

Appendix II**OMB No: 0910-0497****Expiration Date: 10/31/2020**

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 information collection is estimated to average 90 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.

**Food Allergen Advisory Statement Focus Groups
Moderator's Guide****A. WELCOME AND GROUND RULES (10 min)**

Thank you for taking the time to join us today. I am _____ from RTI, a non-profit research organization and we are conducting a research study on behalf of the U.S. Food and Drug Administration. The purpose of tonight's discussion is to get your thoughts about things you might see on a food label. Your feedback is very important to us. Our discussion will last about 90 minutes.

Before we start, I want to review a few important things.

- Your participation today is voluntary, and you have the right to stop being in the focus group at any time.
- None of my questions are very personal, but you can choose not to answer any of them if you are uncomfortable. Just let me know that you prefer not to answer.
- Anyone can speak out; you don't need to wait for me to call on you, just make sure you speak up and speak one at a time. However, please keep in mind that we have a lot to talk about and materials to review, so it's important that I hear from everyone and that we discuss all the topics.
- Audio/video/observers
 - o We are audio and video recording this discussion so that I can give you my full attention and not have to take notes. When writing up our findings, we will not include any information that could identify you. Your name, address, and phone number will not be given to anyone, and no one will contact you about this research after this group is over.

- o Your information will be kept secure to the extent provided by the law.
 - o I have colleagues listening to our discussion and taking notes behind the glass. At the end of our conversation, I may go into the back to see if there are any last minute questions for you.
 - o We are also live-streaming our session so that other members of the research team who couldn't be here today can observe our discussion remotely.
- Please set your cell phones to vibrate or turn them completely off. If you need to use the restroom, please feel free to step out and join us once you are done.
 - Most importantly, there are no right or wrong answers. None of these are trick questions. I want to know your opinions and about your experiences.
 - I am not selling anything, I do not work for the people sponsoring this research, and I haven't created any of the things we'll look at, so don't hold back on giving me your honest opinions.
 - Also, I am not an expert about the topics we are going to discuss today or a medical doctor, so you may have questions that I can't answer.
 - All of your comments will be kept secure to the extent provided by law so feel free to say exactly what is on your mind. I will draft a report of the focus group session, and I may include direct quotes in my report, but I never attribute any quote to any particular person. Your name will never appear in any report I develop about this research

Do you have any questions before we continue?

B. PARTICIPANT INTRODUCTIONS - WARM-UP (5 minutes)

Moderator: You are all here because you told the recruiter that you are allergic to certain foods or that you take care of someone who is allergic to certain foods. Today we are going to discuss labels on food packages, but before we begin, I'd like to go around and have you say:

- your first name,
- what food or foods you or the person you take care of are allergic to, and
- what would happen if you or they ate that food?

C. PRIOR EXPERIENCE WITH FOOD PACKAGE LABELS (10 min)

Moderator: OK. Let's begin. Imagine that you are at a grocery store, shopping for food for yourself and your family. You stop and reach out for a packaged food, which I'm thinking of as a food in a package that you'd find in the aisles, so, for example - bread, granola bars, or chips.

1. How do you decide if you or your family can eat the food?
 - a. Do you look at the package? Why? What part(s)?
 - b. What on the package is helpful? [IF NOT MENTIONED, PROBE ON INGREDIENTS LIST]
 - c. What on the package is confusing?

[SHOW A FOOD LABEL WITH A “CONTAINS” STATEMENT AND A “MAY CONTAIN” STATEMENT TO SEE IF THEY KNOW THE DIFFERENCES BETWEEN THESE TYPES OF STATEMENTS.

Next, I'd like you to look at 2 different labels on a food package. I'd like you to concentrate on the statement at the bottom under the ingredient list [MODERATOR POINTS OUT STATEMENT].

2. What is the main idea of Label A?
3. What is the main idea of Label B?
4. What are the differences you notice between Label A (“contains”) and Label B (“may contain”)?
5. What are the similarities between Label A and Label B?

I want to make sure that we are all on the same page. Label A is what is known as a “contains” statement. When any of the 8 major food allergens [MODERATOR WILL POINT TO LIST ON WHITEBOARD] is an ingredient in the food, manufacturers are required to tell you that it's there.

Label B is what's known as a “may contain” statement. Manufacturers can say that a food “may contain” one of the 8 major food allergens if there is a chance that it is in the food – usually because it is made on the same equipment as another food that does contain the allergen. We will be looking at 6 more of these types of labels one at a time and I'll be asking you questions after each one.

D. EXAMINATION OF INDIVIDUAL ADVISORY STATEMENTS (40 MIN)

[MODERATOR TO USE SAME “MAY CONTAIN” LABEL]

6. Have you ever seen [ADVISORY STATEMENT] on a product label? What product(s)? When? Where?
7. What does it mean to you?
8. What do you think you should do when you see this statement?
9. What do you think the manufacturer wants you to do when you see this statement?
10. Is the statement helpful for making food decisions? How?
11. Would you buy a product with this on it? Why? Why not?
12. Is there a way to make this statement clearer?

13. [SHOW “MAY CONTAIN” STATEMENT ON 2 DIFFERENT PRODUCTS] What are the similarities between these two statements?
14. What’s different?
15. Is one statement better than the other? Why/Why not?

[REPEAT 6-12 FOR REMAINING 6 ADVISORY STATEMENTS]

E. EXAMINATION OF ALL 7 ADVISORY STATEMENTS TOGETHER (20 MIN)

[SHOW ALL STATEMENTS TOGETHER; PROBE FOR DEFINITIONS, INTERPRETATIONS, AND CONTRASTS FOR EACH STATEMENT]

16. What are the differences between the statements?
17. Which of the statements is the most/least helpful and why?
18. Are any confusing and why?
19. Which statement does the best job of making you think that the allergen might really be in the food? Why?
20. Which statement would you pay the most attention to?
21. Which statement would you ignore and why?
22. If you could develop your own system to label foods that might, inadvertently, have an allergen in them because the way the food is produced, what would that look like?

F. THRESHOLDS (10 MIN)

Moderator: Now I want to get your feedback on the concept of allergen thresholds. Thresholds are when there is a food allergen in the product but there isn’t enough to cause an allergic reaction.

23. Have you heard of allergen thresholds before? Where? What did you hear?
24. Should manufacturers be required to put an advisory statement on the food label if *they know there’s a possibility* that the allergen could be in the food?
25. Should manufacturers be allowed to put an advisory statement on the food label if *they do not believe* there is any allergen in the food?

G. CLOSE (10 min)

[CLOSING THOUGHTS ABOUT ALLERGEN ADVISORY STATEMENTS

Definitions for “Contains Statements” and “May Contain Statements”

1. Contains Statement = When any of the 8 major food allergens is an ingredient in the food, manufacturers are required to declare its presence a) within the ingredients list, b) at the end of the ingredients list, or c) immediately adjacent to the list, using the food allergen’s common or usual name.
 - 8 major food allergens: milk, egg, fish, shellfish, tree nuts, wheat, peanuts, soybeans
2. ‘May Contain’ Statement = also called ‘Allergen Advisory Statement’ and ‘Precautionary Labeling’. Statements manufacturers in the US are currently allowed to put on the food label if a food allergen may be inadvertently in a product that was not made to contain the allergen.