

Appendix I

“Gluten-Free Labeling of Food Products Focus Groups” Participant Screener

Recruiting Goals

- Four focus groups, two groups in each location: Washington DC and North Carolina.
- Ages 18 and over, with a range of ages in each group.
- Most participants will be individuals a) with medically diagnosed (self-report) celiac disease whose diet includes packaged, processed food products and who follow a gluten-free diet or b) who either regularly purchase groceries or prepare foods for someone with medically diagnosed (self-report) celiac disease whose diet includes packaged food products and follows a gluten-free diet.
- Some participants (up to 3 per group) may have medically diagnosed (self-report) gluten intolerance whose diet includes packaged, processed food products and who follow a gluten-free diet **or** be adult consumers who purchases groceries or prepares foods for someone who has a gluten intolerance and whose diet includes packaged, processed food products and who follow a gluten-free diet.
- The groups will be segmented by level of education.
- The groups will have a mix of races and ethnicities. Please note that Asian and Caribbean Black individuals have no known incidence of celiac disease.
- All groups will be mixed gender with no more than 4 men in each group.
- All participants must be able to read, understand and speak English.
- All participants must have grocery shopped within the past month.
- 12 recruits per group in order to get 8-12 to participate.
- Participants will receive \$75 incentives.
- Each focus group will last approximately 120 minutes. Groups will be audio- and video-taped.
- Obtain participant’s consent. The identity of the participants will remain confidential.
- Groups will be observed by staff from the Food and Drug Administration.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate.

Hello Mr./Ms. _____, my name is _____ and I'm calling about a market research study in your area. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about gluten-free food product labels. Would you mind answering a few questions?

Screening Questions

1. Before I start, are you at least 18 years old?
 - YES
 - NO → Can I speak with someone at least 18 years old? If no, when would be a good time to call back and speak with someone at least 18 years old?

2. Do you or does someone from your immediate family work for any of the following:
 - Market Research Firm → eliminate [thank respondent politely]
 - The Food and Drug Administration, U.S. Department of Agriculture, or State or local food agency → eliminate [thank respondent politely]
 - Food Industry or Food Retailer → eliminate [thank respondent politely]
 - Gastroenterologist or Gluten Interest Groups or Association → eliminate [thank respondent politely]

3. Do you shop for groceries for yourself or others?
 - Yes → continue
 - No → eliminate [thank respondent politely]

4. When was the last time you went grocery shopping?
 - More than one month ago → eliminate

5. 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?
 - YES, I have medically diagnosed celiac disease → go to 6
 - YES, I purchase groceries or prepare food for someone with medically diagnosed celiac disease → go to 6
 - YES, I have medically diagnosed gluten intolerance → go to 6
 - YES, I purchase groceries or prepare food for someone with medically diagnosed gluten intolerance → go to 6
 - NO → eliminate [thank respondent politely]

6. How was this diagnosis made? Please listen to 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. ACCEPT UP TO 3 PER GROUPS FOR GLUTEN INTOLERANCE]
 - Blood tests
 - Biopsy of the small intestine.
 - Blood tests and a biopsy of the small intestine
 - None of the above. → eliminate [thank respondent politely]
 - Don't know → eliminate [thank respondent politely]

7. Do you, or does someone for whom you regularly prepare food or buy groceries, follow a gluten-free diet?
- YES, I follow a gluten-free diet. → continue
 - YES, someone for whom I regularly prepare food or buy groceries for follows a gluten-free diet → continue
 - NO → eliminate [thank respondent politely]
8. Do you eat (or serve) *packaged, processed foods*?
- Yes → continue
 - No → eliminate [thank respondent politely]

Demographic Questions

9. Determine gender
- Male
 - Female
10. I am going to read some age categories --- could you please tell me in which category your age falls?
- 18-45 → continue
 - 45 and over → continue
- Q9a. What is your age exactly?
- [Specify] _____
11. What is the highest level of education that you have completed?
- Less than high school → lower education group
 - High school graduate or GED → lower education group
 - Technical/vocational school → lower education group
 - Community college → lower education group
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- Some college (1-3 years towards Bachelor's degree) → higher education group
 - College (Bachelor's degree) → higher education group
 - Advanced degree (post graduate degree) → higher education group
12. Are you of Hispanic or Latino origin?
- Yes → continue
 - No → continue
13. What is your race? I am going to read several categories of race. You may choose as many as they apply. Are you?
- White → continue
 - Black or African American → continue
 - Asian → continue
 - Native Hawaiian or other Pacific Islander → continue
 - American Indian or Alaskan Native → continue
 - [DON'T READ] Hispanic → continue
 - [DON'T READ] Other → continue

We would like to invite you to participate in a focus group to discuss issues relating to gluten-free labels on food products. The discussion will last approximately two hours and will be video- and audio-taped and observed by staff from the Food and Drug Administration, the FDA. Your participation and everything you say during the discussion will remain confidential. You will receive a \$75 incentive. Additionally, we will provide a light gluten-free meal before the group discussion starts. Are you interested in participating in this focus group?

- Yes → continue
- No → [Thank the person for his/her time]

I'm glad that you will be able to join us! The focus group will take place on (Day), (Date), at [6:00 or 8:00 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 letter and directions to the facility. In order to do so, could you please tell me your mailing address (or fax number, e-mail address) and a phone number where you can be reached:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____

Email: _____

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.

Appendix II

Moderator's Guide Gluten-Free Labeling of Food Products Focus Groups

Opening Remarks – Introductions and Rules

Ice Breaker (5 min.)

Moderator: Let's go around the room and introduce ourselves. Please tell me your first name, and a little bit about you and your experience with celiac disease or gluten intolerance or tell me about the person with celiac disease or gluten intolerance for whom you prepare foods or buy groceries. How have you dealt with it?

Diets

Moderator: Do you (or other person) follow a gluten-free (GF) diet? How long have you followed a GF diet? What is a GF diet? How do you follow a GF diet? What are the challenges involved in following a GF diet? Do you ever eat foods that contain gluten?

Gluten-free in general

Moderator: Tonight's discussion is going to be about gluten-free (GF), specifically, gluten-free labeling (15 min.)

1. What do you think of when you hear the following statements: made in GF facility, or not made in a facility that processes gluten-containing foods?
2. Why types of foods do you think are inherently GF or GF by nature?

How to better label GF

Moderator: Because GF labels have not been formally regulated by the FDA, we want to hear some of your input on this issue (15 min.)

3. Do you think the following messages mean that the *all* foods of the same type are also GF? E.g., "Milk, a GF food" as compared to "All milk is GF". What alternative wording would better convey the same message?
4. Do you think that the GF labeling claim is necessary for *all* or just *certain* inherently GF foods to indicate that all foods of the same type are also GF? If the answer is for just certain inherently GF foods, what foods are these?
5. Do you think the inclusion of additional information (e.g., does not contain 20 micrograms or more gluten per gram of food) on food labels will help you better understand the term GF?

[Pass out food labels]

The combination of a GF labeling claim

Moderator: Food labels sometimes contain several claims or advisory statements. Please let us know your likes and dislikes about them (10 min.)

6. Should the word "wheat" appear in the ingredients list or in a separate "Contains" statement?
7. Should the label use a voluntary advisory statement (e.g., processed in a facility with gluten-containing foods or may contain traces of gluten)?

Reduced-Gluten

Moderator: We have been talking about gluten-free. Now I want to ask some questions about other kinds of claims about the amount of gluten in a food (10 min.).

8. What does the claim "reduced gluten" mean to you if you or one of your family members is following a GF diet?
9. Do you think it is necessary to require additional information on the food labels so that the consumers won't be misled by the claim "reduced gluten"? For example, one slice of this wheat starch bread contains [X number] micrograms gluten or [X fraction or portion of] the gluten in a slice of regular wheat flour bread?

GF is not a static concept

Moderator: If a food like a dried soup mix as packaged was not GF, but when the soup was prepared according to instructions with the addition of water would be considered GF, then how should the statement appear on the label of that food (10 min.)?

10. Can the instructions say that the food was GF when prepared according to instructions? If so, where and how should the statement appear on the label of that food?
11. What other suggestions/questions do you have in terms of GF labeling?

Thank you, those are all the questions I have.