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 group findings to test and refine their ideas, but they 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: An Investigation of Allergy to Cosmetics in the United States

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA, CFSAN) is seeking OMB approval under the generic clearance OMB Control Number 0910-0497 to conduct focus groups as part of the project "An Investigation of Allergy to Cosmetics in the United States."

   The purpose of this investigation is to conduct a focus group study to collect qualitative information from consumers about their use of cosmetic products and their awareness of and/or experience with adverse reactions to cosmetic products. More specifically, the research will help us explore (1) knowledge of cosmetics, (2) use of cosmetics, (3) use of product labels and expiration dates, (3) effects of labeling information, including ingredient lists, and advertisements on purchasing decisions, (4) experience and response to previous reactions to cosmetic products, and (5) likelihood of reporting adverse events to FDA. The focus group study is part of a larger project intended to evaluate the current state of cosmetic product safety.

2. **Intended use of information:**

   This information collection request involves qualitative research that will be used in conjunction with other data collection results to develop recommendations regarding the impact of allergens on the cosmetics industry.

   The focus group results will be used along with the results of a consumer survey and stakeholder interviews and the analyses of secondary data to gain a more thorough and detailed understanding of the impact of allergens on consumers and the cosmetics industry.

3. **Description of respondents:**

   FDA has contracted with RTI International (RTI) to conduct a total of eight 105-minute in-person focus groups, which will include

   - two focus groups with men without allergies to cosmetic products,
   - two focus group with women without allergies to cosmetic products,

- one focus group with men with allergies to cosmetic products,
- one focus group with women with allergies to cosmetic products, and
- two focus groups with parents of children aged 5 years or younger with allergies to cosmetic products that have been confirmed by a patch test.

RTI will work with a focus group facility in each of two locations to recruit potential participants. Five of the eight groups will be conducted at a facility in Raleigh, NC, and three of the eight groups will be conducted at a facility in Las Vegas, NV. Using their contact databases and the approved study screening questionnaire (see Appendix A), each facility will recruit eligible participants. If the prevalence of confirmed allergies by patch test is deemed low, the facility may contact local dermatologists to increase enrollment by recruiting parents of young children whose allergies to cosmetic products has been confirmed by a patch test. In addition to meeting the requirements for inclusion in the specific subpopulations, all individuals must meet the following eligibility criteria:

- are adults (18+ years old);
- have the ability to read and/or understand written English materials;
- have not participated in a focus group in the past 6 months;
- consent to be audio- and videotaped; and
- have not been employed by the federal government; the cosmetic industry; or a marketing research, advertising, or public relations company (including immediate family members) in the past 5 years.

Each facility will recruit 12 eligible participants to ensure 8 to 10 participants show for each focus group. Each group will include a mix of ages, education levels, and races/ethnicities that are reflective of the general population in each location.

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

The focus group discussions will be held approximately 6 weeks from the date of OMB approval. The focus groups will be conducted at focus group facilities in Raleigh, North Carolina, and Las Vegas, Nevada.

We selected these two locations because they provide geographic diversity for the information obtained from the focus groups. These locations also offer suitable focus group facilities and recruitment capabilities that will enable us to recruit participants who meet the criteria described in Section 3 above.

The facilities chosen in each location were selected because they have a proven track record for recruiting individuals who meet study requirements and have a reputation for providing well-equipped and easily accessible facilities with state-of-the-art amenities.

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

Recruitment Information

Each focus group facility will recruit potential participants using their contact databases and the study screening questionnaire (see Appendix A). Once initial contact is made with a potential participant by telephone, a facility recruiter will inform the individual that RTI is conducting a research study and that s/he has some questions to see if the individual qualifies to participate in the study. The recruiter will obtain verbal consent from potential participants before screening them for eligibility. Individuals who meet all eligibility requirements will be invited to participate in the focus group.

In addition, each local market research company will send confirmation letters with directions and make reminder calls to recruited individuals before their scheduled group discussion.

Focus Group Discussions

RTI will conduct eight 105-minute focus groups. Each group will be conducted with 8 to 10 participants, resulting in a total sample size of up to 80 participants.

Upon arrival to the focus group facility, participants will read and sign an informed consent form (see Appendix B) and answer a few questions to confirm eligibility.

RTI staff members will conduct the focus group discussions and use a moderator guide (see Appendix C), which will serve as an outline and provide structure for the focus group discussions.

Each focus group discussion may be monitored by FDA staff behind a one-way mirror. With respondent consent, each focus group will be professionally audio- and video-recorded by the local market research companies. The audio-recordings will be professionally transcribed.

RTI will comply with safeguards for ensuring participant information is kept private 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:**

A total of eight focus groups will be conducted.

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

In preparation for these focus groups, RTI consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose awarding $75 as a token of our appreciation for 105 minutes for the focus group and 15 minutes for completing the consent form to ensure that we are able to attract a reasonable cross section of participants.

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 focus group participation.

Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the focus groups. Our incentive was chosen based on 1) an estimated cost related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, and the 105 minute check-in and check-out procedures, focus group discussion and 15 minute consent form completion), which is approximately $48[1]; 2) an estimated cost for an average driving commute to and from the facility of approximately $18[2]; 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.[3] The proposed amount of $75 is comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. Parents of young children are often more difficult to recruit than more general audiences, and the incentive needs to be enough to help the participants cover outside childcare costs if needed. 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.

The importance of monetary compensation for focus group participation has been discussed by Krueger and Casey (2014), who indicate that offering minimal levels of monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.[4] Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage

[1] Assumes an hourly rate of $16 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
[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.
[4] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.

points over comparison groups.[5] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[6] and internal proprietary research conducted by our contractor, RTI.

8. **Questions of a sensitive nature:**

   None.

9. **Description of statistical methods (i.e., sample size & method of selection):**

   Because this study is qualitative in nature, no statistical methods will be applied to responses. To analyze the focus group data, an RTI study team member will review the video-recordings and transcripts of the focus group discussions and prepare a detailed summary of each discussion and then systematically analyze the detailed summaries to identify common themes and any exceptions to these themes. The contractor will summarize these findings in a final report to FDA.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Potential focus group participants vetted through screening questionnaire	640	8	85
Review and completion of focus group consent form	80	15	20
Participants chosen for focus groups and time taken for check in, focus group discussion, and check out	80	105	140
Total			245

REQUESTED APPROVAL DATE: February 28, 2018

NAME OF PRA ANALYST & PROGRAM CONTACT:

[5] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79.
[6] Berlin, M., L. Mohadjer, J. Waksberg, A. Kolstad, I. Kirsch, D. Rock, & K. Yamamoto. An experiment in monetary incentives. American Statistical Association, Proceedings of Survey Research Methods Section; Alexandria, VA: 1992. pp. 393–398.

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