groceries or prepare food for someone with medically diagnosed gluten intolerance
* NO (retain only as needed for control group quotas. SKIP Q5.)

 **PUBLIC DISCLOSURE BURDEN STATEMENT**

 **Public reporting burden for this collection of information is estimated to average twenty ( 20) 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/PRB Comments/HFS-24
5100 Paint Branch Parkway
College Park, MD 20740-3835.**

2. How was this diagnosis made? Please **read** **ALL** the options and then **choose just one.** Was the diagnosis made by:

* Removing foods with gluten from your or the person’s diet (NOT APPROPRIATE FOR CELIAC DIAGNOSIS.)
* Blood tests
* Biopsy of the small intestine.
* Blood tests and a biopsy of the small intestine
* None of the above. (retain only as needed for control group quotas)
* Don’t know (retain only as needed for control group quotas)

3. About how many days per week do you include packaged, processed food products when you eat (or serve) food?

1,2,3,4,5,6,7

Don’t know

4. About how long ago were you, or the person for whom you buy groceries or prepare food, diagnosed with Celiac Disease or gluten-intolerance?

 \_\_\_\_less than 6 months ago

 \_\_\_\_ between 6 months and 1 year ago

 \_\_\_\_ between 1 year and 3 years ago

 \_\_\_\_\_ more than 3 years ago

 \_\_\_\_ Never diagnosed

5. About how much of your diet is gluten-free? Or, how much is the diet of the person for whom you buy groceries or prepare foods gluten-free?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

0% 25% 50% 75% 100%

6. About how much of the food you eat/serve is purchased from stores that specialize in gluten-free food products (not web stores)?

None ----------------------------------------------------All

0% 25% 50% 75% 100%

7. About how much of the food you eat/serve is purchased from web-sites that specialize in gluten-free food products?

None ----------------------------------------------------All

0% 25% 50% 75% 100%

8. Do you own a gluten-free cookbook (specific to gluten-free cooking)?

No

Yes

Don’t know

serve

7. How important is it to you to follow (or provide) a gluten-free diet?

Not at all -------------------------------------------------------------------Very much

 1 2 3 4 5

9. How often do you, or the person for whom you purchase groceries or prepare food, knowingly eat foods that contain gluten?

Never -------------------------------------------------------------------Always

 Rarely Sometimes Often

10. How difficult is it for you to follow (or provide) a gluten free diet?

Not at all -------------------------------------------------------------------Very difficult

 1 2 3 4 5

11. How expensive is it for you to follow (or provide) a gluten-free diet?

Not at all expensive -------------------------------------------------------------Very expensive

 1 2 3 4 5

12. Do you feel there are enough gluten-free food choices available for you to easily follow(or provide) a gluten-free diet?

 Not at all -------------------------------------------------------------------Very much

 1 2 3 4 5

13. What are your feelings about needing to eat(or provide) gluten-free foods?

 Frustrated

Angry

 Sad

 Annoyed

Not at all -------------------------------------------------------------------Very much

 1 2 3 4 5

14. How satisfied are you with the information about eating gluten-free that you receive from health care professionals?

Not at all -------------------------------------------------------------------Very much

 1 2 3 4 5

15. How satisfied are you with the level of support you receive from friends and family members

about following a gluten-free diet?

Not at all -------------------------------------------------------------------Very much

 1 2 3 4 5

15. How often do you look for a “gluten-free certification” on packaged foods?

Never -------------------------------------------------------------------Always

 Rarely Sometimes Often

16. Compared to other people your age, would you say your overall health is…

Much better than average

Better than average

About the same as other people’s health

Worse than average

Much worse than average

17. About how many of your friends or family members follow a gluten-free diet?

\_\_\_\_\_\_\_\_

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**[The following questions are for all participants unless otherwise noted: Do not give questions 18, 23, 24, 26, and 27 to participants viewing the no-claim control label]** [Question 18: Participants will see Gluten-Free related labels for the Alpine Krunch chocolate bar. Participants will be able to move ahead without choosing but will not be told that they do not need to choose.]

 **INSTRUCTIONS**

Next we will show you some food labels for a common food product.The brand and the labels are not real but are made up for the purpose of this study. Please use the food label to help you answerthe questions.

18. Imagine you are shopping or preparing food for someone who has Celiac Disease. Choose one item and put it into the basket if you want to purchase it.

**INSTRUCTIONS**

For the next set of questions, we will show you only one food label. Again, the brand and the label are not real but are made up for the purpose of this study. Please use the food label to help you answerthe questions.

19. How likely is it that this product contains gluten?

 Not at all likely------------------------------------------------------------------Highly likely

 1 2 3 4 5

20. How easy was it for you to make your choice?

Not at all easy --------------------------------------------------------------------Very Easy

 1 2 3 4 5

21. How noticeable is the information about gluten on this food label?

 Not at all noticeable-----------------------------------------------------------Very Noticeable

 1 2 3 4 5

22. How safe is this product for someone with Celiac Disease or a gluten-intolerance to eat?

Not at all safe------------------------------------------------------------------Very Safe

 1 2 3 4 5

Please indicate your level of agreement with the following statement(s)

23. The purpose of the information about gluten on the food label is to ***inform*** consumers with Celiac Disease or gluten-intolerance.

24. The purpose of the information about gluten on the food label is to ***protect*** consumers with Celiac Disease or gluten-intolerance.

25. The purpose of the information about gluten on the food label is to ***warn*** consumers with Celiac Disease or gluten-intolerance.

Strongly Disagree --------------------------------------------------------------- Strongly Agree

 1 2 3 4 5

26. How likely would you be to eat/serve this product (to someone with Celiac Disease)?

 Not at all likely------------------------------------------------------------------Highly likely

 1 2 3 4 5

27. Please rate the statement about gluten on this label using the following scale

 Unbelievable ----------------------------------------------------------------Believable

 1 2 3 4 5

 Untrustworthy---------------------------------------------------------------- Trustworthy

Not convincing---------------------------------------------------------------- Convincing

 Not credible---------------------------------------------------------------- ---Credible

 Unreasonable ----------------------------------------------------------------Reasonable

Dishonest---------------------------------------------------------------- ----Honest

 Unquestionable --------------------------------------------------------------Questionable

 Inconclusive---------------------------------------------------------------- Conclusive

 Not authentic ----------------------------------------------------------------Authentic

 Unlikely ----------------------------------------------------------------------Likely

Not helpful ----------------------------------------------------------------Helpful

28. How would you rate this product in terms of quality?

Poor ------------------------------------------------------------------Excellent

 1 2 3 4 5

**-----------------------------------------------------------------------------------------------------------------------------**

**Thank you very much for your responses so far. The next section is for us to know a little bit about you. Please keep in mind that your responses are kept confidential. The information requested below will be used for statistical purposes only.**

29. Do you belong to any of the following celiac disease special interest groups or are you a member of a celiac disease group that is associated with any of the groups listed below? Please check as many as apply.

* American Celiac Disease Alliance (ACDA)
* American Celiac Society (ACS)
* Celiac Disease Foundation (CDF)
* Celiac Sprue Association (CSA)
* Gluten Intolerance Group of North America
* National Foundation for Celiac Awareness(NFCA)

# **(Online panel respondents will not receive demographic questions.)**

# Demographic Questions

30. Please select one of the following. Are you:

* Male
* Female

31. What is your age in years?

* \_\_\_\_\_\_\_

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

* Less than high school
* High school graduate or GED
* Technical/vocational school
* Community college
* Some college (1-3 years

towards Bachelor’s degree)

* College (Bachelor’s degree)
* Advanced degree (post graduate degree)

33. Are you of Hispanic or Latino origin?

* Yes
* No

34. What is your race? You may choose one or more categories. Are you?

* White
* Black or African American
* Asian
* Native Hawaiian or other Pacific Islander
* American Indian or Alaska Native
* Other
* R.O.C.K. (Raising Our Celiac Kids)

35. Please provide any comments you wish.

THANK YOU VERY MUCH