

**Appendix II**  
**CFSAN Safety Alert and Outbreak Advisory Focus Groups**  
**Screeners**

**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 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](mailto:PRASStaff@fda.hhs.gov).

**Recruiting Goals:**

1. Recruit 10-12 participants for each group to seat 6;
2. Participants need to be a mix of age groups for each group;
3. Participants will be a mix of men and women with no more than 2 men per group;
4. Participants will have a mix of race/ethnicity reflective of the population in the region;
5. Groups will be segmented by education level (high, low);
6. Groups will also be segmented by device used during testing (laptop, cellphone);
7. Participants:
  - Half of the groups (6 groups) should be caregivers to young children (less than 24 months old) who use infant formula products (**Caregiver Groups**);
  - The other half of the groups (6 groups) should be individuals with tattoo(s) or individuals who are considering getting tattoo(s) (**Tattoo Groups**);
8. Participants must also be one of the primary food shoppers in the household.

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**PARTICIPANT SCREENER SCRIPT**

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. We are holding a group discussion on [DATE] with approximately 6 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?

- Yes
- No → eliminate *[thank respondent politely]*

**DETERMINE GENDER**

- Male → recruit no more than 4 males per group; with aim of no more than 2 sitting in a group
- Female

**Q1. Do you work for any of the following:**

- A Market Research Firm → eliminate *[thank respondent politely]*
- Food Industry, Restaurant or Food Retailer → eliminate *[thank respondent politely]*
- A Public Health Organization → eliminate *[thank respondent politely]*
- State or local food agency → eliminate *[thank respondent politely]*
- U.S. Department of Agriculture → eliminate *[thank respondent politely]*
- U.S. Food and Drug Administration → eliminate *[thank respondent politely]*

**Q2. Are you the person who does at least half of the grocery shopping for your household?**

- Yes
- No → eliminate *[thank respondent politely]*

**Q3. I am going to read some age categories, could you please tell me in which category your age falls?**

**[Note to recruiter: Recruit a mix of age groups for each group]**

- Under 18 years old → eliminate *[thank respondent politely]*
- 18-30
- 31-40
- 41-50
- 51-60
- 61 and over

**Q4a. Are you the primary caregiver of a young child (age under 24 months)?**

- Yes → proceed to Q4b
- No → proceed to Q5a

**Q4b. Do you use infant formula to feed your child currently?**

- Yes → recruit to Caregiver Groups
- No → proceed to Q5a

**Q5a. Have you gotten a tattoo in the past five years?**

- Yes → recruit to Tattoo Groups
- No → proceed to Q5b

**Q5b. Are you considering, or have you recently (e.g. in the past 12 month) considered, getting a tattoo?**

- Yes → recruit to Tattoo Groups
- No → eliminate if participants **have not** been recruited to Caregiver Groups  
*[thank respondent politely]*

**[Note to recruiter: If there are participants who fit both Caregiver and Tattoo Groups' criteria, they can be recruited to either group.]**

**Q6. 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?**

- Yes → eliminate *[thank respondent politely]*
- No

**Q7. During the focus group discussion, you will be using a laptop or a cell phone. Are you comfortable with using:**

- both laptop and cellphone → proceed to Q8
- laptop ONLY → recruit to Laptop Groups
- cell phone ONLY → proceed to Q8
- neither laptop or cell phone → eliminate *[thank respondent politely]*

**Q8. Do you have your own smart phone with a working web browser that you can bring to the focus group?**

- Yes → (1) If participant chose “both laptop and cell phone” for Q7, recruit to either Laptop or Cell Phone Group  
(2) If participant chooses “cell phone ONLY” for Q7, recruit to Cell Phone Groups
- No or don't know → (1) If participant chose “both laptop and cell phone” for Q7, recruit to Laptop Group  
(2) If participant chose “cell phone ONLY” for Q7, eliminate *[thank respondent politely]*

**Q9. What is the highest level of education that you have completed?**

- Less than high school graduate → recruit to Lower Ed Groups

- High school graduate or GED → recruit to Lower Ed Groups
- Attended or graduated technical/vocational school → recruit to Lower Ed Groups
- Some community college → recruit to Lower Ed Groups
- Some college or community college graduate → recruit to Higher Ed Groups
- College graduate → recruit to Higher Ed Groups
- Attended or graduated with advanced degree → recruit to Higher Ed Groups

**Q10. Are you of Hispanic or Latino origin?**

**[Note to recruiter: Recruit a mix of race/ethnicity for each group]**

- Yes
- No

**Q11. What is your race? I am going to read several categories of race. You may choose one or more categories. Are you...?**

**[Note to recruiter: Recruit a mix of race/ethnicity for each group]**

- White
- Black or African American
- Asian
- Native Hawaiian or other Pacific Islander
- American Indian or Alaska Native
- Prefer not to answer

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Thank you for answering the questions. 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.

Would you like to participate in the group discussion at [TIME] on [DATE]?

- Yes
- No → *[thank respondent for his/her time]*

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 arrive at least 15 minutes before the start of the group to ensure you have time to sign in and to get a meal/snack. If you arrive 15 minutes early, your name will go into a drawing to win an extra \$25 Visa gift card as a token of our appreciation. You must be signed in at that time to be eligible for the drawing. If you have any questions or find that you are unable to attend, please call [facility's phone number] as soon as possible.

**[For Cell Phone Group participants]: Please make sure you bring your own smart phone (with access to web browsers) to the focus group.**

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 Jenna Brophy of RTI International, at (919) 541-8881. If you have concerns about how participants are being treated in the study, you may call RTI's Office of Research Protection at 1-866-214-2043.

**\*\*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 sending you a reminder letter or email and giving you a call to remind you of the discussion group. We will destroy all contact information at the end 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].