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

Retailer interviews are designed to elicit information from tobacco retailers in order to support FDA communication and education activities. Retailers who work in retail outlets that sell tobacco will be asked to discuss their experiences and thoughts around FDA regulations, reducing tobacco use among youth, decision-making processes and behaviors, communicating with the larger retail community, and motivating retailers to support FDA regulation and compliance. They will represent a mix of retail outlets and will be demographically and geographically diverse. As retailer interviews are designed to elicit qualitative information and do not yield meaningful quantitative findings, they cannot be used to drive the development of policies, programs, and services.

TITLE OF INFORMATION COLLECTION: Interviews with Tobacco Retailers to Inform Retailer Education; 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 interviews, "Interviews with Tobacco Retailers to Inform Retailer Education," to inform future research and communication 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:**
   This study will be used to help FDA better understand how to communicate with retailers about FDA regulations through FDA's Break the Chain of Tobacco Addiction retailer education campaign and other retailer communications strategies.

   This qualitative study will (1) assess the primary influences on clerks' and managers' decision making and behavior with regards to compliance with the tobacco point of sale age verification and selling requirements; (2) assess the role and influence of communications, including FDA's Break the Chain of Tobacco Addiction campaign, on the perceptions, decisions and behavior of clerks and managers; (3) identify appropriate channels through which to communicate with retailers.

   Findings from this study will be paired with FDA's previous research with key stakeholders that was conducted to understand the communication needs and decision-making challenges in the retail environment from an expert perspective[1]. Experts included those from academic institutions, federal and state government, retailer associations, and public health associations. The information gathered from these stakeholders was used to inform the development of the retailer interview protocol for the current study. The expert stakeholder interviews and interviews with retailers will be used to develop a framework—or mental model—to better understand retailer decision making. The mental model will be used to identify potential points in the decision-

[1] The *Stakeholder Interviews for Break the Chain Retailer Education Campaign* research was completed in October 2012. This study received OMB approval June 6, 2012.

making process that can be supported through FDA education and communication strategies. For more information about mental models research and the expert model developed based on the *Stakeholder Interviews for Break the Chain Retailer Education Campaign* research, please see Appendix A.

3. **Description of respondents:**
Understanding the communication needs of retailers requires eliciting qualitative information from a variety of retailers. For the purposes of this research, tobacco retailers will be defined as "clerks" and "managers" who work in retail outlets that sell tobacco. The contractor (Decision Partners) is planning to conduct interviews with no more than 90 retailers. These interviews will be conducted individually with clerks (45 interviews) and managers (45 interviews).

Retailers will be recruited from a mix of retail locations (e.g. convenience stores, grocery stores, gas stations, mass merchandisers) within a 90-mile radius of three cities: Seattle, WA, Cleveland, OH, and Raleigh, NC. These case study cities were selected because they were all above the national mean in Synar-reported state-level retailer violation rates for 2009; they also reflect a variation in geographic and demographic characteristics of the U.S.; and they have a mix of urban, suburban and rural communities within a 40-mile radius of the downtown area.

Eligibility Requirements
Given the diversity of the target population of tobacco retailers, sample development and recruitment methods will require a combination approach, including coordinating with retailer organizations, community organizations, or other key stakeholders in the study locations and those beyond the study locations who have connections to retailers in the study locations. To be eligible to participate, retailers must be at least 18 years of age and be currently employed by (or own) a retail outlet that sells cigarettes, cigarette tobacco, or smokeless tobacco. Types of retail outlets will include: convenience stores (without gas), gas stations (with or without convenience stores), grocery stores, and mass-merchandisers. Research has identified these types of outlets sell 98% of the tobacco sold in the United States (Ribisl, 2011). Given the limited scope of this project, people who work for pharmacies, restaurants, liquor stores, outlets on Native American reservations, or Internet retailers will be excluded from the study. Interviewees must have a direct role in the sale of tobacco, or in supervising or managing those who make sales. They must be willing and able to participate in a phone or in-person interview, conducted in English. An effort will be made to recruit a diverse group of participants (e.g. gender, age, race/ethnicity, type of retailer outlet, location of retail outlet). Stores will be ineligible to participate if there is an open legal investigation or pending litigation between the store and FDA; we will work with senior management in CTP's Office of Compliance and Enforcement to identify these stores. Retailers will not be recruited from identified stores.

Sampling, Recruitment, and Screening Procedures
The sampling frames will be created through lists of retail outlet locations that were provided to FDA through the state inspection contracts. Participants will be randomly selected from stores within defined zip codes to allow for inclusion of urban, suburban and rural locations (as determined by the 2010 U.S. Census data). The number and location of zip codes will be defined based on the final determination of the most appropriate mix of sample development and recruitment methods in each case study

location. In each case study, we will target sample sizes of 30 (15 salespeople, 15 managers) for a total of 90 interviews across all three cities. To protect privacy and encourage open and honest discussions, clerks and managers will not be recruited from the same store.

After the store has been selected through the abovementioned sampling method, the contractor will use a combination of the following methods to aid in the recruitment of participants.

- **Partnering with a retail chain:** for example, working with a particular chain to identify and recruit managers and clerks from stores in various locations.
- **Partnering with retail or other industry associations,** and chambers of commerce, to which retailers may be affiliated.
- **Partnering with community-based associations**, which may be particularly helpful in recruiting harder-to-reach retailers, such as independent retailers, or retailers located in marginalized or disadvantaged neighborhoods.
- **Public advertisements**, if needed, inviting people who work for retail establishments that sell cigarettes, cigarette tobacco, or smokeless tobacco to participate in a research interview.

In all the above partnerships, the level of coordination may include:

- Permission to recruit through organizations' listservs, websites, newsletters, or other store-level communication
- Permission to post in-store recruitment flyers (e.g., in worker lounges)
- Permission to release member contact information so that researchers can contact directly for recruitment
- Permission to recruit clerks and managers directly at the store location (recruitment information would be handed out in the store but actual screening would be done via phone to ensure privacy)

A combination of recruitment techniques is necessary because of the difficulty in recruiting this population. The project team is working closely with Dr. Kurt Ribisl, an expert in retailer education and research from the University of North Carolina Chapel Hill, who advised that we take a broad and diverse approach to recruitment to ensure adequate participation.

Recruitment materials have been developed that can be adapted for inclusion in the abovementioned recruitment techniques (see Appendix B).

Clerks and managers who are interested in participating in the interviews will be screened via telephone to ensure they are eligible for participation (see Appendices C-D). The screener includes questions related to type of retail outlet, position/job title, years of employment, and age. The recruitment screener also includes questions related to English proficiency. This is intended to recruit individuals who are both capable of and comfortable participating in an interview conducted in English. Race/ethnicity and sex will be captured in the screener but will be used descriptively when reporting findings rather than as inclusion/exclusion criteria. Participants will be recruited and screened until approximately 30 interviews (15 clerks, 15 managers) per location are conducted.

4. **Date(s) to be Conducted:**
   The retailer interview research will begin in April 2013 and be completed by February 2014. The interviews will be held in-person and via telephone.

5. **How the Information is being collected:**
   IDIs will last approximately 45 minutes. Approximately one-third of the interviews will be held in-person at a neutral, private location within the community. The remaining interviews will be conducted via telephone. The questions will be designed to elicit information based on participants' professional experiences, thoughts, beliefs, and perceptions (see Appendices E-F).

   Prior to the start of the interview, the interviewer will ask for verbal consent to audio record the interview. If verbal consent is given from the participant, the interviews will be voice recorded. If consent for audio-recording is not received, detailed hand-written notes will be taken. The audio recording will later be transcribed and will assist the interviewer in analyzing the data. The audio recording will be destroyed upon completion of the transcription. One paper and one electronic copy of the interview transcripts will be supplied to FDA upon completion of the data collection. To protect participant privacy, the contractor will redact any potentially identifiable information about the participant in the transcripts.

   Interviews will be led by a trained interviewer who will use a script to guide the discussion (see Interviewer's Guides). The discussion will cover the following topics: (a) work and store responsibilities; (b) perceptions, beliefs, and decisions at the point of sale; (c) experiences with customers who come into the store to purchase cigarettes and other tobacco products; (d) communication and training within the store; (e) store rules and federal laws related to the sale of tobacco products, including perceptions and attitudes toward these; (f) awareness and perceptions of FDA; and (g) reactions to FDA's Break the Chain campaign and other communication and education strategies. Additionally, managers will be asked to discuss the communication of rules and policies to employees. The interviewer will emphasize the purpose of the interview is <u>not</u> to discuss specific compliance behaviors or violations and that this research activity is independent from CTP OCE compliance and enforcement activities.

   Participation is voluntary and participants can choose not to answer any question. The data collected will be used to develop a more sophisticated and robust understanding of the communication needs of retailers.

6. **Privacy of Respondents:**

   Decision Partners is conducting retailer interviews as a contractor to FDA. Decision Partners is familiar with federal confidentiality and privacy provisions and conducted the *Stakeholder Interviews for Break the Chain Retailer Education Campaign* discussed in Section 2.

   Prior to the start of the interview, the interviewer will ask for verbal consent to audio record the interview. If verbal consent is given from the participant, the interviews will be voice recorded. If consent for audio-recording is not received, detailed hand-written notes will be taken. The audio recording will later be transcribed and will assist the

interviewer in analyzing the data. The audio recording will be destroyed upon completion of the transcription. One paper and one electronic copy of the interview transcripts will be supplied to FDA upon completion of the data collection. To protect participant privacy, the contractor will redact any potentially identifiable information about the participant in the transcripts.

All data will be collected with an assurance that the respondents' discussions will remain private to the extent provided by the law. The store location represented by each participant will not be disclosed to management or third-parties. The recruitment materials and study interview guides emphasize to participants 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 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. All data received by FDA will remain in a secured area. No data will contain identifying information. Upon final analysis by FDA, transcripts and digital recordings will be destroyed.

The following is documentation of Decision Partner's privacy 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 clerks and managers participants of their rights to privacy is included in the interview discussion guides (see Appendices E and F).*
- *FDA may be aware which store locations are being invited to participate in an interview but data will be reported in aggregate so as not to identify specific individual or store responses.*
- *The identity of the research participants will be kept private within the Decision Partners and FDA project team. Specific stores 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., clerk from urban convenience store).*
- *The interview will be conducted in person or 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 produce transcriptions to supplement 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**

As participants often have competing demands for time, incentives are used to encourage participation in qualitative research studies, including interviews. Incentives must be high enough to cover travel costs, time, and to provide enough incentive to attend the focus group rather than another activity. 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 recruitment, travel costs, and interviewer time (Morgan and Scanell, 1998).

At the conclusion of the interview session, participating clerks will be offered a cash incentive of $30.00 and managers will receive $50.00. This payment was set at approximately three times the average hourly wage for these positions (Bureau of Labor Statistics, 2011). In addition to having a higher average hourly wage, managers are being incentivized at slightly higher rates than clerks because there are fewer of them than clerks and it is anticipated this will be a difficult group to recruit. Having the perspectives of both clerks and managers is critical to our understanding of decision making and communication within the retail environment and ultimately to the ability of FDA to effectively and appropriately communicate its regulations around compliance and enforcement.

8. **Questions of a Sensitive Nature**

Questions around decision-making and compliance behaviors may be potentially sensitive to retailers since they may believe that discussion of non-compliant behaviors may result in law enforcement actions. To address this concern, the questions in this study are <u>not</u> designed to elicit discussion of specific non-compliant behaviors exhibited or witnessed. Rather, the questions in this study are designed to encourage discussion of general influences on decision-making, knowledge, awareness, and perceptions of existing regulations, and communication preferences. The interviewer will emphasize the purpose of interview is <u>not</u> to discuss specific compliance behaviors or violations and that even if they do mention (spontaneously) such activity that this research activity is independent from CTP OCE compliance/enforcement activities. Participants will be informed about their right to privacy and the steps being taken to protect their privacy and are told they are free to refrain from answering any questions they do not wish to answer. In addition, information gathered during the interviews will be reported in aggregate in a final report, thus not linking any mentions of non-compliant behaviors back to a particular retail outlet or employee.

If the participant expresses discomfort or appears to be uncomfortable, interviewers will be instructed to remind the participant that the information collected will be kept private, that it will not be shared with FDA, store management, or other third parties, that there are no right or wrong answers, that all comments are important to the research, that the recording device can be switched off if the participant prefers, that their participation is voluntary, and that they may refuse any question they wish. In addition, information gathered during the interviews will be reported in aggregate in a final report, thus not linking any non-compliant behaviors back to a particular retail outlet or employee.

This study was submitted to CTP's Research Involving Human Subject Committee (RIHSC) for review on December 20, 2012. It was submitted to FDA's RIHSC as a request for exemption on March 11, 2013.

9. **Description of Statistical Methods**

Interviews rely on qualitative methods and are not intended to yield results that are statistically projectable. This qualitative research employs the mental models approach and associated analyses. Mental models research is a robust qualitative research method (see Appendix A for more information). Standard analytical tools and techniques used by mental models researchers to ensure that coding and analysis is conducted to a high research standard will be employed. This will include coding and analyzing the interview data against an expert model (a depiction of influences on retailer behavior developed in the previous research with expert stakeholders); summarizing the key research findings of each cohort; and conducting an analysis of the gaps and alignments between the mental models research findings and the expert model.

A coding guide will be developed to define and describe codes aligned with the expert model. The coding process begins by parsing participant responses into discrete segments. Each segment is assigned one or more codes from the codebook that best aligns with the various expert model nodes. Additional tags or keywords may be applied to the segments to capture finer details such as tone.

At the beginning of the coding phase, several interviews will be coded independently by two coders. Differences will be resolved by discussion, with final determination by the research lead. Segments that express new concepts not anticipated in the research design will be assigned new codes, which will be reviewed and incorporated into the coding guide. Once the coding procedure is deemed stable, each remaining interview will be coded by one coder. To ensure data quality the research lead will review and perform checks for drift in coding throughout the coding process. The research lead will conduct regular briefings with the coding team to review and make any necessary clarifications or changes to coded interviews or the coding guide as needed.

At the completion of the coding process, more detailed analyses will be conducted on segments using interview question numbers, tags, codes, keywords, or any combination thereof, in order to explore and subjectively assess the results and possible associations among concepts. Summaries of these analyses will be included in the research reports. In addition, aggregate mental models diagrams will be constructed, which provide a summary of the relative "weighting" of the degree of influence of variables represented by the various nodes within the expert model on the participants' collective thinking. Nodes in the expert model will also be qualitatively weighted based on the subjective assessment of the prevalence and degree of strength of the themes captured within each node. Themes that emerge in the research findings that were not previously identified in the expert model will be depicted as new nodes and highlighted in the mental model as necessary. Similarly, nodes that appear on the mental model but that were not found to be significant influences through the mental models research will be highlighted in the expert model.

Where appropriate, we may be able to draw on quantitative tools and techniques to explore possible associations (e.g., suggested differences in the thinking of managers vs.

salespeople, men vs. women, etc.). However, this research method generally precludes statistical analyses that can be generalized as representative of the broader U.S. population. As retailer interviews are designed to elicit qualitative information, they do not yield meaningful quantitative findings. As such, they cannot be used to drive the development of policies, programs, and services.

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 Per Interview (minutes)	Burden (hours)
Clerk Interviews	45	55	41.25
Manager Interviews	45	55	41.25
Total	**90**		**82.5**

REQUESTED APPROVAL DATE: April 17, 2013

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

ATTACHMENTS:

- **Appendix A:** Background Information about Mental Models Research and Expert Model Developed from Stakeholder Interviews Research [Note: this attachment is not an instrument, it merely supplements and illustrates information provided in the memo above]
- **Appendix B:** Recruitment Materials
- **Appendix C:** Clerk Screener
- **Appendix D:** Manager Screener
- **Appendix E:** Clerk Interview Guide
- **Appendix F:** Manager Interview Guide