FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Focus Groups on Consumer Understanding and Behaviors Related to Plant-Based Dairy Alternatives

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The Food and Drug Administration (FDA) proposes to undertake focus group research to determine consumers' attitudes, motivations and habits related to plant-based dairy alternatives. One of the purposes of the Food, Drug, and Cosmetic Act and FDA's food labeling regulations and policies is to protect consumers against misleading labeling. Over time, there has been an emergence of plant-based dairy alternatives labeled with names that include the names of dairy foods, for example, "soy milk," "almond milk," and "soy yogurt." Many dairy foods have standards of identity and are defined by regulation. For instance, milk is described as the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows (Title 21 Code of Federal Regulations, 131.110(a)). Dairy foods are commonly recognized by the names under which these definitions and standards are established (e.g., "milk," "yogurt," "mozzarella cheese"). There are divergent views regarding whether labeling plant-based dairy alternatives with these names is misleading and whether or not consumers understand what they are purchasing when they choose these products.

   The objective is to investigate consumer understanding of plant-based dairy alternatives labeled with names that include the names of dairy foods.

   More specifically, we would like to answer the following research questions:

   - What is consumer understanding of and expectations about the content and nutritional profile of plant-based dairy alternatives;
   - How consumers understand the differences between plant-based dairy alternatives and traditional dairy products, e.g., do they assume nutritional equivalency;
   - What is consumer purchase and use behavior, e.g., substituting;
   - What motivates consumer use of plant-based dairy alternatives; and
   - What are consumer expectations regarding naming terminology of plant-based dairy alternatives.

2. **Intended use of information:**

The focus groups will help to provide FDA with the information necessary to understand requests presented in two petitions received. One is a petition from the Soy Foods Association of North America requesting that the FDA issue a regulation recognizing "soymilk" as the established common or usual name of the liquid food obtained by combining aqueous-extracted whole soybean solids and water, or by combining other edible-quality soy protein solids, soybean oil, and water. The other petition is from the Good Food Institute requesting the FDA issue regulations and provide guidance to industry clarifying how foods may be named by reference to names of other "traditional" foods (including standardized foods) in a manner that makes clear to consumers their distinct origins and properties. The petition asserts that these regulations and guidance to industry would help to avert perceived regulatory uncertainty for the industry and the court system.

The focus group results will help FDA understand consumer knowledge, motivations and behavior related to using various plant-based foods. The results will also help FDA to determine whether consumers currently understand the differences between dairy and plant-based products with regard to nutritional value, functional properties, and allergenicity when making their purchase decisions.

3. **Description of respondents:**

This qualitative research project will include 12 focus groups with adult participants who do at least half of the grocery shopping for their households and who purchase plant-based dairy alternatives. All groups will include individuals ages 18 and over and will include participants of diverse ages and races/ethnicities. (See Appendix I)

These groups will be segmented by education level, gender and age of participants; half of the group discussions in each location will be conducted with lower education participants who hold an Associate's degree from a community college or lower, and the other half with higher educated participants who hold a Bachelor's degree or higher; at the same time, half of all groups in each location will be conducted with participants with a child/children age from 2 to 17, and the other half with participants who don't have any children living with them in their household (See the Table below).

Focus Group Segmentation

Group No.	Location	Parental Status	Level of Education
Group 1 & 2	Bethesda, MD (Metropolitan DC)	With at least one 2 – 17 year old child in household	Higher
			Lower
Group 3 & 4		Without any children in household	Higher
			Lower
Group 5 & 6	Raleigh, NC (Southeast)	With at least one 2 – 17 year old child in household	Higher
			Lower
Group 7 & 8		Without any children in household	Higher
			Lower
Group 9 & 10	Portland, Oregon (West)	With at least one 2 – 17 year old child in household	Higher
			Lower
Group 11 & 12		Without any children in household	Higher
			Lower

*Proposed locations are subject to change.

4. **Date(s) to be conducted and location(s):**

The focus groups will be conducted in one city in each of three different geographic regions: Bethesda, MD (Metropolitan DC); Raleigh (Southern East Coast); and Portland, OR (West Coast). Four groups will be conducted in each location for a total of 12 focus groups. Focus groups will begin in April 2019, approximately four weeks from the date of OMB approval. Three urban locations were selected based on the demographic diversity of the local population; the presence of a large population, which will contribute to recruitment success; and the availability of professional focus group facilities that have a proven track record of successful recruiting. All selected cities have professional focus group facilities and a large enough population to ensure recruitment success.

5. **How the information is being collected:**

Recruitment Information

All recruitment will be conducted by a local professional focus group facility, which will enable us to meet the criteria described in section 3, above.

In all three cities, facility staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. They will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

A RTI senior social science researcher will serve as a moderator for all focus groups. Prior to beginning each discussion, the moderator will review the informed consent form (Appendix II) and have all participants sign and date one copy. The moderator will then use the attached moderator's guide (Appendix III) to ensure that all relevant topic areas are addressed.

Prior to beginning the discussion, the moderator will ensure that the FDA project director and other members of this initiative may observe all the sessions either from the observation rooms at the focus group facilities or remotely using streaming video technology. The streaming technology vendor will make both audio and video recordings of each group, as well as provide a near-verbatim transcript of each discussion, to ensure that participants' views and opinions are accurately captured. These transcripts will form the basis of the data analysis.

RTI and all contracted vendors (e.g., focus group facilities, streaming video vendor) will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. **Number of focus groups:**

Twelve focus groups, each with 8 to 10 participants, will be conducted. We recruit 12 participants per group. We will only select 8-10 to participate in the discussion and the remaining participants will be dismissed.

7. **Amount and justification for any proposed incentive:**

To prepare for these focus groups, we consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose offering $75 to show a token of our appreciation to participants. The incentives will ensure that we are able to attract a reasonable cross section of participants who meet our screening requirements to participate in the focus groups.

Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the commonly accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment;
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants); and
- Increased probability that a focus group may need to be cancelled or postponed because of insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the focus groups. Incentives are based on (1) estimated costs related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately $54[1]; (2) estimated cost for an average driving commute to and from the facility of approximately $20[2]; and (3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the

[1] Assumes an hourly rate of $18 per hour for a professional babysitter

[2] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf, accessed 7/1/2016.

complete absence of any incentives.[3] The proposed amounts are comparable to what has been the level of reimbursement for the target audiences in similar government-funded activities. As noted above, we expect that lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

8. Questions of a Sensitive Nature:

There will be no questions of a sensitive nature asked of participants.

9. Description of Statistical Methods (i.e., Sample Size and Method of Selection):

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. The contractor will contact prospective participants by telephone and screen them for eligibility to participate (see Appendix I).

Sufficient recruits will be screened in order to achieve a target of 8-10 participants per group. To maximize participation rates, recruiters will make at least five attempts to contact each potential participant to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene.

BURDEN HOUR COMPUTATION *(Number of respondents (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	480	5	40
Adult 18+	144	90	216
Total			256

REQUESTED APPROVAL DATE: April 5, 2019

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[3] See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, *16*(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.