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

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. Thus, 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 they 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: Merchant Interviews and Youth Focus Groups to Understand Reactions to Other Tobacco Product Flavor Bans; 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 qualitative research, "Merchant Interviews and Youth Focus Groups to Understand Reactions to Other Tobacco Product Flavor Bans."

   The aim of the proposed study is to assess youth and merchant reactions to recent policies in large U.S. cities. New York City and Chicago implemented rules banning flavored non-cigarette tobacco products. The study will identify issues among these audiences that will be important to consider in future message and communications development and future research efforts by FDA.

2. **Intended use of information:**

   The U.S. Food and Drug Administration, regulates the manufacture, distribution and marketing of tobacco products. With better information about how merchants and youth respond to policy changes, FDA can develop more effective methods of communicating changes in policy to these two groups.

   In October 2009, New York City enacted a law to put in place a citywide ban on the sale of tobacco products other than cigarettes with certain characterizing flavors other than menthol or tobacco. Similarly, in July 2014 the city of Chicago, Illinois became the first locality in the U.S. to prohibit the sale of all flavored tobacco products (defined as any tobacco product that contains a constituent that impacts a characterizing flavor, including menthol and electronic cigarettes) in retail outlets within 500 feet of any elementary, middle or secondary school.

   Thus, NYC and Chicago now provide an opportunity to study the implementation of tobacco control policies, such as flavor bans, at two different points in the policy implementation cycle: during the earlier stages of implementation (Chicago) and after several years of implementation (NYC). Specifically, the NYC study will afford us the opportunity to explore reactions from retailers and consumers, learning more about perceptions and communications related to compliance with the law, sales of specific

products, purchasing patterns, product use, and quitting behavior. Our research in Chicago will allow us to explore perceptions and communications related to flavored tobacco product availability, placement, promotion (i.e., advertising) and price post-policy implementation. We expect to learn about how information about the bans has been communicated, and the degree to which key stakeholders and residents, are aware of and understand the bans.

The purpose of this qualitative research is to assess how youth and merchants are reacting to recent tobacco control policies, such as flavor bans, how the policies are being implemented, and how information about the policies are being communicated. Interviews with merchants and focus groups with youth will be used to inform future communication strategies, message development, and research efforts. Since this study is designed to elicit qualitative information and will not yield meaningful quantitative findings, findings will not be used to drive the development of policies, programs, and services.

3. **Description of respondents:**

Merchant Interviews: NYC

A total of 25 semi-structured, in-person and telephone interviews will be conducted with retail store owners or managers who legally sell tobacco products in NYC. A sample of 25 retailers will be identified from a list of licensed tobacco retailers in NYC obtained from the New York Department of Consumer Affairs. Retailers will represent the store-type mix of retail outlets in NYC. We will draw one primary and two replacement samples of retailers to obtain a final sample of 25 retailers.

Merchant Interviews: Chicago

A total of 90 semi-structured telephone or in-person interviews will be conducted with retail store owners or managers who sell tobacco products. A random sample of 30 retailers will be identified in each of the three study sampling strata: 1) stores located within 500 feet of a school; 2) stores located within 501-1000 feet of schools; and, 3) stores located beyond 1000 feet of schools. Retailers will represent a mix of retail outlets in Chicago and will be demographically and geographically diverse. The interviews will provide detailed information on barriers to complying with the ban for those retailers' located within 500 feet of a school, as well as how the Chicago Flavored Tobacco Ban has affected all retailers' tobacco business. We will draw one primary and two replacement samples of 30 retailers from our three strata to obtain a final sample of 90 retailers.

Youth Focus Groups: Chicago

A convenience sample of 40 in-school adolescents, attending one of the schools affected by the Flavored Tobacco ban, aged 14-18 (9^{th} through 12^{th} grade) who have ever used flavored tobacco products, will be recruited through schools and community organizations. Four focus groups of 10 youth each, stratified by location and distribution of the schools affected by the ban (2 North, 1 Central, 1 South), will be recruited at one point in time from ban implementation. Study participants will consist of youth who self-report that they have ever used a flavored tobacco product. Approximately 200-300 adolescents will be screened in order to obtain a sample size of 40.

4. **Date(s) to be Conducted:**

Merchant Interviews: NYC
Interviews are projected to occur between March 1, 2015 and April 30, 2015.

Merchant Interviews: Chicago
Interviews are projected to occur between July 1, 2015 and September 30, 2015.

Youth Focus Groups: Chicago
Focus groups are projected to occur between September 1, 2015 and November 31, 2015

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

FDA is sponsoring a third-party to collect the data and has contracted with RTI International (RTI), and, through a subcontract with RTI, the Institute of Health Research and Policy at the University of Illinois at Chicago (UIC). ***Study protocol approval from the FDA IRB: Office of the Commissioner Research in Human Subjects Committee (OC RIHSC) and both RTI's and UIC's Institutional Review Boards will be obtained prior to the start of any of the activities described below.***

Merchant Interviews: NYC
The information will be collected in person and via telephone by trained interviewers. A day and time that is convenient for the merchant will be scheduled in advance of all interviews. All participating merchants, defined as a store owner or manager, will be verbally consented prior to initiating the interview. The interviewers will engage participants in a series of questions using semi-structured interview guides (Attachment 1). The semi-structured guide is used to provide some structure and information about the topics to be covered but also allow flexibility to enable issues relevant to the retailers to be raised. The guide will focus on how merchants reacted to the flavor ban, how the bans were implemented, and how information about the ban was communicated. With participants' permission, interviews will be audio-recorded and transcribed. Semi-structured interviews will last 10-15 minutes.

Merchant Interviews: Chicago
The information will be collected by trained interviewers via telephone. A day and time that is convenient for the merchant will be scheduled in advance of all interviews. All participating merchants, defined as a store owner or manager, will be verbally consented prior to initiating the telephone interview. The interviewers will engage participants in a series of questions using semi-structured interview guides (Attachment 2). The semi-structured guide is used to provide some structure and information about the topics to be covered but also allow flexibility to enable issues relevant to the retailers to be raised. The guide will focus on how the new ban has affected the tobacco retail environment and will also help us identify any unintended consequences to the ban. With participants' permission, interviews will be audio-recorded and transcribed. Semi-structured interviews will last 10-15 minutes.

Youth Focus Groups: Chicago

The information is being collected using a trained moderator, with assistance from the study Principal Investigator and Project manager who both have experience leading youth focus groups. After screening youth prior to selection in the focus group, the focus groups will be conducted at UIC's Institute for Health Research and Policy (IHRP). IHRP is equipped with focus group meeting rooms. Focus groups will last 90 minutes. After confirming that all youth assent and parent/legal guardian consent documents have been obtained, youth will first complete a written check-in survey (10-15 min.) that includes questions regarding demographics and flavored tobacco use (Attachment 3). This will be followed by a brief introduction regarding the purpose and a summary of ground rules for the focus group (10 min.). The moderator and study staff will then engage participants using a focus group guide with questions and prompts that includes questions on use and access to flavored tobacco products, as well as awareness and perception of the flavored tobacco ban (Attachment 4). With participants' permission, focus groups will be by audio-recorded. The last fifteen minutes will be used to pay youth for their participation in the groups.

6. **Confidentiality of Respondents:**

Merchant Interviews: NYC and Chicago

Semi-structured interview data will be kept private to the extent allowable by law by assigning identification numbers for each merchant participant. A master list of names and identification numbers will be developed with restricted access, and all merchant participants will be assigned a unique identification number. Master lists will be kept in a locked cabinet or password-protected computer file, separate from all other data, along with other materials that will have the store/subject's name (e.g., retailer contact information). Surveys will not be marked with the respondent's name, but only their identification number. Identifying information and other data are not stored together. Neither an individual's assigned ID nor their collected data will be released to anyone other than authorized project staff. The only personnel with access to the research data and contact information will be the principal investigator and select approved members of the research teams who have completed RTI or UIC investigator training.

The FDA OC RIHSC, RTI Institutional Review Board (IRB) and the UIC IRB will review all NYC and Chicago merchant interview data collection materials, respectively.

Youth Focus Groups: Chicago

Participants will be informed that they can withdraw from the study at any time. The voluntary nature of the study will be emphasized. Immediately before the focus group begins, the moderator will explain that students may "Pass" on questions that they do not want to answer. They will be told to let the focus group moderator know if they would like to stop their participation in the study at any point in focus group discussion. While the focus group is not expected to upset participants, any participants showing visible distress will be asked if they would like to take a break and if they would like to remain in the discussion. An assent form will be distributed to youth participants and collected, as well as a parental/legal guardian consent form.

Incentives will be provided for all participants who attend the focus groups. If participants decide they would like to stop their participation, they will be given the

incentive when they leave. Incentives will not be withheld for those who decide they do not want to participate in the full discussion.

Because no personal identifiers are recorded during the focus groups, remarks made during the groups and captured in the transcripts will not be linked to specific individuals. Data including respondents' full name, contact information (for possible member checks/data validation), gender, age, and location will be held in locked storage cabinets at the secure offices of UIC's Institute for Health Research and Policy (IHRP). Taped transcripts will also be kept in locked storage cabinets at the same location. The UIC IRB will review all Chicago youth focus group data collection materials. UIC IHRP study staff will also apply for a certificate of confidentiality for the focus group data.

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

Merchant Interviews: NYC and Chicago
Merchants will receive a $40 token of appreciation for participating in the semi-structured interview.

Youth Focus Groups: Chicago
Youth will receive a $30 token of appreciation for participating in the focus groups.

Economic incentives will be provided because they have proven to increase study participation in under-served and vulnerable populations,[1-2] which could be particularly relevant for the youth participants. The use of incentives is also based on the idea of "giving something to" participants, rather than "taking something from" them, which is relevant for both merchants and youth.

This study requires participants to comment on an activity that may be sensitive subject matter to the participants and could cause them to be reluctant to participate. Thus, it is critical to provide adequate incentives to encourage and retain participation among potential youth and merchant respondents.

Additionally, participants, particularly merchants, often have competing demands for their time, incentives are used to encourage participation in research. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking respondents to provide thought-intensive, open-ended feedback on peer crowds, brands, and creative concepts that require a high level of engagement. This token of appreciation is considered an adequate compensation for time spent participating in the study, and not an inducement for participation. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation[3].

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[1] Singer, E. &Kulka, R.A.(2002). Paying respondents for survey participation. In: VerPloeg M, Moffitt RA, Citro CF, eds. *Studies of welfare populations: data collection and research issues*. Washington DC: National Academy Press, 105–22.

[2] Groth, SW. Honorarium or coercion: use of incentives for participants in clinical research. *Journal of the New York State Nurses Association*. 2010.

[2]

[3] Halpern, SD., Karlawish, JH., Casarett, D., Berlin, JA., Asch, DA. Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine.* 2004; 164(7), 80l-803.

Incentives must be high enough to equalize the burden placed on participants with respect to their time and cost of participation,[3] as well as provide enough motivation for them to participate in the study rather than another activity. Inadequate compensation for time spent participating in a study may result in a difficult and lengthy recruitment process and/or participants who agree to participate and then drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with facility rental and facilitator and observer time. Additionally, this can cause a difficult and lengthy recruitment process that, in turn, can cause delays in launching the research, both of which lead to increased costs.

8. **Questions of a Sensitive Nature**

Merchant Interviews: NYC and Chicago

Merchants will be asked questions about their retail business in a one-on-one situation. None of the questions should be of a sensitive nature. However, merchants may be uncomfortable providing personal identifying information as part of the interview, or possibly with some of the interview questions related to their business. Merchants will be informed that they can "skip" any questions they do not want to answer. Only those willing to participate will be included in this study. Also, participants can withdraw at any time.

Youth Focus Groups: Chicago

Because we are asking youth about their tobacco use behavior, there is a slight risk that some of the focus group topics may contribute to the temporary distress of respondents; however, in our experience this risk is very minimal, and any questions that provoke discomfort may be skipped. Prior to the start of the focus groups, the moderator will explain that participants may "Pass" on questions that they do not want to answer. However, participants will also be reminded that their information will not be shared with anyone not on the research team. Only those willing to participate will be included in this study. Also, participants can withdraw at any time.

Raw data that include sensitive information (e.g., screening questionnaires, youth or parent contact information) are not retained once the data have been extracted and aggregated.

9. **Description of Statistical Methods**

Qualitative data analysis techniques will be utilized for both merchant interview and youth focus group data. This research is not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters.

Semi-structured interview and focus group audio-recordings will be transcribed verbatim and input into a qualitative data management software for analysis. Project staff will also take hand written notes during the focus groups, and these will be used to supplement transcript data. Analyses will be conducted using qualitative content analysis to identify the themes to both inform the proposed study, as well as serve as the foundation for future intervention development. Content analysis techniques will be used to identify common themes in the transcripts and summaries of the semi-structured interviews and focus groups for the development of code lists. Words or sentences that capture the critical issues/thoughts of the participants will be highlighted to help identify

patterns/themes in the data. As themes are developed, the PI, Co-Investigator, and Research Specialist will work together to assign a working definition to each code, as well as analyze the codes by themes to identify: (a) supports and barriers experienced by retailers related to complying with the relevant ban; (b) changes in business practices that were a direct result of the ban; (c) changes in flavored tobacco product usage and purchasing behavior among adolescents; and (d) perceptions among adolescents about the flavored tobacco product ban. Multiple strategies will also be employed to validate and ensure the trustworthiness of the qualitative data, e.g., member checks, data analysis with multiple sources, etc.

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

Youth Screener and Assent | estimated participation time: 10 minutes
Parental Opt-Out/Consent | estimated participation time: 5 minutes
Merchant Screening | estimated participation time: 5 minutes
Youth Participants | estimated participation time: 90 minutes
Merchant Participants | estimated participation time: 15 minutes

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screened Potential Participants			
Youth Screening Recruitment Script, Questionnaire, and Assent (Att. 6, 7 & 10)	300	10	50
Parental Opt-Out / Consent (Att. 5)	300	5	25
Merchant Screening (Att. 8 & 9)	345	5	29
Total Screened	**945**		**104**
Youth Focus Group Participants (Att. 3 & 4)	40	90	60
Merchant Participants (Att. 1 & 2)	115	15	29
Total Participants	**155**		**89**
Total[1]	**945**		**193**

[1] **The total universe (number of respondents) for this individual generic collection of information is 945; 155 represent the total number of participants in this study. The total number of participants (945) will be pre-screened for participation in the study, and only 155 will actually partake in the study after screening. The total number of responses is 1,100 (945 pre-screened responses and 155 screened participant responses.)**

REQUESTED APPROVAL DATE: February 27, 2015

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

Attachments:
Chicago Demographic Questionnaire (Attachment 3)
Chicago Focus Group Guide (Attachment 4)
Chicago Parental Consent (Attachment 5)
Chicago Participant Consent (Attachment 6)
Chicago Youth Assent (Attachment 7)
Chicago Merchant Interviews Recruitment Script (Attachment 8)
Chicago Recruitment Flyer
Chicago Merchant Interview Guide (Attachment 2)
NYC Merchant Interview Guide (Attachment 1)
NYC Merchant Interviews Recruitment Script (Attachment 9)
Chicago Focus Groups: Recruitment Script (Attachment 10)