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 of Salon Professionals and Consumers to Determine Reactions to Labeling Statements on Cosmetic Labels

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Hair Smoothing Product Labeling Focus Groups". The purpose of this focus group study is to collect qualitative information to help FDA better understand how salon stylists, salon clients and retail consumers of permanent hair smoothing products understand current and draft cautionary labels, developed by FDA, that appear on professional hair smoothing products that release formaldehyde. The study will consist of focus groups with salon professionals, salon clients and retail consumers. The findings from the research will provide background information to FDA's Office of Cosmetics and Colors (OCAC) on certain professional hair smoothing products that may be hazardous when used improperly.

FDA notes that well-designed warning labels can be successful in catching the attention of consumers and communicating precautions to be taken while using these products. Unless the message is clear and easily understood, the warning is likely to be ineffective. Critical design elements include font size, color, spacing, and location of warning message on the cosmetic product. Pictorial images/symbols (see Appendix VII) may also be critical in order to address users for whom English is a second language; however, while these focus groups will include participants with varied racial and ethnic backgrounds, English literacy will be a screening criterion. The purpose of this study is to determine whether any of the proposed warning messages (1) sufficiently inform consumers and salon workers about the potential health risks associated with formaldehyde-containing cosmetics; and (2) provide adequate direction for safe use. Additionally, the study will examine respondents' reactions to the FDA Web information *Hair-Smoothing Products That Release Formaldehyde When Heated* available at http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm228898.htm.

FDA plans to conduct focus groups with salon stylists at the Premiere Beauty Show in Columbus, Ohio on October 9-10, 2016 and the International Salon and Spa Beauty Show in Long Beach, California on January 28-30, 2017. Additionally, we would like to complete focus groups with salon customers and retail consumers by the end of January

2017, so that OCAC can use the study findings to inform development of warning labels for products that contain formaldehyde and formaldehyde-releasing agents, and to receive background information on the consumer need related to the use of such products in a timely manner.

2. **Intended use of information:**
This information collection request involves qualitative research that will be used to inform development of warning labels on products containing formaldehyde and formaldehyde-releasing agents informing users about proper use and safety precautions when using these products.

3. **Description of respondents:**

A total of twelve focus groups are planned with three different target audiences, as follows:

(1) Four focus groups will be conducted with *salon stylists*, onsite at hair or beauty shows. Two focus groups will be conducted at each of two separate hair/beauty shows. These participants will be stylists who perform hair smoothing and hair straightening procedures or plan on performing such procedures in the near future. The focus groups will be segmented by stylists' years of experience.

(2) Four focus groups will be conducted with *salon clients* who have had a hair straightening procedure done, such as Brazilian Blowout or Keratin Treatment, Japanese straightening, hair relaxer or other type of chemical hair smoothing at a professional salon. These focus groups will be segmented by education.

(3) Four focus groups will be conducted with *retail consumers* of hair smoothing products who have purchased a hair smoothing product and have done a hair smoothing or straightening at home (for themselves or someone else). These focus groups will be segmented by education.

All groups will include individuals ages 18 and over. Each focus group will include a mix of ages and races/ethnicities. No more than 10 participants will participate in a group (Appendices I through III). Separate screeners were developed, one for each target audience: salon stylists, salon clients and retail consumers. FDA has contracted with Westat to recruit and conduct these in-person focus groups.

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

Focus groups with salon stylists will be conducted during beauty/hair shows in the Fall of 2016 and the Spring of 2017 Focus groups with salon customers and retail consumers will be conducted approximately two months from the date of OMB approval. These focus groups will be conducted in Rockville, Maryland and Los Angeles, California. The Maryland location was selected because of the proximity to the FDA's Center for Food Safety and Applied Nutrition, which will give the opportunity for OCAC staff to observe these focus group sessions in-person through a one-way mirror. Los Angeles, California was selected in order to collect data in a distinct geographic location and because it is

densely populated, which will allow for efficient recruitment of desired target audiences. Both of these locations offer suitable focus group facilities.

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

Recruitment Information

Because the target audiences for this study (salon stylists, salon customers and retail consumers of permanent hair smoothing products) are more difficult to recruit than general population consumers, the recruitment will be completed through a mix of methods, such as advertisements placed on Craigslist and other online venues (Appendices X_A through D), recruitment from proprietary lists, social media, and snowballing. Recruitment in Rockville, MD will be conducted by Westat and recruitment in Los Angeles, CA will be conducted by a local professional recruitment facility to enable us to obtain group participants who meet the criteria described in section 3 above. Both Westat and Los Angeles 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 Westat senior social science researcher will serve as a moderator for all focus groups. The FDA project director will observe all of the sessions either from the observation rooms at the focus group facilities (salon clients and retail consumers focus groups) or directly in the room (salon stylist focus groups at the beauty/hair shows). OCAC staff will observe the focus groups remotely using streaming technology.

The moderator will use the attached moderator guides (Appendices IV through VI) to ensure that all relevant topic areas are addressed. Separate moderator guides were developed, one for each target audience: salon stylists, salon clients and retail consumers. The focus group facilities will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants or the names of their hair salons 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 12 focus groups are planned.

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

In preparation of these focus groups, we consulted with facilities that host focus groups to determine incentive rates. Based on these consultations, we propose an incentive of $65

for 90 minutes to ensure that we are able to attract specialized respondents who meet our screening requirements to participate in the focus groups. These participants will include salon stylists and salon clients who perform/undergo hair smoothing using permanent chemical processing and retail consumers of permanent hair smoothing products. This target audience constitutes a limited sub-category of general population and each of these groups of individuals poses unique recruitment challenges. 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 to reduce recruitment costs; maintain data quality; cover any out of pocket expenses incurred by participants who are required to travel to the focus group venue; and demonstrate our appreciation and respect to participants for the time and effort they give in talking to researchers discussed in Groth, 2010, and Russell et al, 2000.

While salon hair stylists will not bear a cost to cover their travel to a focus group facility, the incentive will provide compensation for taking them away from sessions and demonstrations at the beauty show they have already paid to attend. While the show will offer them classes allowing them to earn continuous education credits and a wide variety demonstrations that can teach them new marketable skills; obviously, a focus group cannot offer earning such credits or teach them new skills.

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. 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 points over comparison groups. Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992).

Although it is a common practice these days to provide incentives to qualitative research participants, unfortunately there is little published research studying the impact of incentive amounts in qualitative research. However, we do know from our experience, the experience of our contractor Westat, and the experience of recruiting facilities that we worked with throughout the years (OMR, Shugoll Research, and Delve) that lower incentives result in higher recruiting costs and higher no-show rates. A meta-analysis of recruiting efforts conducted by Westat found that the average recruiting hours spent per participant scheduled doubled from 1.91 hours per recruit when an incentive of between $65 and $75 was paid, compared with 3.99 hours when an incentive of $50 was paid. In a focus group study conducted for the National Cancer Institute (NCI), an incentive of $50 for a 90 minute group resulted in a no-show rate of 54.2% which impacted the cost of recruitment but also, and probably most importantly, on the quality of the data collected since analysis was based on only half the number of sampled participants.

In another focus group project, sponsored by FDA's CDER in 2006, to examine usefulness of drug risk communication, pharmacists received $100 for their participation in a focus group. Similarly to the salon stylists' focus groups, these focus groups were conducted at the Maryland Pharmacist's Association 2006 annual meeting in Ocean City, Maryland.

Our proposed incentive amount of $65 is comparable to the level of reimbursement for general population studies which were conducted at Westat. For example, $75 incentives were paid to men who took part in focus groups about their health care decisions conducted on behalf of NCI, and the same amount was paid to focus group participants in another study of adults on behalf of the Maryland Health Care Commission to test their website. For harder to reach groups examples include a $100 incentive payment to Supplemental Nutrition Assistance Program recipients who took part in a focus group study conducted on behalf of the U.S. Department of Agriculture, and the same amount to participants in another focus group study involving College Guidance Counselors carried out on behalf of the U.S. Department of Education.

8. **Questions of a Sensitive Nature:**
   None.

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

   The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (Appendices I through III). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

   Table 1 shows the estimated annual reporting burden for the groups, assuming 10 participants per group.

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

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	720	5	60
Focus group discussion	120	90	180
Total			240

REQUESTED APPROVAL DATE: September 30, 2016

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Appendices

Appendix I: Screener – Salon Stylists

Appendix II: Screener – Salon Clients

Appendix III: Screener – Retail Consumers

Appendix IV: Moderator's Guide – Salon Stylists

Appendix V: Moderator's Guide – Salon Clients

Appendix VI: Moderator's Guide – Retail Consumers

Appendix VII: Symbols

Appendix VIII: Mock-ups

Appendices IX (A through C): Consent Forms

Appendices X (A through D): Flyers and Ads