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: Listeria in Pasteurized Soft Cheese Focus Groups

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)/Office Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group study, "Listeria in Pasteurized Soft Cheese Focus Groups", to collect qualitative information about how certain consumers perceive existing dietary recommendations related to pasteurized soft cheese and *Listeria*. The purpose of these focus group studies is to explore participants' attitudes, beliefs, motivations, and reported behaviors in an effort to better inform the agency's public education about *Listeria* and pasteurized soft cheese.

2. Intended use of information:

"Listeriosis" is a foodborne illness caused by a harmful bacterium called *Listeria monocytogenes*. Every year, 2,500 Americans become ill with listeriosis, and one in five cases result in death.

The FDA and Health Canada recently published results of a listeriosis risk analysis comparing the risk associated with consuming pasteurized and unpasteurized soft cheese. The report shows that, compared to consuming pasteurized soft cheese, unpasteurized soft cheese consumption is extremely risky, especially for vulnerable populations such as pregnant women, immune compromised, and elderly people. This risk analysis used data up to 2008.

Since 2008, Listeria outbreaks associated with consuming pasteurized soft cheese have become more prevalent. Five out of six *Listeria* outbreaks associated with soft cheese from 2011 to 2015 involved pasteurized cheese products. FDA is working with producers to implement Hazard Analysis and Critical Control Point (HACCP) processes to reduce pathogen contamination. Meanwhile, CDC has recommended that FDA revise its consumer messaging around cheese to include the risks associated with consuming pasteurized soft cheese, particularly with vulnerable populations.

Therefore it is important to better understand the motivations, behaviors, and attitudes of vulnerable populations with regard to *Listeria* in soft cheese. Pregnant women and their developing fetuses have a higher risk of developing listeriosis; about one-third of listeriosis cases happen during pregnancy. Elderly individuals are generally considered a vulnerable population mainly because of the percentage in that demographic that have compromised immune systems due to age-related changes in physiology, chronic illness and other comorbidities.

In addition, many people rely on their health care providers to supply information about what is safe or not safe to consume. Some studies show, however, that health care providers would benefit from more training in communicating with patients about safe handling of food and risky food consumption.

FDA plans to use the study to explore consumers' understanding of the benefits and risks of pasteurized soft cheese consumption (See messages for testing in Appendix I). The agency will use the findings to help inform its informational content and approach with regard to Listeria and pasteurized soft cheese.

3. Description of respondents:
A total of 18 focus groups are planned. Six of the focus groups will be with Non-Hispanic pregnant women, segmented by education; four will be with Hispanic pregnant women, segmented by language spoken at home; four groups will be with adults age 70 and older, segmented by education; two will be with adults under 70, segmented by education; and two will be with Health Care Providers (HCPs). We will recruit 12 participants for each group, and expect to have 8 to 10 participants per group. No more than 12 participants will participate in a group. (See Appendix II)

4. Date(s) to be conducted and location(s):
Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted in six locations: Washington, DC (metro area), Las Vegas, NV, Northeast/Mid-Atlantic/South, and West Coast.

5. How the Information is being collected:
With the aid of a moderator's guide (see Appendix III), a moderator supplied by the independent contractor will guide the focus group discussions that will solicit information from the participants. The focus group discussion will be recorded and transcripts will be made from these recordings. Transcripts and notes taken by the project staff will be the bases for data analysis. Transcripts and notes will be used to analyze data.

6. Number of focus groups:
Eighteen focus groups will be conducted.

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 an incentive of $120 to recruit health care providers and $75 to recruit pregnant women and participants in the older and younger adult groups. Each of these groups of individuals poses unique recruitment challenges. These 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 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)
- Increased probability that a focus group may need to be cancelled or postponed due to 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 amounts will help ensure that respondents honor their commitment of participating in the focus groups. Our incentives for health care providers was based on research showing that physicians are responsive to monetary -versus nonmonetary- incentives [1] and government produced national estimates of mean wages for physicians showing a mean hourly wage of $95.05[2] For all other participants, 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 $48[3]; 2) an estimated cost for an average driving commute to and from the facility of approximately $18[4]; and 3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[5] The proposed amounts are comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. Health care providers are often more difficult to recruit than more general audiences. 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 & 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 IV). To maximize participation rates, recruiters will contact each potential participant at least five times to screen for eligibility and recruit for participation. Additionally, participants will receive a reminder call and confirmation letter before the groups convene.

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[1] Kellerman, SE and Joan Herold. 2001. Physician Response to Surveys: A Review of the Literature. American Journal of Preventive Medicine, 20(1):61-67.

[2] Employment estimates and mean wages for physicians and surgeons reported at http://www.bls.gov/oes/current/oes291069.htm, accessed 7/1/2016.

[3] Assumes an hourly rate of $16 per hour for a professional babysitter

[4] 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.

[5] 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.

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	1200	5	100
Non-Hispanic pregnant women	72	120	144
Hispanic pregnant women	48	120	96
Adults 70+	48	120	96
Adults under 70 years	24	120	48
Health Care Providers	24	120	48
Total	1200*		532

*Of the total 1,200 screened possible respondents (the total universe of respondents), 72 non-Hispanic pregnant women, 48 Hispanic pregnant women, 48 adults 70 years of age or older, 24 adults younger than 70 years, and 24 health care providers are expected to be chosen for these focus groups.

REQUESTED APPROVAL DATE: August 2016

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