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

Stakeholder interviews are designed to elicit information from people who influence the target audience. Stakeholders will be selected based on their professional experience with retailer education and/or tobacco control, their ability to provide insight into the motivators and communications needs of retailers, and their ability to provide a federal, state, or community perspective on retailers and tobacco control. As stakeholder interviews are designed to elicit qualitative information from those who influence a target audience, they do not yield meaningful quantitative findings. As such, they cannot be used to drive the development of policies, programs, and services.

TITLE OF INFORMATION COLLECTION: Stakeholder Interviews for Break the Chain Retailer Education Campaign; 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 series of stakeholder interviews, "Stakeholder Interviews for Break the Chain retailer education campaign," to inform future research and campaign activities for CTP's retailer education campaign. It is critical to understand the communication needs of retailers and what influences their decision-making processes. This will help CTP provide targeted communications to retailers that assists in their implementation of and compliance with regulations under the Act.

2. **Intended use of information:**
   Interviews with key stakeholders will be used to learn more about the attitudes, beliefs, motivations, and decision-making processes of retailers and those that influence them in order to develop and deliver appropriate communications to this audience.

   We will take the information we learn from key stakeholders to help develop a more sophisticated and robust understanding of the communication needs of retailers and to further refine our questions for retailers that will be used in a subsequent phase of this research project. The information will also be used to continue development and dissemination of messages and materials for the *Break the Chain of Tobacco Addiction* (*Break the Chain*) retailer education campaign.

3. **Description of respondents:**
   Understanding the communication needs of retailers requires eliciting qualitative information from key stakeholders, including academic researchers, tobacco control experts, representatives from corporate level retail organizations, members of retail associations, and leaders of national and state anti-smoking campaigns. Respondents will be selected because of their professional experience in retailer education and/or tobacco control. There will be no more than 26 interviews conducted with these stakeholders. The interviews will be held via telephone and webinars.

4. **Date(s) to be Conducted:**
   The stakeholder interviews will begin in March 2012 and be completed by June 2012. The interviews will be held via telephone and webinars.

5. **How the Information is being collected:**
These interviews will be conducted either individually (8-10 interviews) or in small groups made up of individuals with similar professional backgrounds (2 groups comprised of 6-8 individuals each). The information is being collected by the interviewer, and the session will be held via telephone (individual interviews) and webinars (small group discussions). If consent is given from the participant, the interviews will be voice recorded. The interviewer will lead participants through a series of questions to elicit their experiences and thoughts around educating retailers, tobacco control, communicating with the larger retail community, and motivating retailers to support FDA regulation and compliance. Respondents will not be asked about specific compliance violations, or other such sensitive questions, as that is not the intent of this research project. The data collected will be used to further refine questions for retailers that will be asked of them in subsequent phases of this project and to develop a more sophisticated and robust understanding of the communication needs of retailers.

Individual interviews will be conducted with large retailer representatives, academic researchers, representatives from CTP's Office of Compliance, and tobacco control advocates. Small group discussions will be held with state and national tobacco control representatives and members of the retail industry. These participants will be selected based on their professional experience around retailer education and/or tobacco control and represent federal, state, and community perspectives that are critical for tailoring communications in the *Break the Chain* retailer education campaign. Stakeholders represent various facets and interests of the retailer community.

The groups are conducted by a professional interviewer who asks participants to describe their professional experiences around retailer education and/or tobacco control and how best to meet the needs of the retailer community. The interviewer uses a moderator's guide to guide both the individual and small group discussions.

6. **Confidentiality of Respondents:**

Decision Partners is conducting stakeholder interviews as a contractor to FDA to better understand the communication and education needs of retailers as they relate to implementing FDA tobacco regulations. Decision Partners is familiar with federal confidentiality and privacy provisions.

Before each interview begins, the moderator will obtain verbal consent from the participants to audiotape the sessions. In the event consent is not given, the Contractor will refrain from audiotaping the session.

The contractor will ensure that all interviews are audiotaped, if consent is given. One copy of each session will be supplied in digital format that can be listened to on a computer or other audio device. 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 interview 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 interview. 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.

The independent contractor will not share personal information regarding participants 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.

The following is documentation of Decision Partner's privacy and confidentiality procedures:

Decision Partners adheres to the highest standards of research ethics in accordance with our Human Research Protection Plan (HRRP), which is available upon request. Per our standard practices, the following are the key components of our privacy plan for this project:

- A statement informing Expert Interview participants of their rights to privacy is included in the interview discussion guide (see Appendices B and C).

- FDA may be aware which organizations (and in cases, specific individuals) are being invited to participate in an interview but data will be reported in aggregate so as not to identify specific individual or organization responses.

- The identity of the research participants will be kept private within the Decision Partners and FDA project team. Specific organizations or individuals who participate in an interview will not be identified in any summaries or reports, unless permission is granted. The Summary Report and any future reports will describe participants in general terms (e.g., federal government official, corporate official at a large retail chain).

- The interview will be conducted by phone by one or two senior researchers from Decision Partners. FDA will not participate in any way in the interviews.

- Researchers will take detailed handwritten notes of the interview. With permission, the phone interviews will be audio recorded to ensure accuracy and completeness of the interview notes. The recording will be securely stored by

Decision Partners and will be destroyed at the completion of the project as per our HRPP.

- A Summary Report will be prepared from the interview notes. No identifying information will be included in the Report. The Summary Report and any future reports will consolidate the responses of all participants, and no quotes will be attributed to any individual.

7. **Amount and justification for any proposed incentive**
   Participants are being selected to participate in the stakeholder interviews because of their expertise in retailer education and/or tobacco control. As we are eliciting their professional opinions, we will not provide participants with incentives.

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. In this case, potential participants hold professional positions that require involvement with retailer education and/or tobacco control. 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. Respondents will not be asked about specific compliance violations, or other such sensitive questions, as that is not the intent of this research project. However, the interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable. This information collection fully complies with all aspects of the Privacy act and respondents are assured that the information is voluntary, and will be treated as private and confidential to the fullest extent allowed by law.

   Raw data from data collections that include sensitive information (e.g. 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.

   This study was exempted by the FDA Research Involving Human Subjects Committee.

9. **Description of Statistical Methods**
   Interviews rely on qualitative methods and are not intended to yield results that are statistically projectable. Stakeholders will be identified based on their professional experience with retailer education and/or tobacco control. It is important for participants to represent federal, state, and community perspectives in order to have a robust understanding of the needs of the retail community at large and of retailers at the community level. For these stakeholder interviews, all respondents will be initially contacted by telephone or through e-mail; some over-recruiting may be done to compensate for non-respondents.

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

Type/Category	No. of Respondents	Participation	Burden

of Respondent		Time (minutes)	(hours)
Individual Interviews	10	96	16.0
Small group discussions	16	156	41.6
Total	**26**	**96**	**57.6**

REQUESTED APPROVAL DATE: February 24, 2012

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