

**Appendix I
Allergen Advisory Labeling Focus Groups
Screener**

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 portion of the information collection is estimated to average 5 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.

Recruiting Goals:

1. Recruit 12 participants for each group.
2. Participants need to have a doctor-diagnosed food allergy to one of the 8 major food allergens; at least 3 per group can be caregivers to a dependent with a doctor-diagnosed food allergy who is living in the household.
3. Participants need to be a mix of age groups.
4. Participants will be a mix of men and women with no more than 4 men per group.
5. Participants will have a mix of race/ethnicity reflective of the population in the region.
6. Groups will also be segmented by education level (high, low)
7. Participants must be one of the primary food shoppers in the household.

[Note to recruiter – Before terminating interview, ask whether they know someone with a diagnosed food allergy who might be willing to participate in the focus groups]

Screener:

My name is () and I'm calling about a market research study we are conducting on behalf of the U.S. Food and Drug Administration in your area. We are recruiting for an upcoming focus group with people who have a doctor-diagnosed food allergy or people who are parents or caregivers to someone with a doctor- diagnosed food allergy. We are holding a group discussion on [DATE] with approximately 10 people. The group will start at [TIME] and will last no longer than 90 minutes. Groups will be audio and

video recorded. You will be provided with an incentive as a token of our appreciation for participating in this study for your time, effort, and travel expenses. Would it be OK if I ask you a few questions now to see if you're eligible to be in one of the groups? (if yes, continue; if no, thank and terminate).

1. Do you have a food allergy that has been diagnosed by an allergy doctor? (IF NEEDED: Do not count allergies you used to have or that don't bother you anymore)
- Yes [GO TO QUESTION 1a]
 No [GO TO QUESTION 2]

1a. Is your food allergy to one or more of the following? [READ OUT LOUD AND RECORD FOR EACH]

- Peanut
 Tree nut
 Shellfish
 Fish
 Dairy
 Wheat
 Soy
 Egg
 Not allergic to any items on the list → GO TO QUESTION 2

[IF ANY OF THE ABOVE FOODS SELECTED, CONSIDER FOR FOOD ALLERGIC GROUP.] [GO TO QUESTION 3.]

2. Are you a parent or caregiver to someone with a food allergy that has been diagnosed by an allergy doctor? (IF NEEDED: Do not count allergies they used to have or that don't bother them anymore)

- Yes [GO TO QUESTION 2a]
 No [ELIMINATE]

2a. Is their doctor-diagnosed food allergy one or more of the following? [READ OUT LOUD AND RECORD FOR EACH] [RECRUIT NO MORE THAN 3 CAREGIVERS PER GROUP]

- Peanut
 Tree nut
 Shellfish
 Fish
 Dairy
 Wheat
 Soy
 Egg
 Not allergic to any items on the list → Eliminate

[IF ANY OF THE FOODS SELECTED – CONSIDER FOR CAREGIVERS GROUP] [GO TO QUESTION 3.]

3. Have you shopped for groceries for yourself or your household in the past two months?
 - a. Yes → continue
 - b. No → eliminate
4. Do you ever buy candy, cookies, or crackers for you or your household?
 - a. Yes → continue
 - b. No → eliminate
5. Do you or anyone from your immediate family:
 - a. Work in market research or social science research → eliminate
 - b. Work at a food product manufacturing company → eliminate
6. I am going to read some age categories --- please tell me which category your age falls in. [RECRUIT A MIX OF 3 AGE SEGMENTS. FOR CAREGIVERS GROUP, CAN HAVE FEW 18-25 YEAR OLDS.]
 - a. Under 18 years old → eliminate
 - b. 18-25 → continue
 - c. 26-45 → continue
 - d. 46+ → continue
7. Determine gender.
 - a. Male (Do not recruit more than 4 men per group of 12.)
 - b. Female
8. What is the highest level of education that you have completed?
 - a. Less than high school graduate → lower education group
 - b. High school graduate or GED → lower education group
 - c. Attended or graduated technical/vocational school → lower education group
 - d. Some community college → lower education group
 - e. Some college or community college graduate → higher education group
 - f. College graduate → higher education group
 - g. Attended or graduated with advanced degree → higher education group
9. Are you of Hispanic or Latino origin?
 - a. Yes → continue - recruit a mix of race/ethnicity
 - b. No → continue - recruit a mix of race/ethnicity
10. What is your race? I am going to read several categories. You may choose one or more categories. Are you...? [RECRUIT A MIX PER GROUP]

- a. White
- b. Black or African American
- c. Asian
- d. Native Hawaiian or Other Pacific Islander
- e. American Indian or Alaska Native

11. Finally, during the focus group discussion, you will be asked to review written materials and offer your opinions, so I need to ask whether you have a medical or nonmedical condition that affects your ability to read and/or understand written materials in English?
- a. Yes → eliminate
 - b. No → continue

You qualify for our study. The discussion group will be held on [DATE] at [TIME] and will last about 90 minutes. For your time and opinions, you will receive \$75 as a token of our appreciation at the end of the session.

12. Would you like to participate in the group discussion at [TIME] on [DATE]?
- a. Yes → continue
 - b. No → eliminate

Great! May I please have your mailing and/or e-mail address to send you a confirmation letter with directions? [Verify address and phone number.]

Thank you. That's all the questions I have today. Please try to arrive at least 15 minutes before the starting time. If you have any questions or find that you are unable to attend, please call [facility's phone number] as soon as possible. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].

Read if necessary:

If you have any questions about the study, you may contact Jennifer Alexander of RTI at 301-770-8219. If you have concerns about how participants are being treated in the study, you may contact RTI's Office of Research Protection toll-free at 1-866-214-2043.

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****NOTE** THIS PAGE MUST BE STORED SEPARATELY FROM THE SCREENER AND FOCUS GROUP DATA. PLEASE DESTROY UPON COMPLETION OF FOCUS GROUP.**

We are asking for your contact information only for the purpose of sending you a reminder letter and giving you a call to remind you of the discussion group. We will destroy all contact information at the conclusion of the groups.

NAME: _____

ADDRESS: _____

CITY: _____

ZIP CODE: _____

E-MAIL _____

What is the best time to reach you? What is the best telephone number to reach you at that time?

BEST TIME TO BE REACHED: _____

BEST PHONE NUMBER: _____

Is there another time and number we can try if we miss you?

ALTERNATE TIME:

ALTERNATE PHONE NUMBER:

Thank you. That's all the questions I have today. Please try to arrive at least 15 minutes before the starting time. If you have any questions or find that you are unable to attend, please call [facility's phone number] as soon as possible. Thank you again for your time. We look forward to seeing you at [TIME] on [DATE].