FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS (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: Consumer perceptions as a foundation for CTP positioning initiative; OMB Control Number 0910-0497

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is seeking OMB approval under the generic clearance 0910-0497 to conduct focus groups to assess consumer perceptions and knowledge with respect to the role of CTP in the tobacco control arena.

   To more effectively regulate the manufacture, distribution, and promotion of tobacco products and educate the public about the harms of tobacco product use, CTP intends to develop a unique value proposition that resonates with key audiences, improving our ability to raise awareness, understanding, and support for our programs and activities, build relationships that advance our mission, and manage our reputation so as to enhance our ability to meet our primary objective of reducing the death, disease, and disability caused by tobacco products . The focus groups will be part of the foundation for developing CTP's position in the tobacco control arena. As such, it is critical that consumers and other key stakeholders view CTP as a credible and relevant source of information. This research will serve as a foundation for crafting CTP's identity and position and will be used to enhance the credibility, consistency, and effectiveness of CTP activities and programs. Unless the public is able to effectively understand and engage with CTP communications, FDA will not be serving the public as mandated under the Tobacco Control Act.

2. **Intended use of information:**
   FDA's Center for Tobacco Products will conduct activities related to the regulation of tobacco products, including educational and communication programs, as authorized by Section 1003(d)(2)(D) of the Federal Food, Drug & Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)).

   To develop CTP's identity and increase the potential public health impact of the Agency activities and programs, research must be conducted to gain insight into consumer perceptions and knowledge with respect to CTP and our role. This positioning initiative will be used to define and express CTP's identity and clarify the role that CTP plays within a field of other organizations with related missions.

   The information from these focus groups will be used to inform how CTP portrays itself to the public and how messaging about CTP activities are conducted in support of the

provisions of the Tobacco Control Act. This will be followed by additional qualitative research that will be used to develop messaging and engagement strategies necessary to publicly position CTP as a credible and effective player in the tobacco control arena. The data collection in this study is not intended for and will not be used to inform policy.

3. **Description of respondents:**
Respondents to this collection will be part of eight focus groups representing a diverse population. The interviews and groups will be conducted in areas of the United States which best represent our target audience (Louisville, KY; Portland, OR; New York, NY). The target audience includes both adolescents (ages 15-17) who are at risk for tobacco use; and adults (ages 18-50) who are either former or current smokers. Additionally, focus groups will include diversity in minority and ethnic backgrounds, occupation, and level of education and income. The groups will be separated by age (adolescent and adult), gender, and smoking status (former users, current users). Eight individuals will be recruited for each focus group discussion, with the expectation of having 7-8 participants per group.

4. **Date(s) to be conducted and location(s):**
The research is projected to begin March 26th 2012 and be completed by April 23rd, 2012. The focus groups will take place in Louisville, KY; Portland, OR; and New York, NY.

5. **How the Information is being collected:**
The information is being collected by a contractor who will conduct sessions in a room containing the participants. The sessions will be live, face-to-face, and will be videotaped if consent is provided from each individual. The contractor will ask a series of questions, and record the answers and reactions to those questions.

   Focus groups are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy and materials development.) Focus groups are usually composed of 8 - 10 people who have characteristics similar to the target audience, or subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion outline, which allows him/her to change direction as the discussion unfolds and new topics emerge.

6. **Number of focus groups:**
There will be eight focus groups representing a diverse population.

7. **Amount and justification for any proposed incentive:**
In an e-mail message from FDA's OMB Desk Officer on October 5, 2011, OMB policy stated that teens should receive no more than $30 and their parents no more than $25 to participate in government-sponsored surveys. OMB also suggested that young adults and adults receive no more than $50 for government-sponsored surveys. These surveys fall within the OMB-suggested incentive guidelines, as the total amount of the proposed incentive for these series of surveys is $50, which includes $30 to teens, $20 to parents of teens, and $50 for adults. Given the potential difficulty in recruitment among low socio-economic populations, rural settings, high risk populations (current or former smokers

and those susceptible to smoke), and youth ages 15-17; we intend to provide respondents with the proposed amount as an incentive as well as token of appreciation.

If the incentive is not adequate enough, participants may agree to participate and then not show up for the group. Low participation may result in inadequate data collection, or, in the worst cases, cancellation of groups and loss of costs associated with facility rentals, recruitment, travel costs, and moderator and observer time (Morgan and Scanell, 1998).

8. **Questions of a Sensitive Nature:**
Some studies require the inclusion of people who match selected characteristics of the target audience that FDA is trying to reach. This may require asking questions about race/ethnicity, income, education and/or health status on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that FDA speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as private and anonymous to the fullest extent allowed by law. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997 (http://www.whitehouse.gov/omb/fedreg/1997standards.html).

This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Questions of this nature, while not as personal as those about sexual behavior or religious beliefs, still require some sensitivity in how they are worded and approached. In face-to-face data collections, questions of this kind are generally asked later in the interview or group discussion, when respondents are more comfortable with the interview situation and are more at ease with the interviewer/moderator. Participants are informed prior to actual participation about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable.

FDA tobacco communications is also concerned with discouraging tobacco use by adolescents before they start. FDA acknowledges the sensitivity of questions about the purchase and use of tobacco, which is illegal for minors in some states. Interviews conducted with youth will be conducted by moderators specifically trained for interaction with adolescents.

Raw data from data collections that include sensitive information (for example, screening questionnaires and video/audio tapes) are not retained once the data have been extracted and aggregated. The information never becomes part of a system of records containing permanent identifiers that can be used for retrieval.

Confidentiality of Respondents:

Affini Global Qualitative Research is conducting focus groups so that the FDA can better understand adolescents' and adults' thoughts and knowledge about tobacco products and are familiar with federal confidentiality and privacy provisions.

Before each group or interview begins, the moderator will obtain verbal consent from the participants to videotape the sessions. In the event consent is not provided, the contractor will refrain from videotaping the session.

The contractor will ensure that all focus group sessions are videotaped, if consent is provided by all participants. The videotapes for all groups will be in DVD format and will be analyzed for 1-2 weeks after completion of the focus groups, after which they will be made available to the FDA.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by the law. The moderator's discussion guide and consent form will contain a statement that no one will be able to link the respondent's identity to their responses. Identifying information will not be included in the data files delivered by contractors to the agency.

Focus group agencies will not share personal information regarding panel members with any third party without the participant's permission unless it is required by law to protect their rights or to comply with judicial proceedings, court order, or other legal process. Identifying information will not be included in the transcripts and digital recordings delivered to the agency. All data received by FDA will remain in a secured area. No data will contain identifying information.

Please see the attached privacy statement for Affini Global Qualitative Research.

The privacy procedures that we routinely implement to maintain the privacy and confidentiality of study data are listed below.

- The privacy protections must be described in the informed consent form that participants sign.
- The Market Research Codes of Conduct govern all local field agencies who will participate in the recruiting and staging of the focus groups; and client/client topic confidentiality is a key component of these codes.
- Staff members (both field and on-site) are informed that they must not discuss any aspects of an individual study case with anyone who is not directly involved in the project, and that discussions among colleagues should take place only when necessary for the accurate and timely completion of work.
- Access to hard copy or electronic data is restricted to authorized staff members.
- Electronic data are stored in a location within the Affini network that provides the appropriate level of security based on the sensitivity or identifiability of the data.
- Staff members are not allowed to interview or process data for subjects they know personally.
- The disclosure of personal identifiers to outside sources requires the subject's specific consent (unless disclosure is required by state or federal law)

In addition to collecting sensitive information from subjects during some projects, Affini sometimes acquires data from outside sources. During the initial contact with these data providers, we discuss our policies on confidentiality and privacy issues, and when using the data obtained from them, we also follow their guidelines for privacy and confidentiality.

9. **Description of Statistical Methods**

This study is based on qualitative methods and is not intended to yield results that are statistically projectable. However, tobacco communication messages will be designed and marketed with specific audiences in mind (e.g., 15-17 year olds, 18-50 year olds, former tobacco users, current tobacco users, etc). Screening methods will be used to select a sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Youth – Male (Two focus groups of 8; 15-17 years old)	16	120	32
Youth – Female (One focus group of 8; 15-17 years old)	8	120	16
Adults Current Smokers (Three focus groups of 8; 20-50 years old)	24	120	48
Adult Former Tobacco Users (Two focus groups of 8; 20-50 years old)	16	120	32
Total	**64**	**120**	**128**

REQUESTED APPROVAL DATE: Monday March 26th, 2012

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FDA CENTER: Center for Tobacco Products (FDA/CTP)