FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF PRETESTING COMMUNICATIONS ON TOBACCO PRODUCTS (0910-0674)

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TITLE OF INFORMATION COLLECTION: Consumer Perceptions of New and Emerging Tobacco Products; OMB Control Number 0910-0674

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 0910-0674 to conduct a set of individual in-depth interviews (IDIs) and focus groups, "Consumer Perceptions of New and Emerging Tobacco Products," to assess consumer perceptions and knowledge with respect to novel tobacco products, such as dissolvable tobacco. This information will inform the Tobacco Products Scientific Advisory Committee (TPSAC) and Agency's understanding of the nature and impact of dissolvable tobacco on public health as required by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

2. **Intended use of information:**
   Section 907(f)(1) of the Tobacco Control Act states "The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i). (2) Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

   In order to understand the potential nature and impact of dissolvable tobacco products on public health, FDA must conduct research to gain insight on consumer perceptions and knowledge with respect to these new tobacco products. The data collected in this research will assist TPSAC and the FDA in better understanding the nature and public health impact of dissolvable tobacco products, will be used to conduct subsequent quantitative research around novel tobacco products, and will be used to identify audiences and messages for future communications.

3. **Description of respondents:**
   Respondents to this collection will be part of 12 individual in-depth interviews (IDIs), 6 small groups, and 12 focus groups representing a diverse population. The interviews and groups will be conducted in areas of the United States that have been used as industry test markets to pilot dissolvable tobacco products (Columbus, OH; Portland, OR; Charlotte, NC). Twelve IDIs will be conducted with young smokers (15-17 years of age). Additionally, there will be 6 small groups (groups of two or three people) of young adults (18-24 years) who have used dissolvable tobacco products and 12 focus groups of young adult tobacco users (18-24 years). The groups will be separated by gender and will also vary by race, education status, income, and/or smoking status (e.g., regular users,

occasional users, those planning to quit, etc.). The contractor will recruit approximately 16 individuals for the IDIs, with the expectation of conducting a total of 12 IDIs. Similarly, the contractor will recruit approximately 4-5 individuals for each small group, with the expectation that only 2-3 people will participate in each small group discussion. The contractor will recruit 12 individuals for each focus group discussion, with the expectation of having 8-10 participants per group.

4. **Date(s) to be Conducted:**
   The research will begin in November 2011 and be completed by February 2012. The focus groups and IDIs will be conducted in Columbus, OH; Portland, OR; and Charlotte, NC.

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

   Focus groups, small group, and individual interviews 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. Individual and small group (pairs/triads) interviews follow the same protocol as focus groups. Smaller groups are typically used when there is a sensitive topic or difficult-to-recruit population participating. In this case, individual interviews were chosen for the youth because of the sensitive nature of a discussion around a new tobacco product. The small group format was chosen for young adults who have used dissolvable tobacco products because the product is not currently used by a large number of people.

6. **Confidentiality of Respondents:**
   RTI International (RTI) is conducting discussion groups as a contractor to FDA to better understand adolescents' thoughts and knowledge about tobacco products and is 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 given, the Contractor will refrain from videotaping the session.

   The contractor will ensure that all focus group sessions are audiotaped and videotaped, if consent is given. One copy of each session will be supplied in digital format that can be viewed on a computer. We will also produce transcriptions of the tapes to assist in report writing and to provide the FDA with a written record of the sessions. One paper and one electronic copy of the focus group transcripts will be supplied. The audiotapes and transcripts for a given group will be available to the FDA within two weeks of the

completion of that focus group. To ensure participant confidentiality, the contractor will redact the recordings and transcripts.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by the law. The study moderator's 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.

Neither independent contractor, or focus group agencies, will 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. Upon final delivery to FDA, transcripts and digital recordings will be destroyed. All data received by FDA will remain in a secured area. No data will contain identifying information.

Below is RTI's statement of privacy and confidentiality.

RTI's Privacy and Confidentiality Procedures
RTI is dedicated to maintaining the privacy of all information on human subjects, particularly sensitive or identifiable data. Because disclosure of research data could have serious consequences for research participants, we manage information about human subjects in ways that prevent unauthorized access to study data at any time during the study. Our privacy guidelines specifically limit the release of personally identifying information about participants. Generally, these identifiers are kept in separate data files and are not released to anyone outside the project team. Respondents must be fully informed about how and to whom their information is released. Each project staff member is required to uphold our privacy guidelines and procedures. The primary responsibility for protecting the privacy of subjects rests with the project director, who oversees the proper implementation of the procedures and who institutes any changes necessary to ensure privacy.

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

- The project director must describe for the IRB the privacy and data security measures to be used in the study as part of the IRB approval process.

- The privacy protections must be described in the informed consent form that participants sign.

- The project director provides the necessary instruction on privacy requirements and procedures to all project staff.

- Each staff member involved in any phase of handling sensitive personal information is required to sign a legally binding confidentiality agreement. (Both existing staff and newly hired personnel working on the contract must sign the agreement.)

- Field staff are required to sign a pledge of confidentiality that reinforces confidentiality requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action.

- 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 RTI 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)

- The project director implements any other procedures required for a study to ensure confidentiality, based on other study considerations (e.g., Internet data collection, biospecimens, genetic testing).

In addition to collecting sensitive information from subjects during some projects, RTI 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.

7. **Amount and justification for any proposed incentive**
   As participants often have competing demands for time, incentives are used to encourage participation in focus groups. Incentives must be high enough to cover travel costs, time, and to provide enough incentive to attend the focus group rather than another activity. Additionally, incentives typically are higher for harder-to-recruit populations. 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).

Recruitment facilities consider youth (ages 15-17) and young adults (ages 18-25) who use tobacco products difficult-to-reach populations given their prevalence in the general population. We are further narrowing our scope by requiring participants to be familiar with and/or have had experience with novel tobacco products that are in limited supply in the three test markets. In addition, youth are particularly difficult to recruit due to the sensitive nature of the topic—they must admit they are a current tobacco user or are susceptible to use. Thus, is it critical to this data collection that we are able to provide adequate incentives to encourage participation among the limited number of potential youth and young adults.

The amount of the proposed incentive for youth is $30, with an additional $25 offered to parents of these youth. We propose compensating parents of adolescent participants to facilitate participation of the youth. Young adults will be provided $50 for their participation.

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 a question 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. 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).

Because FDA tobacco communications may be concerned with the prevention of premature mortality from heart disease and oral and respiratory cancers, some projects may involve asking questions about (or discussing) how one perceives his/her own personal risk for serious illness. 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.

9. **Description of Statistical Methods**
Pretesting for potential respondents to this collection includes various methods and approaches. Methodologies and sample sizes are based on a review of the relevant literature, consultation with experts in the field, and a baseline of data gathered over many years of pretesting materials on cancer and other negative tobacco-related health outcomes among professional, patient, and public audiences.

In general, pretesting relies 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., 13-17 year olds, 18-24 year olds, tobacco users who intend to quit, non-users, and tobacco retailers). Quota sampling will be used to select a convenience sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience. Response rate is not applicable to quota sampling because this type of sampling results in a nonprobability sample which is not representative of the population. For this research, all respondents will be initially contacted by telephone or through the mail, and some over-recruiting may be done to compensate for not following up with non-respondents.

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)
Young Smokers (12 IDIs)	12	96	19.2
Young Adult Smokers (12 focus groups of 9; 18-24 years old)	108	96	172.8
Young Adult Dissolvable Users (Small groups; 18-24 years old)	18	96	28.8
Total	**138**	**96**	**220.8**

REQUESTED APPROVAL DATE: November 18, 2011

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