

Appendix IV
Food Allergen Advisory Focus Group Consent Form

Purpose:

- This study is about food allergen advisory statements.
- The U.S. Food and Drug Administration (FDA) is conducting this study to learn about how people with food allergies and caregivers to people with food allergies think about food labels.

What is involved:

- You are being asked to be part of a focus group discussion.
- We will ask you some questions about food labels and statements about allergens on the food label.
- The focus group discussion will take 90 minutes.

Confidentiality:

- Your name and information will be kept secure to the extent allowed by law.
- We will audio and video record the discussions. We will keep the recordings secure to the extent allowed by law and destroy them by 2021.
- Nothing you say will be connected with your name. We will be writing a report on all of the focus groups and may use quotes from you in our report but will not use your name.

Risks:

- It is your choice to do this focus group discussion.
- You can stop participating at any time.
- There are no known risks for participation in this study.

Benefits:

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research project.

Questions:

- If you have questions about the project you may call the Project Director, Jennifer Alexander at 301-770-8219.
- If you have any questions or complaints about your rights as a research subject, please contact FDA’s IRB, Research Involving Human Subjects Committee, at RIHSC@fda.hhs.gov and 301-796-9605 or RTI’s Office of Research Protection at 1-866-214-2043.

You will receive \$75 as a thank you for your participation.

If you agree to participate, please sign below. You will be given a copy of this consent form to keep.

I have read and understand the statements above. I consent to participate in this focus group.

Participant’s signature

Date

Paperwork Reduction Act Statement: The public reporting burden for this collection of information has been estimated to average 90 minutes per response. 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.

1. Confirmation Letter

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.

Dear [Participant Name];

Thank you for agreeing to participate in our market research study about food allergies which is being conducted on behalf of the U.S. Food and Drug Administration. The group will be held on [DATE] at [LOCATION]. The group will begin promptly at [TIME]. 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.

[FACILITY INFORMATION]

2. Reminder Letter

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

Dear [Participant Name];

This is just a reminder letter that the market research study about food allergies conducted on behalf of the U.S. Food and Drug Administration in which you agreed to participate will be coming up on [DATE]. The group will be held at [LOCATION] and will begin promptly at [TIME]. 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.

[FACILITY INFORMATION]