Appendix I

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 PRAStaff@fda.hhs.gov.

Nutrition Facts Label Campaign Focus Groups: Concept Testing Phase Participant Screener

The target audience for these focus groups is primary shoppers ages 35-50 years.

Recruiting Goals

• Six (6) focus groups will be conducted in each Phase. The groups will take place in three US regions, and will be segmented by education, as follows:

Phase 1:

Group No.	Location	Level of Education
Group 1	Mid Atlantic (Local)	Lower
Group 2	Mid Atlantic (Local)	Higher
Group 3	Mid-West	Lower
Group 4	Mid-West	Higher
Group 5	West Coast	Lower
Group 6	West Coast	Higher

- The groups will include adults of ages 35 to 50.
- Each participant must live in a household with at least one other person (including dependents or non-dependents).
- The groups will consist of participants who make most of the decisions about food purchases for their household.
- Participants will not have an advanced degree nor will their annual household incomes exceed \$125,000
- All participants must be able to read, understand, and speak English.
- Focus groups will comprise participants of various races/ethnicities and sexes.
- Participants cannot have participated in a focus group or a similar study in the past six months. Participation in phone surveys is allowed.
- Sufficient recruits will be invited in order to achieve a target of 8-10 participants per group.
- Each participant will receive a \$75 token of appreciation for participating in the focus group.

Study Protocol

• Each group will last approximately 90 minutes (excluding time needed for signing in before the group starts and signing out after the group ends).

- Groups will be audio- and video-recorded and also video-streamed via a password-protected website. Participant written consent will be obtained before the group discussion starts.
- The identity of the participants will remain secure under the Privacy Act and to the extent provided by law.
- Groups will be observed by a research team including staff from FDA.
 Participants do not have to answer any questions that they do not want to, but are encouraged to participate.

PARTICIPANT SCREENER SCRIPT

Hello Ms./Mr. _____, my name is ______ and I'm calling about a research study sponsored by the U.S. Food and Drug Administration in your area. We are looking for adults to take part in upcoming focus group discussions about their grocery food shopping habits.

Are you interested in participating?

Yes	\rightarrow continue
No	\rightarrow eliminate [thank respondent politely]

Can you answer a few questions? This will only take a few minutes of your time.

Yes	\rightarrow continue
No	\rightarrow eliminate [thank respondent politely]

Q1. The focus group will be conducted in English, and will need people in the group to read some text and watch a brief video. Are you comfortable understanding, speaking and reading English? [NOTE: we will be recruiting Hispanic individuals but the groups will be conducted in English.]

Yes	\rightarrow continue
No	\rightarrow eliminate [thank respondent politely]

Q2. I am going to read some age categories, could you please tell me in which category your age falls?

Under 18 years old	\rightarrow eliminate [thank respondent politely]
18-34	\rightarrow eliminate [thank respondent politely]
35-40	\rightarrow continue
41-50	\rightarrow continue
51-60	\rightarrow eliminate [thank respondent politely]
60 and over	\rightarrow eliminate [thank respondent politely]

Q3. Do you or someone from your immediate family work for or as any of the following:

	A Market Research Firm	\rightarrow eliminate [thank respondent politely]	
	Nutritionist or Dietitian	\rightarrow eliminate [thank respondent politely]	
	Food Industry, Restaurant or Food Retailer	\rightarrow eliminate [thank respondent politely]	
	A Public Health Organization	\rightarrow eliminate [thank respondent politely]	
	State or local food agency,		
	U.S. Department of Agriculture, or		
	U.S. Food and Drug Administration	\rightarrow eliminate [thank respondent politely]	
	-		
Have you participated in a focus group within the past 6 months? [Interviewor: participation			

- Q4. Have you participated in a focus group within the past 6 months? [Interviewer: participation in telephone surveys is allowed. If explanation is needed: A focus group is a when a small group of individuals come together to talk about a certain topic.]
 - $\Box \quad Yes \qquad \rightarrow eliminate [thank respondent politely]$
 - $\Box \text{ No } \rightarrow \text{continue}$

- Q5. How many people live in your household?
 - 0-1 \rightarrow eliminate [thank respondent politely]
 - □ 2 or more \rightarrow continue [RECRUIT NO MORE THAN 2 RESPONDENTS PER GROUP FROM DUAL-INCOME, NO CHILD HOUSEHOLDS]
- Q6. Who makes most of the decisions about food purchases for your household?
 - □ Other (e.g., spouse, partner, parent, family member) \rightarrow eliminate [thank respondent politely]
 - \rightarrow continue □ Me
- Q7. How do you usually purchase most of your household's food and packaged food products?
 - Online
 - \rightarrow eliminate [thank respondent politely] □ In Person/In the store \rightarrow continue

(Note: By "store" we mean grocery stores, convenience stores [bodegas, corner stores], warehouses [BJ's, Sam's, Costco], etc.)

Q8. How often do you use the Nutrition Facts label? The Nutrition Facts label is a table with nutrition information typically found on the side or back of a food package.

- \rightarrow eliminate [thank respondent politely] Never → continue [RECRUIT NO MORE THAN 2 PER GROUP] □ Rarely
- □ Sometimes \rightarrow continue
- \rightarrow continue □ Often
- □ Always → continue [RECRUIT NO MORE THAN 2 PER GROUP]

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

- □ Less than high school
- □ High school graduate or GED
- □ Technical/vocational school
- □ Some college (1-3 years towards Bachelor's degree) \rightarrow recruit to higher ed group
- □ College (Bachelor's degree)
- □ Advanced degree (postgraduate degree)
- \rightarrow recruit to lower ed group
- \rightarrow recruit to lower ed group
- \rightarrow recruit to lower ed group
- \rightarrow recruit to higher ed group
- \rightarrow eliminate [thank respondent politely]
- I am going to read some annual income categories; please let me know which one best applies to Q10. your household?1
 - □ Less than \$40,000
 - □ \$40,000 to less than \$65,000
 - □ \$65,000 to less than \$90,000
 - □ \$90,000 to less than \$125,000
 - □ \$125,000 and over
 - □ Prefer not to answer
- \rightarrow eliminate [thank respondent politely]
- \rightarrow eliminate [thank respondent politely]

¹ http://www.pewresearch.org/fact-tank/2016/05/11/are-you-in-the-american-middle-class/

- Q11. Are you of Hispanic or Latino origin?
 - □ Yes [ATTEMPT TO RECRUIT 5-6 PER GROUP]
 - □ No
- Q12. What is your race? I am going to read several categories of race to choose from. You may choose one or more categories. Are you...?
 - □ White
 - **D** Black or African American
 - □ Asian
 - □ Native Hawaiian or Other Pacific Islander
 - □ American Indian or Alaska Native
- Q13. What is your sex?
 - □ Female
 - □ Male

Elimination Script for Ineligible Participants:

Thank you for answering all of my questions. Unfortunately, you are not eligible to participate in this project. There are many possible reasons that people may not be eligible. These reasons were decided earlier by the research team. We value your interest in the focus groups. Thank you for being willing to help us.

Invitation Script for Eligible Participants:

Thank you for answering these questions. We would like to invite you to participate in a focus group to discuss issues relating to grocery food shopping habits with about 8 other participants. The discussion will last about 90 minutes. The discussion will be video- and audio-taped, and also observed by members of a research team. Your participation and everything you say during the discussion will remain secure to the extent provided by law, and your personal identifying information will not be included in any reports. At the end of the focus group, you will receive \$75 as a token of appreciation for your participation. Are you interested in participating in this focus group?

□ Yes

□ No \rightarrow [Thank the person for his/her time]

I'm glad that you are interested! The focus group will take place on (Day), (Date), at [X:00 or X:00 p.m.] at [site location].

Will you be available to participate at this time?

- □ Yes
- **D** No \rightarrow [Thank the person for his/her time]

I would like to send you a confirmation email or letter containing directions to the facility. In order to do so, could you please tell me the best way to reach you (e.g., email and/or a phone number)?

Name:				
Address (if needed to reach participant):				
City:	State:		_Zip:	
or				
Email (if needed to reach participant):				
Phone (if needed to reach participant):				
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.