Regulatory Oversight Behavioral Research Study Protocol

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Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users

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Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users

A Introduction

A1 Study Abstract

RAI Services Company (RAIS),¹ on behalf of R. J. Reynolds Tobacco Company, intends to submit a Modified Risk Tobacco Product (MRTP) application to the U.S. Food and Drug Administration (FDA) requesting that the Agency issue a "risk modification" order for Camel SNUS. The MRTP application will propose modified risk messaging for six (6) Camel SNUS products (collectively "Camel SNUS") currently marketed in the United States. Specifically, RAIS will seek an order for "reduced risk" messaging on Camel SNUS, intended for current regular tobacco users, as follows:

"Smokers who switch completely from cigarettes to Camel SNUS can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease."

This study has been developed to support that application by assessing the potential effects of the proposed Camel SNUS modified risk messaging on the likelihood that:

- current regular tobacco users, including those who are more likely to quit using tobacco (i.e., potential quitters), will start using Camel SNUS
- former regular tobacco users will re-initiate tobacco use with Camel SNUS
- never regular tobacco users will initiate tobacco use with Camel SNUS

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¹ RAIS is a wholly-owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for coordinating regulatory compliance for RAI's FDA-regulated operating companies, namely R. J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc.

A2 Research Objectives

- (1) Primary research objective measure likelihood of use² for Camel SNUS, with versus without modified risk messaging, among consumers overall and among the following self-defined tobacco user groups³:
 - current regular tobacco users: currently use tobacco on a regular or occasional basis
 - potential quitters: current regular tobacco users who report an intention to quit using tobacco⁴
 - former regular tobacco users: have been regular tobacco users in the past, but do not currently use tobacco on a regular or occasional basis
 - never regular tobacco users: have never been regular tobacco users

In addition, likelihood of use will be measured separately for white males in each of the self-defined tobacco user groups. White males are most likely to be affected positively or negatively by the Camel SNUS modified risk messaging, based on the current demographic characteristics of smokeless tobacco users.

- (2) Secondary research objective understand product use intentions among current tobacco users and non-users who anticipate using Camel SNUS (with and without modified risk messaging), as follows:
 - among current regular tobacco users who do not report an intention to quit tobacco,
 - % who anticipate using Camel SNUS in addition to using their current tobacco product(s)

² Likelihood of use operationalized in terms of likelihood to purchase with intent to try and predicted purchase rate (*refer to subsequent sections in the protocol for additional discussion*).

³ There are several ways to define tobacco use status. Self-reported behavior is used because a number of published studies and a meta-analysis (Patrick, Cheadle, Thompson, Diehr, Koepsell, and Kinne, 1994, *American Journal of Public Health, 84(7),* 1086-1093) demonstrate its utility; and, self-reported behavior aligns more closely with the dependent variable (i.e., ratings of likelihood of use) than categorizations based on historical and current tobacco use behaviors. Note, however, that including survey questions about historical use will make it possible to likewise analyze the data using definitions based on those variables.

⁴ Potential quitters are a subset of current regular tobacco users who do not intend to be using any tobacco product 9 months from the time of the survey. A time frame of 9 months was used to match the time period used when creating the algorithm developed to estimate purchase of a tobacco product with intent to try.

- % who anticipate using Camel SNUS instead of using their current tobacco product(s)
 - distribution of ratings of likelihood to switch back to their current tobacco product(s), including more harmful tobacco products
- among former regular tobacco users,
 - distribution of ratings of likelihood to re-initiate use of more harmful existing tobacco products (e.g., using Camel SNUS as a gateway)
- among never regular tobacco users,
 - distribution of ratings of likelihood to switch to more harmful existing tobacco products (e.g., using Camel SNUS as a gateway)

A3 Research Hypothesis

The primary research hypothesis is that there will be a significant interaction for the predicted purchase rate of Camel SNUS among self-defined tobacco groups and the presence or absence of the proposed modified risk messaging, such that: (a) the difference between the predicted purchase rates (i.e., <u>with</u> modified risk messaging versus <u>without</u> messaging) will be larger among current regular tobacco users than among former and never regular tobacco users; and, (b) the predicted purchase rate for Camel SNUS with modified risk messaging will be statistically significantly higher among current regular tobacco users than among former and never regular tobacco users.

B Background

B1 Rationale for the Study

RAIS is in the process of developing an application to FDA to market Camel SNUS as an MRTP. Specifically:

"Under Section 911 of the Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) the law requires the FDA, when evaluating an MRTP application, to take into account the "increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such product will switch to the tobacco product that is the subject of the

application" as well as "the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application." 5

Therefore, consideration for this research began with a thorough review of FDA's draft guidance document, "Guidance for Industry: Modified Risk Tobacco Product Applications" and the Institute of Medicine Report, "Scientific Standards for Studies on Modified Risk Tobacco Products". Those documents recommend conducting objective, hypothesis-driven research with experimental outcomes to estimate usage of a product before it enters the market in order to ultimately estimate the product's potential impact on population health.

Thus, this research was designed to project likelihood of use for Camel SNUS with modified messaging among consumers, overall and among specified sub-groups of tobacco users and non-users (e.g., current regular tobacco users, including those intending to quit tobacco; former regular and never regular tobacco users).

B2 Prior Literature and Studies

Currently, there are no available studies that provide information on the methodologies that best project likelihood of use for an MRTP. As a result, the extensive market research literature associated with projecting usage of new products more generally was used to inform the current methodology. ⁸

An evidence-based algorithm was developed to convert likelihood of purchase with intent to try ratings to projectable estimates of actual purchase (i.e., projected purchase rates).

There is, of course, no way to develop a predictive algorithm specifically for an MRTP because there are currently no such products in the marketplace. For that reason, an algorithm was developed using ratings of likelihood to purchase for a new-to-market cigarette (based on exposure to an advertisement) prior to its launch, and self-reported

⁵ Food and Drug Administration (FDA). (2009, June 22). Family Smoking Prevention and Tobacco Control Act § 911(g)(4)(B)-(C), 21 U.S.C. § 387k(g)(4)(B)-(C). Retrieved from http://www.gpo.gov/fdsys/pkg/PLAW-111publ31.pdf

⁶ Food and Drug Administration (FDA). (2012, March). *Guidance for Industry: Modified Risk Tobacco Product Applications: Draft Guidance*. Retrieved from

http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf

⁷ Institute of Medicine (IOM). (2011, December 14). *Scientific Standards for Studies on Modified Risk Tobacco Products.* Washington, DC: National Academy of Sciences.

⁸ Morwitz V.G., Steckel J.H. & Gupta A. (1997). When do purchase intentions predict sales? Working Paper, Marketing Science Institute, June, Report No. 97-112.

purchase behavior after nine months. The resulting algorithm is expected to overestimate likelihood of use for an MRTP, based on two considerations:

- it assumes that awareness and availability of the MRTP are comparable to a well-recognized and widely distributed cigarette brand (i.e., the algorithm was developed using a Marlboro brand cigarette)
- it assumes that all purchasers continue to use the MRTP, despite the fact that some consumers may not find the product to be acceptable

In five (5) empirical tests using subsequent tobacco products that have been launched, the algorithm over-predicted actual purchase in every instance. For a complete discussion of how that algorithm was developed, and how it has been used to date, refer to Attachment I, "New Tobacco Product "Attractiveness" Study: An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch (Methodological Report)."

C Study Outcomes

C1 Primary Outcome Measures

The primary outcome measure for this study will be, as follows:

 estimated percentages of consumers who will actually purchase Camel SNUS with and without modified risk messaging, developed by submitting likelihood ratings data to an empirically developed, evidence-based algorithm

Data for this measure will be provided for consumers overall, as well as for specified sub-groups outlined in *Section A2* of this study protocol.

C2 Rationale for the Selection of Outcome Measures

The outcome measure, estimated percentage of consumers who will actually purchase Camel SNUS with and without modified risk messaging based on likelihood to purchase ratings, was developed and tested using a number of different tobacco products. For a complete discussion of how the algorithm was developed to transform scalar ratings data into purchase estimates, *refer to Attachment I*.

C3 Research Stimuli

The research stimuli will be high resolution color images of print advertisements for Camel SNUS, with and without modified risk messaging ("test" and "control" stimuli, respectively). The test stimulus will include images and information for the entire Camel SNUS family (two pouch sizes, regular and large; and, five styles including Frost,

Mint, Mellow, Robust, and Winterchill). Each test stimulus will also include one of four randomly assigned mandated warning labels that will cover at least 20% of the area of each image or page of the advertisement. This design is recommended because it mimics the environment in which the proposed modified risk messaging would appear in the marketplace.

The research stimuli images are provided in *Appendix B, "Camel SNUS MRTP Likelihood of Use Stimuli."*

D Study Design

D1 Overview or Design Summary

A. Data Collection Procedures

Research Now will send e-mail invitations to a random subset of panel members who belong to the target population of U.S. adults who are legally eligible to purchase tobacco (as legislated by the states in which they reside), up to a maximum of 75 years old. Each invitation will contain a generic survey title ("Get Rewarded for Your Time – Study about Consumers"), the length of the survey, incentive amount provided for successful completion of the survey, and instructions for accessing the secure website for the survey (hosted by NAXION). Once a panel member enters the secure website, a brief introduction will inform the panel member of the private and voluntary nature of the survey. Individuals who consent to participate in the survey will be able to access the survey by clicking on the link to the survey URL. Panel members who choose to participate will answer a few qualifying questions necessary to monitor quotas.

Upon completion of the screener, respondents will be assigned via survey programming logic to one of eight monadic "arms" created by crossing type of messaging (i.e., with or without modified risk messaging) and four mandated warnings in order to ensure demographic balance across the arms.

B. Survey Content and Structure

The survey itself (refer to Appendix A: "Camel SNUS MRTP Likelihood of Use Survey") will consist of the following elements:

 question about anticipated future tobacco use (to understand future intentions prior to presenting information, including modified risk messaging, specific to Camel SNUS)9

- presentation of an advertisement for Camel SNUS, with or without modified risk messaging
- ratings of likelihood of purchase with the intent to try using a 10-point scale, whereby "1" means "Definitely Would Not Purchase It to Try" and "10" means "Definitely Would Purchase It to Try"
- question to determine how current regular tobacco users, who rate their likelihood to purchase greater than "1", anticipate using Camel SNUS (e.g., instead of, or in addition to, existing tobacco product(s))
- question to determine how likely current regular tobacco users, who rate their likelihood of purchase greater than "1" and plan to use Camel SNUS instead of their current tobacco product(s), are to switch back to their current tobacco product(s) after trying Camel SNUS
- question to determine how likely former and never regular tobacco users, who rate likelihood of purchase greater than "1", are to switch to a more harmful existing tobacco product after trying Camel SNUS
- question to determine why current regular tobacco users, who intend to quit tobacco but rate likelihood of purchase greater than "1", have some interest in using Camel SNUS
- questions that allow consumers to be categorized based on historical tobacco usage
- questions (from the FDA Cigarette Warning Label study¹⁰) for current tobacco users to assess interest, and anticipated success, in quitting tobacco use
- question to determine how long ago former tobacco users quit using tobacco
- questions to determine whether never tobacco users are likely to start using tobacco

D2 Subject Selection and Withdrawal

A. Inclusion Criteria

U.S. adults who are: (1) legally eligible to purchase tobacco products (as legislated by

⁹ A time frame of 9 months was used for this question to match the time period used when creating the algorithm developed to predict purchase rate with intent to try.

¹⁰ Food and Drug Administration (FDA). (2012). *Communicating Smoking Risks through Graphic Warning Labels*.

the states in which they reside), up to a maximum age of 75 years old; and, (2) members of the Research Now panel. Research Now will only invite English-speaking consumers because Camel SNUS modified risk messaging and advertising are expected to be in English only.

B. Exclusion Criteria

Individuals who are not old enough to purchase tobacco legally (based on the minimum tobacco-purchasing age in the state of residence), or who currently use Camel SNUS.

In addition, Research Now is constantly managing panel members labeled as "professional survey takers" or "gamers." Research Now has an extensive process in place to track and remove members who have proven in previous surveys that they are not taking surveys properly. Research Now checks for members who are speeding, entering gibberish into open-ended questions, and/or failing "traps" programmed into some surveys in order to identify whether the member should be flagged. If a member continually exhibits "bad behavior", Research Now flags them. The respondents that are flagged for a propensity for bad survey behavior will then receive only dummy surveys moving forward, i.e., until they show that they are able to properly take surveys. If they exhibit the bad behavior on the dummy surveys, then they are removed from the panel. If they do well with the dummy surveys (exhibiting "good behavior"), then they are reactivated and put back in the panel.

Finally, Research Now also has a continuous process in place that allows respondents to "rest." Panel members set the number of survey invitations they would like to receive per week when they enroll in the panel. Once that limit is reached, they are deemed "resting" and not available for surveys until their frequency limiters are reset. These limiters allow Research Now to maintain their panelists and keep them engaged.

C. Subject Recruitment Plans and Consent Process

Members of the Research Now national consumer online panel, a demographically balanced panel with over three million members from all 50 states in the United States and the District of Columbia (DC),¹¹ will receive an e-mail inviting them to participate in screening for the survey. Those who agree to participate will proceed to answer a few qualifying questions.

D. Randomization Method and Blinding

¹¹ The study sample will be balanced by U.S. Census region (i.e., Northeast, Midwest, South, West), as described in *Table 3*; thus, respondents on Research Now's panel from the Pacific Islands and other territories such as American Samoa, Armed Forces Europe, Armed Forces Pacific, Federated States of Micronesia, Palau, Northern Mariana Islands, Virgin Islands, and Puerto Rico will <u>not</u> be included in the sample.

Invitations will be sent to a random sample from the Research Now panel. The survey sponsor and topic will be blinded.

E. Risks and Benefits

We do not perceive there to be any risks associated with participating in this study, but all respondents will be shown a disclaimer at the conclusion of the survey in order to mitigate the possibility that consumers perceive the survey to be an inducement to use tobacco. Respondents will receive a nominal benefit from Research Now for participating in this study (refer to Section 12 for rewards/reimbursement details).

Panel membership and survey participation are both entirely voluntary. To minimize the prospect that consumers perceive the survey to be an inducement to use tobacco, the following statement will appear at the end of the survey¹²:

"Please note that the goal of this survey is only to examine likelihood of use for tobacco products in the presence and absence of modified risk messaging among current tobacco users and non-users. It is **not** intended to encourage you or anyone else to continue or start using tobacco products."

- Individuals should consider the conclusions of the U.S. Surgeon General, as well as information from the Centers for Disease Control and Prevention, and other public health and medical officials when making decisions regarding the use of tobacco.
- The best course of action for tobacco users concerned about their health is to quit.
- Minors should never use tobacco products, and adults who do not use or have quit using tobacco products should not start.
- Adults who smoke should avoid exposing minors to secondhand smoke; and, adult smokers should comply with rules and regulations designed to respect the rights of other adults.

All information contained in this advertising is provided for your information only and for regulatory research purposes only. [In order to advertise that a smokeless tobacco product is less harmful than a cigarette or another smokeless tobacco product, the company must first obtain clearance from the U.S. Food and Drug Administration ("FDA"). As part of that clearance process, a company must present evidence on the potential for modified risk messaging to affect likelihood of product use among current tobacco users and non-users.] The advertisements used in this research study [, those

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¹² The text in brackets will <u>not</u> be shown to consumers in the "control" (proposed Camel SNUS advertising <u>without</u> modified risk messaging) arm.

that include modified risk messaging for Camel SNUS,] have not and will not be used by the company to promote its products commercially without first obtaining clearance from FDA to do so.

The information and opinions expressed here are believed to be accurate, based on sound science and the best judgment available to the company. However, no action or inaction should be taken based on the contents of this information; instead, you should consult appropriate health professionals on any matter relating to your health."

E Study Procedures

E1 Screening for Eligibility

The sampling frame for the study is all U.S. adults who are legally eligible to purchase tobacco products (as legislated by the states in which they reside), up to 75 years old. Although Camel SNUS modified risk messaging is expressly intended for people who are adult tobacco users, the study intends to examine likelihood of use for the product among all adult consumers (i.e., current regular tobacco users and non-users). Due to concerns about showing tobacco products to minors and consistent with RAIS policy, there will be no attempt to draw a sample of consumers below the legal age for purchasing tobacco products.

The survey will use a convenience sample drawn from the Research Now national consumer online panel, a demographically balanced panel with over three million members from all 50 states and DC. Historically, survey research relied on probability sampling to justify the use of parametric statistics (e.g., to allow calculation of a statistical confidence interval). But non-probability samples are, today, both commonplace and widely accepted in light of the acknowledged challenges of drawing true probability samples and the belief that, with appropriate care, it is legitimate to use well-designed non-probability samples to represent the population at large (for a discussion, see The Journal of Survey Statistics and Methodology, November 2013). Although we will be unable to generalize our findings to individuals who do not use the internet, we have no reason to believe that their likelihood of use, based on predicted purchase rates, for Camel SNUS with modified risk messaging will be sufficiently different from demographically similar internet panel users to have a material effect on the research outcome.

All sampled panel members who, upon receiving an e-mail invitation, agree to proceed through the survey screening will answer a few qualifying questions designed to monitor quotas developed to maximize representativeness of the sample with respect

to basic demographic parameters (e.g., smoking behavior, age, gender, education, and ethnicity/race), and to facilitate weighting of the data to match the U.S. population overall.¹³

E2 Sampling Plan

Upon completion of the screener, consumers will be stratified into one of three self-defined tobacco user groups (see survey document in Appendix A):

- current regular tobacco user
- former regular tobacco user
- never regular tobacco user

Quotas will be in place on the following dimensions:

- tobacco behavior group: current, former, or never regular tobacco users
- age: legal tobacco age, by state, to 30 years, 31 to 50 years, or 51 to 75 years
- gender: male or female
- education: high school or less, some college, 4-year degree, or post-4-year degree
- ethnicity: Hispanic or non-Hispanic
- race: Caucasian, African American, or Asian/Other
- geography: Northeast, South, Midwest, or West

Within in each quota cell (represented by the combination of tobacco user group and demographics), respondents will be randomly assigned to view one of the two stimuli, with or without modified risk messaging, presented with one of the four mandated warnings.

The arms of this survey will be balanced on (1) the number of current regular SNUS users; (2) the number of former regular SNUS users; and (3) the number of current regular cigarette users.

A copy of the proposed screener, eligibility criteria, and quotas can be found in *Appendix A Table 1*.

¹³ The following sources will be used to develop all population counts: Census website (http://www.census.gov/); the March 2013 Annual Social and Economic Supplement to the Current Population Survey (CPS); and, the Tobacco Use Supplement to the Current Population Survey (from May 2010, August 2010, and January 2011).

F Statistical Plan

F1 Sample Size Determination and Power

The total sample size for this study will be approximately 15,000 consumers (i.e., tobacco users and non-users), with half of them seeing an advertisement with modified risk messaging and half of them seeing an advertisement without modified risk messaging. This sample size is driven by a desire to have a sufficiently large sample in each of the three tobacco user groups, i.e., current, former, and never regular tobacco users, and to allow for quota-sampling by combinations of demographic variables (e.g., age groups within the ethnicities and geographic regions).

This sample size is sufficient to allow the data to be weighted to population counts for all parameters of interest in each of the three tobacco user groups, as specified in Section E2, "Sampling Plan".

The following table provides anticipated confidence intervals for key consumer groups and sub-groups, based on standard errors from a previous study of ratings for Camel SNUS Frost Large:

Type of Respondent	Confidence Intervals on Predicted Purchase Rate
All respondents	0.8% - 1.9%
Current regular users	3.6% - 6.9%
Potential Quitters	2.5% - 5.3%
Former regular users	0.6% - 2.4%
Never regular users	0.2% - 0.6%
White males	1.0% - 2.2%

With 7,500 consumers per messaging arm, the study will have approximately 80% power to detect mean differences in predicted purchase rate of roughly 1% across the arms.

F2 Analysis Plan

A. Data Weighting

Data will be weighted to account for quota sampling (see quota groups, Appendix A Table 1). In preparation for weighting, population counts will be developed to estimate the number of individuals in each cell represented by the intersection of geographic region, tobacco use status, and age. The weighting process will then consist of:

- developing base weights by dividing the number of completed interviews in the cells that represent the intersection of geographical region, tobacco use status, and age by the population counts in those cells
- adjusting the base weights using *raking* to weight up to population counts in cells represented by the intersection of the following parameters:
 - tobacco status and gender
 - tobacco status and ethnicity
 - tobacco status and education
 - tobacco status and age
 - tobacco status and region
 - age and ethnicity

Raking¹⁴ helps to account for under-coverage and other sources of bias by adjusting the individual weights that result from the previously applied steps to independent estimates of population parameters from the Census Bureau's Population Estimates Program, the Annual Social and Economic Supplement to the Current Population Survey (CPS), and the Tobacco Use Supplement to the Current Population Survey.¹⁵

B. Analysis

The data will be properly weighted and will be submitted to the previously mentioned algorithm to project purchase estimates for Camel SNUS with and without modified risk messaging. An analysis of variance (ANOVA) will be conducted using message format (with versus without modified risk messaging) and tobacco user group (current, former, and never regular tobacco users) as factors. The same analyses will be conducted for white males only.

F3 Statistical Methods

Projected purchase rates will be used as dependent variables in traditional parametric analyses (i.e., ANOVA and t-tests) to test the hypothesis listed in *Section A3*. Because Research Now uses probability sampling when inviting panel members to be screened

¹⁴ Michael P. Battaglia, David Izrael, David C. Hoaglin, and Martin R. Frankel. (2009, June). *Practical Considerations in Raking Survey Data*. Survey Practice, Volume 2, No. 5.

¹⁵ Centers for Disease Control and Prevention. (2012). *Improving Survey Methodology*. Office of Surveillance, Epidemiology, and Laboratory Services, Behavioral Risk Factor Surveillance System. Retrieved from http://www.cdc.gov/surveillancepractice/documents/DBS BRFSS%20Improvements 12 232372 M REM 5 25 2012.pdf

for survey participation, it is appropriate to use inferential statistics, based on the understanding that assumptions must be made to extrapolate beyond the population of panel members.

G Data Handling and Record Keeping

G1 Confidentiality and Security

NAXION is an ISO 20252:2012 certified company. As such, we comply with documented procedures with regard to confidentiality and security.

Regarding confidentiality, **NA**XION will only entrust survey data with other entities when: 1) the participant gives explicit permission to release this data; 2) the data is shared with an entity who agrees in writing that the data will be held strictly confidential and that the data will be used for research purposes only; or, 3) the release of this data is required by law. This assurance is shown to survey participants before they provide any survey data. They may refuse to participate in the survey as a consequence if they wish.

Participants are also shown an active link to **NA**XION's privacy policy.

No respondent-identifiable information (e.g., name, date of birth, address, phone number, or social security number) will be available to **NA**XION; thus, respondents' identities will never be made known to RAIS.

Data is held securely and in compliance with client instructions and professional codes. Electronic documents are backed up from the network, and at least one copy of the network backups are stored offsite.

Additionally, we adhere to the following:

- all critical systems are backed up
- backups are periodically tested
- virus protection software is effective and current
- data on laptops are not shared across staff members
- memory sticks are encrypted and cleared between use by different staff members

Items above are audited by a third party on an annual basis.

G2 Training

NAXION employees are initially trained by being assigned to tasks that are reviewed by a more experienced employee. For example, a new employee may write a part of a survey which will be reviewed by another employee with sufficient experience to write the survey himself/herself. In the event that formal training is conducted, that training will be recorded by Human Resources on the personnel record. Employees keep a record of the in-house training sessions they have attended.

Otherwise, training needs are primarily identified via performance appraisals. These appraisals are completed by the staff member's supervisor. Training needs are clearly identified. Performance appraisals are conducted at least once per year for staff members below the Group Director level. During the first year of employment, there are also 3-month and 6-month performance evaluations.

G3 Records Retention

NAXION stores its documents in compliance with its clients' requirements. For RAIS, records are stored indefinitely.

Research records will be retained such that a project could be replicated in the future, as necessary, including primary records and supporting records (which include research process management system records). Records will be retained securely and in such a way that they are safe from damage. Electronic records will be backed up, and at least one copy will be stored offsite.

G4 Performance Monitoring

On an annual basis, the Research Process Management System (**NA**XION's internal performance monitoring system) is reviewed by the Quality Manager, COO, and CEO to determine:

- its business effectiveness
- compliance to processes within the company
- need for change or improvement
- that it continues to meet industry standards and legal and regulatory requirements

H Study Monitoring, Auditing, and Inspecting

H1 Study Monitoring Plan

Throughout field, **NA**XION will monitor the number of completed surveys in each quota cell/group daily via a proprietary online reporting system. Survey sampling adjustments can then be made on an ongoing basis to help achieve the desired number of completed surveys in each quota cell.

Experience with online tobacco research suggests that about 15% of those who are sent survey invitations will complete a study. **NA**XION will implement several procedures to maximize participation. We will keep the study questionnaire at a reasonable length to minimize break-offs. Additionally, the following procedures will be used to maximize cooperation and to achieve the desired response rates:

- Research Now will provide toll-free telephone numbers to all sampled individuals, and invite them to call with any questions or concerns about any aspect of the study. NAXION will provide a toll-free telephone number and e-mail address for a NAXION project member should participants have any questions about the study or their rights as a study participant.
- Research Now staff will work with the project staff of NAXION to address any
 problems that arise throughout the course of data collection.

Invited panel members who do not visit the site for screening will receive one e-mail reminder from Research Now requesting their participation in the survey. These "reminder" e-mails will be sent roughly one week after initial survey invitations.

H2 Auditing and Inspecting

As due diligence, NAXION conducted a pre-test with 18 respondents to confirm the clarity of the test materials and the survey length. During the pre-test, respondents were allowed to complete the survey without interruption in order to achieve an estimate on how long it takes to complete the survey, and then a qualified moderator conducted a short qualitative interview ("cognitive debrief") to expose each pretest respondent's thought process while answering questions and whether there were any areas/questions that were unclear or confusing. Respondents represented a mix of the demographic categories being used for quota-sampling purposes. Respondents participating in the pre-test indicated that all questions were clear and that there were no areas of confusion in the survey; therefore, no edits were made to the survey based on the pre-test. Finally, NAXION project managers and other NAXION employees thoroughly tested the programmed questionnaire, along with any algorithms for

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sampling before launching the survey via the Internet. **NA**XION will also have live online reports that show the number of completed surveys throughout field. Reports will run every hour, and will detail completed surveys by tobacco user group and demographic characteristics. These reports allow **NA**XION project managers to ensure that the sampling algorithm is operating as planned throughout the fielding process, and that the desired tobacco-user group and demographics are attained.

I Study Administration

11 Organization and Participating Centers

NAXION will manage the information collection on behalf of RAIS, process the data, and perform all statistical analyses. Michael Polster, Ph.D. is the project director at **NA**XION, with overall responsibility for coordinating study activities. He will be working under the leadership of the firm's CEO. **NA**XION will subcontract to Research Now to collect the survey data.

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12 Subject Stipends or Payments

Research Now panel members earn currency or points for their time participating in surveys. Incentives are based on estimates of the time and effort required to complete a survey. Members can redeem their currency/points for rewards that are of interest to them. Providing every panel member with an incentive for each interaction helps maximize panel retention and survey response rates.

13 Study Timetable

We estimate that this study will require approximately eleven weeks to complete, according to the following timeline:

PROPOSED TIMETABLE

J Publication Plan

Data will be made available as part of the MRTP application process to FDA.

Appendix A: Camel SNUS MRTP Likelihood of Use Survey

Research conducted on behalf of RAIS in anticipation of potential FDA requirements. Research shall only be used and/or disseminated for compliance-related activities.

Camel SNUS Likelihood of Use Survey

- Screener -

Thank you for visiting our survey site to answer a few qualifying questions. This survey is strictly for research purposes only.

It is NAXION's policy to keep interviews anonymous and responses confidential. Consistent with this policy, NAXION will only entrust survey data with other entities when: 1) the participant gives explicit permission to release this data; 2) the data is shared with an entity who agrees in writing that the data will be held strictly confidential and that the data will be used for research purposes only; or, 3) the release of this data is required by law.

You will <u>not</u> be contacted for sales purposes as a result of participating in this survey.

For further information on NAXION's privacy policy, you can view our website at www.naxionthinking.com/privacy-policy-domestic-and-global-information. To view our respondent incentive statement, visit www.naxionthinking.com/incentivestatement.

All questions on each screen must be answered before you move to the next screen, so please be sure you have answered every question before trying to move forward. On the next few screens you will be asked a few questions to see if you qualify for this study. If you qualify, the survey itself should take 10 minutes to complete.

PROGRAMMER:

- 1) INSERT STANDARD INSTRUCTION SCREEN
 FIELD OPS: RECRUIT RESPONDENTS FROM ONLY "TRADITIONAL" RESEARCH NOW PANEL
 DO NOT ALLOW SURVEY TO BE TAKEN VIA iPHONE/BLACKBERRY, etc.
 HAVE RECRUITERS DRAW SAMPLE...
 - 1) ACCORDING TO MINIMUM PURCHASE AGE IN STATE (SEE S7 INSTRUCTIONS)
 - 2) ACCORDING TO QUOTA
 - 3) NOTE THAT NO STATES ARE EXCLUDED

S2.	What is y	our current age?
		Years
PRO	GRAMMER:	

- 1. RANGE IS 10-99
 - 2. IF < 18 OR IF > 75, TERMINATE NOW
- S7. In what state do you currently reside?

[SHOW POP UP LIST OF STATES]

PROGRAMMER:

- 1. IF STATE IS ALABAMA, ALASKA, NEW JERSEY OR UTAH AND S2= 18, TERMINATE NOW
 - (minimum age for tobacco purchase in these states is 19)
- 2. NOTE THAT RESPONDENTS IN ALL 50 US STATES AND DISTRICT OF COLUMBIA ARE ELIGIBLE TO PARTICIPATE IN THIS STUDY

In this survey we are interested in the opinions of people who have been, or are, regular users of certain products, as well as people who have never used them.

S1a. Would you consider yourself to be – or to have been at any time in the past – a "regular user" of any of the following products? We leave it to you to define regular use.

Select "yes" or "no" in each row.

	Yes I am – or was – a regular user	No, I have never been a regular user
Beer or malt-based beverages?	0	0
Bottled water (still or carbonated)?	0	0
Nutritional supplements/vitamins?	0	0
Tobacco products?	0	0

PROGRAMMER:

1) DISPLAY ROWS IN RANDOM ORDER

S1b. Focusing only on the present, how would you <u>currently</u> describe yourself, relative to each of the following categories?

Select one response in each row.

	Current Non-user	Current Occasional User	Current Regular User
Beer or malt-based beverages?	0	0	0
Bottled water (still or carbonated)?	0	0	0
Nutritional supplements/vitamins?	0	, О	0
Tobacco products?	0	0	0

PROGRAMMER:

1) DISPLAY ONLY ROWS ANSWERED AS "Yes" IN S1a, IN SAME ORDER AS IN S1a

CLASSIFY AS:

A) Current Regular User: S1b "Tobacco product" IS "Occasional" or "Regular" (col 2 or 3)

B) Former Regular User: S1b "Tobacco product" IS "Non-user" AND S1a "Tobacco product"

IS "Yes"

C) Never Regular User: S1a "Tobacco product" IS "No"

CO	\A/la at 1 a	~~~d~~?
S3.	What is your	genderr

Male	0
Female	0

S4. What is the highest grade you have completed in school? (Select one)

High school or less	0
Some college or technical/vocational training	0
Four years of college (Bachelor's degree)	0
More than Bachelor's degree	0

S5a. Do you consider yourself to be of Hispanic, Latino, or Spanish origin?

Yes	0
No	0

S5b. What do you consider to be your race? (Select all that apply)

White	
African American / Black	
Asian	
Other	

PROGRAMMER:

1. DISPLAY S5a AND S5b ON SAME SCREEN

S6. Which of the following best describes your total <u>household</u> income?

Under \$25,000	0
\$25,000 to \$49,999	0
\$50,000 to \$74,999	0
\$75,000 to \$99,999	0
\$100,000 or more	0

S8. Earlier you indicated that you [currently use tobacco products./have used tobacco products on a "regular basis" in the past, but that you no longer do.] [Please indicate your usage, if any, of each of the following types of tobacco products./Which of the following types of tobacco products did you use regularly?] (Select [one response in each row/all that apply])

		Use	Used in	Never	Used in
		Currently	the Past	Used	the Past
1	Cigarettes	О	О	О	
2	Roll-your-own Cigarettes	О	О	О	
3	E-cigarettes	О	О	О	
4	Tobacco Heating Cigarettes	О	О	О	
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	О	О	О	
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	О	О	О	
7	Traditional Cigars	О	О	О	
8	Pipe Tobacco	О	0	О	
9	Hookah (WHO-kah)	О	0	О	
10	Smokeless Tobacco, like dip, chew, or snuff	О	О	О	
11	SNUS (SNOOS) Pouches	О	О	О	
12	Dissolvable tobacco	0	О	О	
13	Other tobacco product	О	0	О	

PROGRAMMER:

- 1. ASK IF CLASSIFIED AS "CURRENT" OR "FORMER" TOBACCO USER
- 2. IF S1b "Tobacco product" IS "Occasional" OR "Regular," USE FIRST TEXT IN BRACKETS, ELSE USE $2^{\rm ND}$ TEXT
- 3. SHOW FORMER TOBACCO USERS COLUMN 4 ONLY

S9. Which of the following brands of SNUS do you currently use? Select "yes" or "no" in each row.

	Yes	No
Camel	0	0
Copenhagen	0	0
General	0	О
General Swedish Variety	O	O
Grand Prix	0	0
Klondike	0	0
Marlboro	0	0
Nordic Ice	0	0
Skoal	0	0
Tourney	0	0
Triumph	0	О
Some other brand of SNUS	0	О

PROGRAMMER:

- 1. ASK IF S8 ROW 11 COLUMN 1 IS SELECTED
- 2. MUST SAY "YES" TO AT LEAST 1 ROW
- 3. TERMINATE IF ROW 1 IS "YES"

ARM ASSIGNMENT: CHECK QUOTAS TO SEE IF ELIGBILE FOR EACH SURVEY ARM THERE ARE 8 ARMS IN THIS STUDY:

- Arm 1: Control Warning #1
- Arm 2: Control Warning #2
- Arm 3: Control Warning #3
- Arm 4: Control Warning #4
- Arm 5: Test Warning #1
- Arm 6: Test Warning #2
- Arm 7: Test Warning #3
- Arm 8: Test Warning #4

IF ELIGIBLE FOR MORE THAN ONE ARM, ASSIGN WHERE NEEDED THE MOST TO BALANCE:

- 1. SMOKING STATUS (CURRENT, FORMER, NEVER)
- 2. CURRENT CIGARETTE USER (S8 ROW 1 IS "USE CURRENTLY")
- 3. CURRENT SNUS USER (S8 ROW 11 IS "USE CURRENTLY")
- 4. FORMER SNUS USER (S8 ROW 11 IS "USED IN PAST")
- 5. DEMOGRAPHICS

You have qualified for our survey, and we'd like to invite you to participate. The survey will require ten minutes to complete, and we ask for your undivided attention once you begin it. If you do not have ten minutes right now, please click "Stop," and return any time during the next 24 hours when you have an uninterrupted ten minutes.

Camel SNUS MRTP Likelihood of Use Survey

- Survey -

1. Now, please think ahead to nine months from now. Based on your experience, product preferences, and personal goals, do you expect that you will be using the following types of products nine months from now?

Select "yes" or "no" in each row.

	Yes	No
Cigarette	0	0
Cigar/cigarillos	0	0
Pipe	0	0
Chewing tobacco	0	0
Snuff	0	0
SNUS	0	0
Any other type of tobacco	0	0

PROGRAMMER:

- 1. ASK ALL
- 2. DEFINE AS "CURRENT REGULAR USER INTENDING TO QUIT" IF CURRENT REGULAR USER AND ALL ROWS ARE "NO"

This survey focuses on new information about an existing tobacco product. <u>Everyone</u> is asked <u>all</u> of the questions in this survey, regardless of the products they currently use or their expectations regarding future tobacco use.

Please take your time and review the information on the next few screens closely so that you will be able to answer the questions that follow.

[INSERT CAMEL SNUS MRTP STIMULI]

2a. Assuming the product were available today, how likely would you be to purchase Camel SNUS in order to try it?

Select one.

	itely Wo	ould <u>No</u> to Try)	<u>t</u>		Definitely Wo Purchase It (to T				
1	2	3	4	5	6	7	8	9	10
0	0	0	0	0	0	0	0	0	0

PROGRAMMER:

1) ASK ALL

2b. You indicated that you have some interest in purchasing Camel SNUS in order to try it. How would you envision using Camel SNUS?

Select one.

I would use Camel SNUS <u>instead of</u> my current tobacco product(s) (would stop using my current tobacco product completely)	0
I would use Camel SNUS <u>in addition to</u> my current tobacco product(s) (leading to an overall increase in tobacco use)	0
I would use Camel SNUS <u>in place of some</u> of my current tobacco product(s) (leading to <u>no</u> net increase in tobacco use)	0
Don't know	0

PROGRAMMER:

- 1. ASK IF CURRENT REGULAR USER AND Q2a RATING IS ≥ 2
- 2. SKIP IF CURRENT REGULAR USER INTENDING TO QUIT

2c. How likely would you be to switch back to your current (existing) tobacco product after you try Camel SNUS?

Select one.

Switch	t All Lik h Back t cco Proc	o my C	urrent				Back	kely to to my C cco Pro	Current
1	2	3	4	5	6	7	8	9	10
0	0	0	0	0	0	0	0	0	0

PROGRAMMER:

1. ASK IF Q2b ROW 1 IS SELECTED

2d. You indicated that you have some interest in purchasing Camel SNUS in order to try it. If you were to try Camel SNUS, how likely would you be to switch to a different tobacco product [that presents more risk, such as cigarettes,] after you try Camel SNUS?

Select one.

Not At All Likely to Very Likely to Switch to a Different Tobacco Switch to a Different Tobacco Product(s) [that Presents More Product(s) [that Presents More Risk] Risk] 2 3 4 5 6 7 8 10 1 0 0 0 0 0 0 0 0

PROGRAMMER:

- 1. ASK IF FORMER REGULAR OR NEVER REGULAR USER AND Q2a RATING IS ≥ 2
- 2. SHOW REPLACEMENT TEXT IN THE QUESTION TEXT AND GRID IF ARM 5, 6, 7, OR 8 (TEST)

2e. You indicated that you plan to quit using tobacco, but that you have at least <u>some</u> interest in purchasing Camel SNUS in order to try it (that is, you did not rate your intention to try Camel SNUS a "1" in the previous question).

Which one of the following reasons best explains why you have some interest in trying Camel SNUS?

Select one.

To help me quit	0
It will allow me to use tobacco in situations where I cannot use my current product	0
I'm just curious about it	0
Don't know	0

PROGRAMMER:

1. ASK IF CURRENT REGULAR USER INTENDING TO QUIT AND Q2a RATING IS ≥ 2

3a1. Have you ever used any of the following tobacco products, even one or two times?

(Select "yes" or "no" in each row)

		Yes	No
1	Cigarettes	О	О
2	Roll-your-own Cigarettes	О	О
3	E-cigarettes	О	О
4	Tobacco Heating Cigarettes	О	О
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	О	О
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	О	О
7	Traditional Cigars	О	О
8	Pipe Tobacco	О	О
9	Hookah (WHO-kah)	О	О
10	Smokeless Tobacco, like dip, chew, or snuff	О	О
11	SNUS (SNOOS) Pouches	О	О
12	Dissolvable tobacco	О	О
13	Other tobacco product	О	О

PROGRAMMER:

1) ASK ALL

3a2. Have you ever used any of the following tobacco product(s) fairly regularly? (Select "yes" or "no" in each row)

		Yes	No
1	Cigarettes	О	O
2	Roll-your-own Cigarettes	О	О
3	E-cigarettes	О	О
4	Tobacco Heating Cigarettes	О	О
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	О	О
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	О	0
7	Traditional Cigars	О	0
8	Pipe Tobacco	О	О
9	Hookah (WHO-kah)	0	0
10	Smokeless Tobacco, like dip, chew, or snuff	0	0
11	SNUS (SNOOS) Pouches	О	О
12	Dissolvable tobacco	0	0
13	Other tobacco product	О	О

PROGRAMMER:

- 1) ASK IF ANY ROW IN 3a1 IS "YES"
- 2) ONLY SHOW ROWS THAT ARE "YES" IN 3a1

3b. How many cigarettes have you smoked in your entire life? A pack usually has 20 cigarettes in it. *Select one.*

1	1 or more puffs but never a whole cigarette	0
2	1 to 10 cigarettes (about ½ pack total)	0
3	11 to 20 cigarettes (about ½ pack to 1 pack)	0
4	21 to 50 cigarettes (more than 1 pack but less than 3 packs)	0
5	51 to 99 cigarettes (more than 2 ½ packs but less than 5 packs)	0
6	100 or more cigarettes (5 packs or more)	0

PROGRAMMER:

1) ASK IF 3a1 ROW 1 = "YES"

3c. Please indicate how often you currently use each of the following types of tobacco. Select one response in each row.

		Every Day	Some Days	Not at All
1	Cigarettes	0	0	0
2	Roll-your-own Cigarettes	0	0	0
3	E-cigarettes	0	0	0
4	Tobacco Heating Cigarettes	0	0	0
5	Cigarillos (si-geh-RI-lohs) and Filtered Cigars	0	0	0
6	Bidis (BEE-dees) or Kreteks (KREH-techs)	0	0	0
7	Traditional Cigars	0	0	0
8	Pipe Tobacco	0	0	0
9	Hookah (WHO-kah)	0	0	0
10	Smokeless Tobacco, like dip, chew, or snuff	0	0	0
11	SNUS (SNOOS) Pouches	0	0	0
12	Dissolvable tobacco	0	0	0
13	Other tobacco product	0	0	0

PROGRAMMER:

- 1) ASK IF ANY ROW IS "YES" IN 3A1
- 2) SHOW ROWS THAT ARE "YES" IN 3A1

PROGRAMMER TO CLASSIFY RESPONDENTS AS FOLLOWS:

DEFINE AS NEVER USER IF:

- 3a1 is "NO" FOR ALL ROWS

IF DO NOT QUALIFY AS NEVER USER, DEFINE AS CURRENT CIGARETTE USER IF:

- 3a1 ROW 1 (Cigarettes) IS "Yes" AND
- 3b IS ROW 6 (100+ Cigarettes) AND
- 3c ROW 1 (Cigarettes) IS "EVERY DAY" OR "SOME DAYS"

IF DO NOT QUALIFY AS NEVER OR CURRENT CIGARETTE USER, DEFINE AS <u>CURRENT TOBACCO USER (NON-CIGARETTE)</u> IF:

- 3a1 ROW 2 IS "YES" AND
- 3a2 ROW 2 IS "YES" AND
- 3c ROW 2 IS "EVERY DAY" OR "SOME DAYS"
- CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS <u>CIGARETTE EXPERIMENTER</u> IF:

- 3a1 ROW 1 IS "YES" AND
- 3b IS <u>NOT</u> ROW 6 (100+ CIGARETTES) <u>AND</u>
- 3c ROW 1 IS "EVERY DAY" OR "SOME DAYS"

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS <u>NON-CIGARETTE EXPERIMENTER</u> IF:

- 3a1 ROW 2 IS "YES" AND
- 3a2 ROW 2 IS "NO" AND
- 3c ROW 2 IS "EVERY DAY" OR "SOME DAYS"
- CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS FORMER CIGARETTE USER IF:

- 3a1 ROW 1 IS "YES" AND
- 3b IS ROW 6 (100+ Cigarettes) AND
- 3c ROW 1 IS "NOT AT ALL"

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS <u>FORMER TOBACCO USER (NON-</u>CIGARETTE) IF:

- 3a1 ROW 2 IS "YES" AND
- 3a2 ROW 2 IS "YES" AND
- 3c ROW 2 IS "NOT AT ALL"
- CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS <u>FORMER CIGARETTE</u> EXPERIMENTER IF:

- 3a1 ROW 1 IS "YES" AND
- 3b IS NOT ROW 6 (100+ CIGARETTES) AND
- 3c ROW 1 "NOT AT ALL"

IF DO NOT QUALIFY FOR ANY OF THE ABOVE, DEFINE AS <u>FORMER NON-CIGARETTE</u> <u>EXPERIMENTER</u> IF:

- 3a1 ROW 2 IS "YES" AND
- 3a2 ROW 2 IS "NO" AND
- 3c ROW 2 IS "NOT AT ALL"
- CYCLE THROUGH THIS LOGIC FOR ALL ROWS 2 THROUGH 13 TO SEE IF AT LEAST ONE ROW/PRODUCT QUALIFIES

ANALYSES GROUPS:

- 1) CURRENT USERS =
 - a. CURRENT CIGARETTE USERS
 - b. CURRENT TOBACCO USERS (NON-CIGARETTE)
- 2) FORMER USERS =
 - a. FORMER CIGARETTE USERS
 - b. FORMER TOBACCO USERS (NON-CIGARETTE)
 - c. FORMER CIGARETTE EXPERIMENTERS
 - d. FORMER NON-CIGARETTE EXPERIMENTERS
- 3) NEVER USERS
- 4) EXPERIMENTERS =
 - a. CIGARETTE EXPERIMENTERS
 - **b. NON-CIGARETTE EXPERIMENTERS**

For this next series of questions, we are interested in your anticipated behavior <u>if no new tobacco products are introduced to the market.</u>

4a. During the past 12 months, have you stopped using tobacco for one day or longer because you were trying to quit using tobacco? *Select one*.

Yes	0
No	0

PROGRAMMER:

- 1) ASK IF "CURRENT REGULAR USER" (BASED ON S1 SERIES) OR "CURRENT USER" (NEW DEFINITION BASED Q3 SERIES)
- 4b. How much do you want to quit using tobacco? Select one.

Not at all	О
A little	О
Somewhat	О
A lot	О
No opinion	О

PROGRAMMER:

1) ASK IF "CURRENT REGULAR USER" (BASED ON S1 SERIES) OR "CURRENT USER" (NEW DEFINITION BASED Q3 SERIES)

4c. How likely do you think it is that you will try to quit using tobacco within the next 30 days?

Select one.

Very unlikely	О
Somewhat unlikely	О
Somewhat likely	О
Very likely	О
No opinion	О

PROGRAMMER:

- 1) ASK IF "CURRENT REGULAR USER" (BASED ON S1 SERIES) OR "CURRENT USER" (NEW DEFINITION BASED Q3 SERIES)
- 4d. If you did try to quit using tobacco within the next 30 days, how likely do you think it is that you would succeed in quitting? *Select one*.

Very unlikely	0
Somewhat unlikely	0
Somewhat likely	0
Very likely	0
No opinion	О

PROGRAMMER:

- 1) ASK IF "CURRENT REGULAR USER" (BASED ON S1 SERIES) OR "CURRENT USER" (NEW DEFINITION BASED Q3 SERIES)
- **CLASSIFY RESPONDENT AS POTENTIAL QUITTER IF:**
 - 4a = YES AND
 - 4b = SOMEWHAT OR A LOT AND
 - 4c = SOMEWHAT OR VERY LIKELY AND
 - 4d = SOMEWHAT *OR* VERY LIKELY

5. How long has it been since you quit using tobacco? *Select one.*

Less than 6 months	О
6 months or longer	О

PROGRAMMER:

1) ASK FORMER REGULAR USER (BASED ON S1 SERIES) OR FORMER USER (NEW DEFINITION BASED Q3 SERIES)

6a. Do you think you will smoke a cigarette in the next year? Select one.

1	Definitely yes	О
2	Probably yes	О
3	Probably no	О
4	Definitely no	О
5	Don't know	О

6b. If one of your best friends were to offer you a cigarette, would you smoke it? *Select one.*

1	Definitely yes	О
2	Probably yes	О
3	Probably no	О
4	Definitely no	О
5	Don't know	0 -

PROGRAMMER:

- 1) ASK Q6A AND Q6B IF NEVER REGULAR USER (BASED ON S1 SERIES) OR NEVER USER (NEW DEFINITION BASED Q3 SERIES)
- 2) ROTATE ROW ORDER (BUT ALWAYS KEEP ROW 5 LAST) SO THAT HALF OF RESPONDENTS SEE ROWS 1, 2, 3, 4, 5 AND HALF SEE 4, 3, 2, 1, 5 (ROW ORDER SHOULD BE THE SAME IN BOTH GRIDS)

Please note that the goal of this survey is only to examine likelihood of use for tobacco products in the presence and absence of modified risk messaging among current tobacco users and non-users. It is **not** intended to encourage you or anyone else to continue or start using tobacco products.

- Individuals should consider the conclusions of the U.S. Surgeon General, as well as information from the Centers for Disease Control and Prevention, and other public health and medical officials when making decisions regarding the use of tobacco.
- The best course of action for tobacco users concerned about their health is to quit.
- Minors should never use tobacco products, and adults who do not use or have quit using tobacco products should not start.
- Adults who smoke should avoid exposing minors to secondhand smoke; and, adult smokers should comply with rules and regulations designed to respect the rights of other adults.

PROGRAMMER:

1. SHOW ALL

All information contained in this advertising is provided for your information only and for regulatory research purposes only. [In order to advertise that a smokeless tobacco product is less harmful than a cigarette or another smokeless tobacco product, the company must first obtain clearance from the U.S. Food and Drug Administration ("FDA"). As part of that clearance process, a company must present evidence on the potential for modified risk messaging to affect likelihood of product use among current tobacco users and non-users.] The advertisements used in this research study[, those that include modified risk messaging for Camel SNUS,] have not and will not be used by the company to promote its products commercially without first obtaining clearance from FDA to do so.

The information and opinions expressed here are believed to be accurate, based on sound science and the best judgment available to the company. However, no action or inaction should be taken based on the contents of this information; instead, you should consult appropriate health professionals on any matter relating to your health.

THANK YOU SCREEN

PROGRAMMER: SHOW ALL

SHOW REPLACEMENT TEXT TO ARMS 5, 6, 7, AND 8 ONLY

Table 1 (n=15,000): Quotas per Arm (8 arms)

	Current Tobacco User	Former Tobacco User	Never-Tobacco User
	625	625	625
Northeast	88 – 125	88 – 125	88 – 125
Midwest	113 – 163	113 – 163	113 – 163
South	188 – 250	188 – 250	188 – 250
West	113 – 163	113 – 163	113 – 163
18-30	163 – 200	75 – 100	163 – 200
31-50	238 – 275	200 – 238	238 – 275
51-75	163 – 200	288 – 325	163 – 200
Male	282 – 344	282 – 344	282 – 344
Female	282 – 344	282 – 344	282 – 344
Hispanic	82 – 107	82 – 107	82 – 107
Non-Hispanic - White	375 – 438	375 – 438	375 – 438
Non-Hispanic - Black	63 – 88	63 – 88	63 – 88
Non-Hispanic - Asian/Other	44 – 63	44 – 63	44 – 63
Up to High School	300 – 338	213 – 250	200 - 238
Some College	163 – 200	163 – 200	150 – 188
Bachelor's Plus	100 – 138	188 – 225	213 – 250

Northeast
Connecticut
Maine
Massachusetts
New Hampshire
Rhode Island
New Jersey
New York
Pennsylvania
Vermont

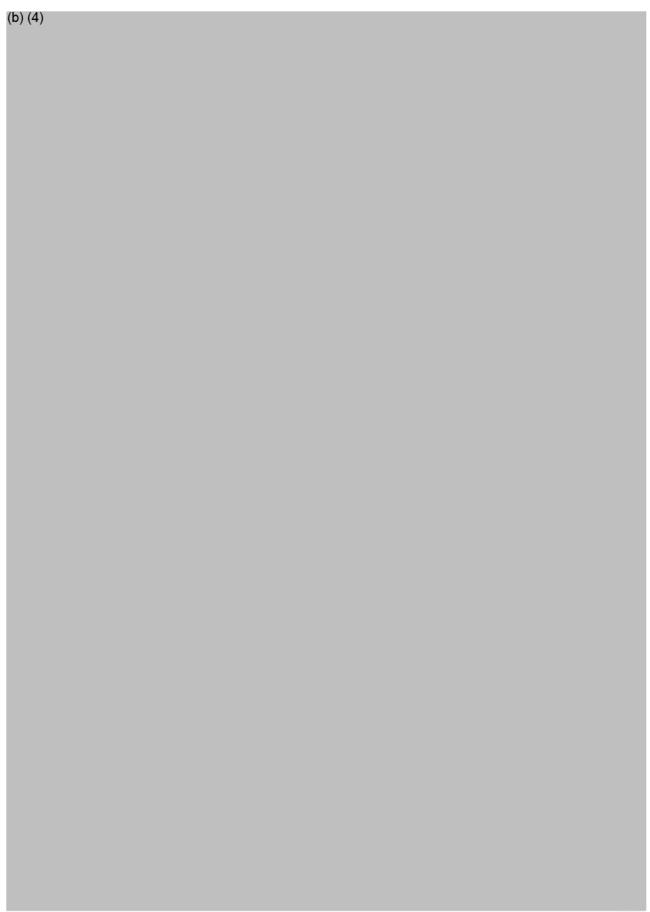
Midwest
Indiana
Illinois
Iowa
Kansas
Michigan
Minnesota
Missouri
Nebraska
North Dakota
Ohio
South Dakota

Wisconsin

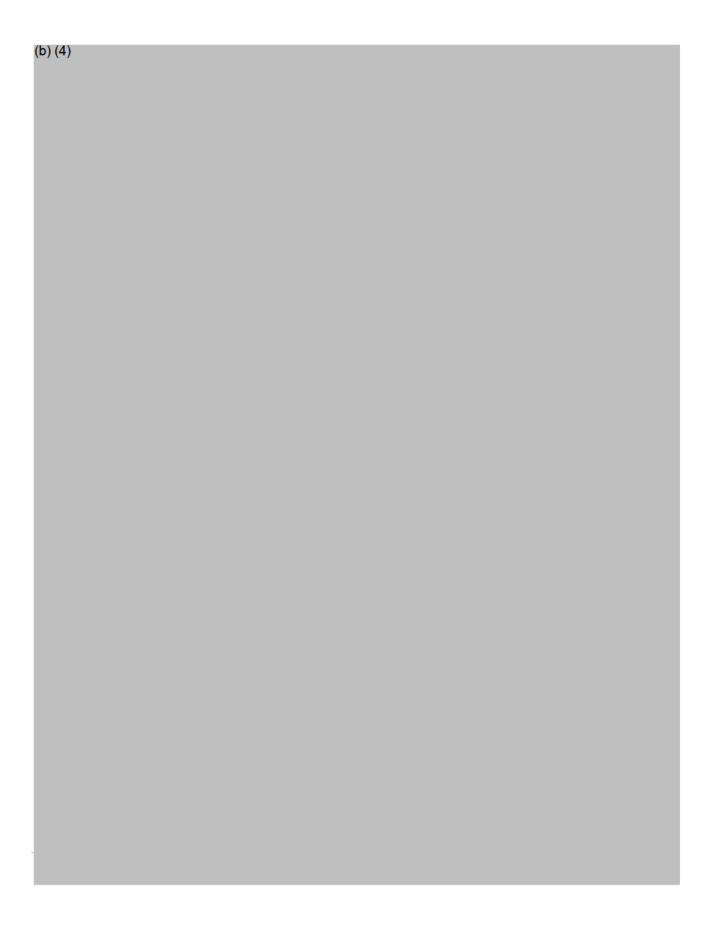
South Alabama Arkansas Delaware District of Columbia Florida Georgia Kentucky Louisiana Maryland Mississippi North Carolina Oklahoma South Carolina Tennessee Texas Virginia West Virginia

West
Alaska
Arizona
California
Colorado
Hawaii
Idaho
Montana
Nevada
New Mexico
Oregon
Utah
Washington
Wyoming

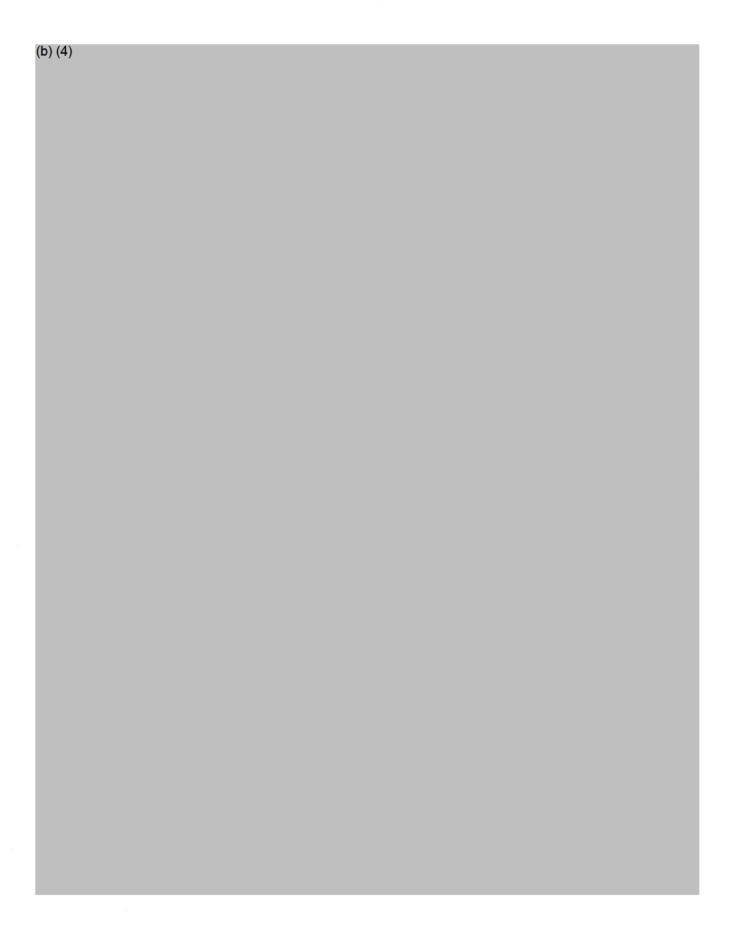
/ L \ / / \	Appendix B: Camel SNUS MRTP Likelihood of Use Stimuli
(b) (4)	



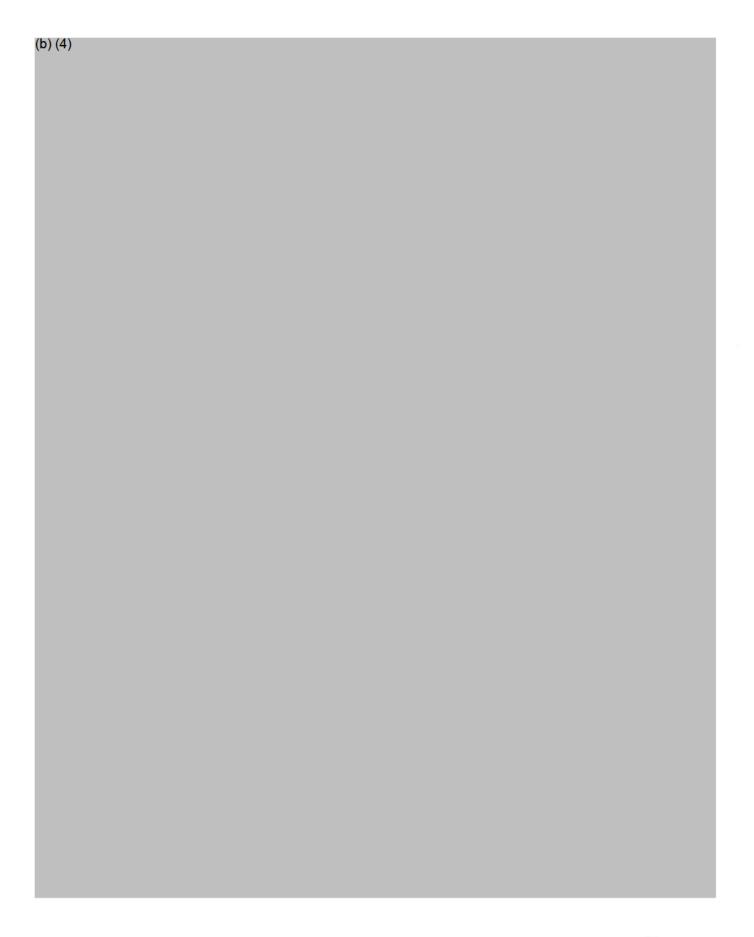
(b) (4)		



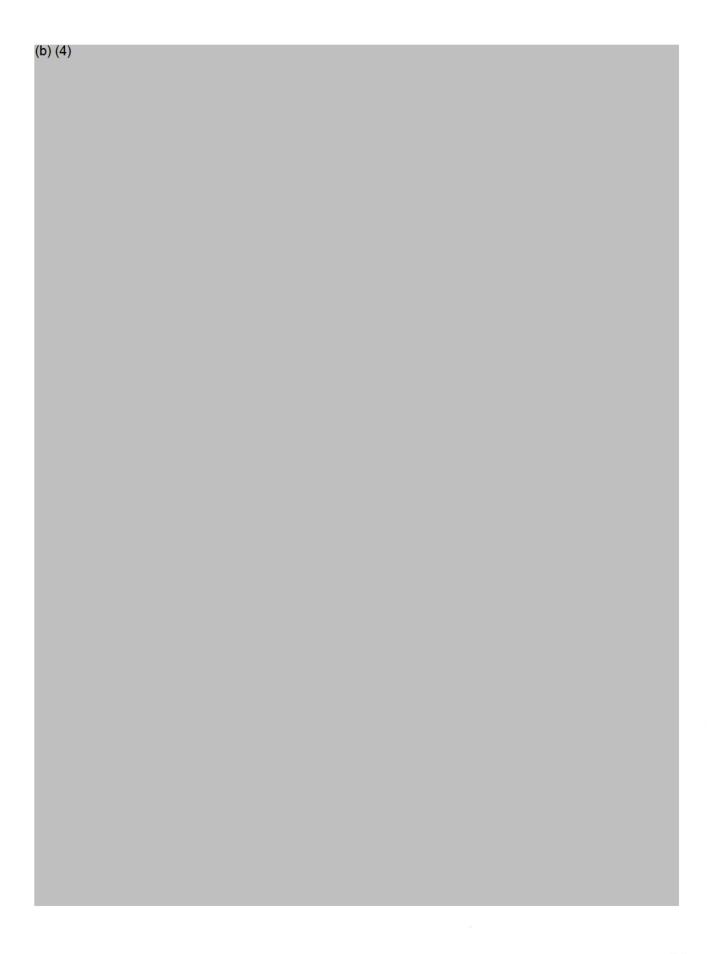
(b) (4)		

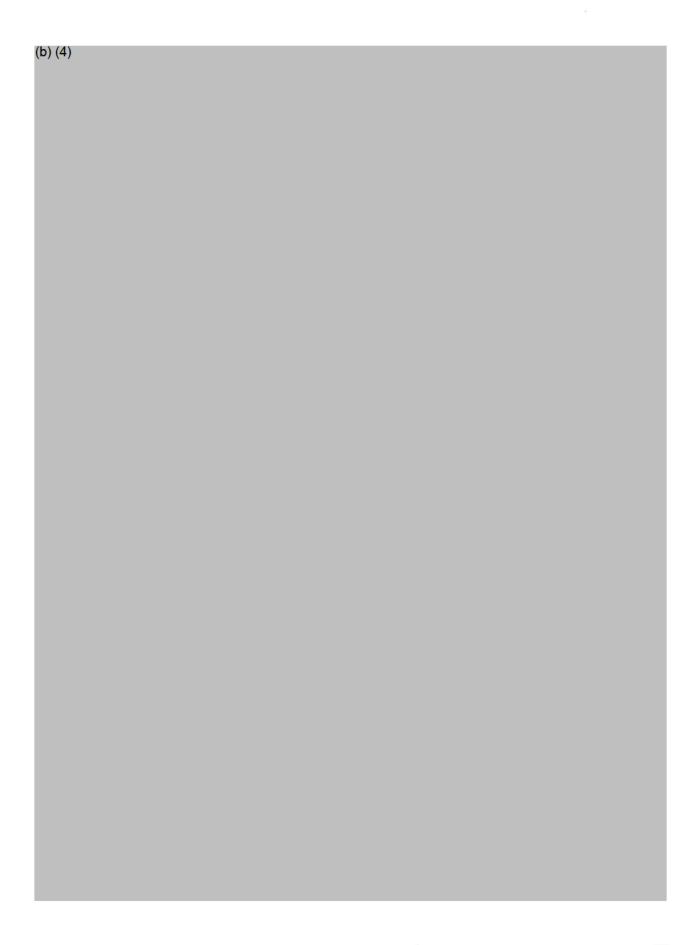


(b) (4)		



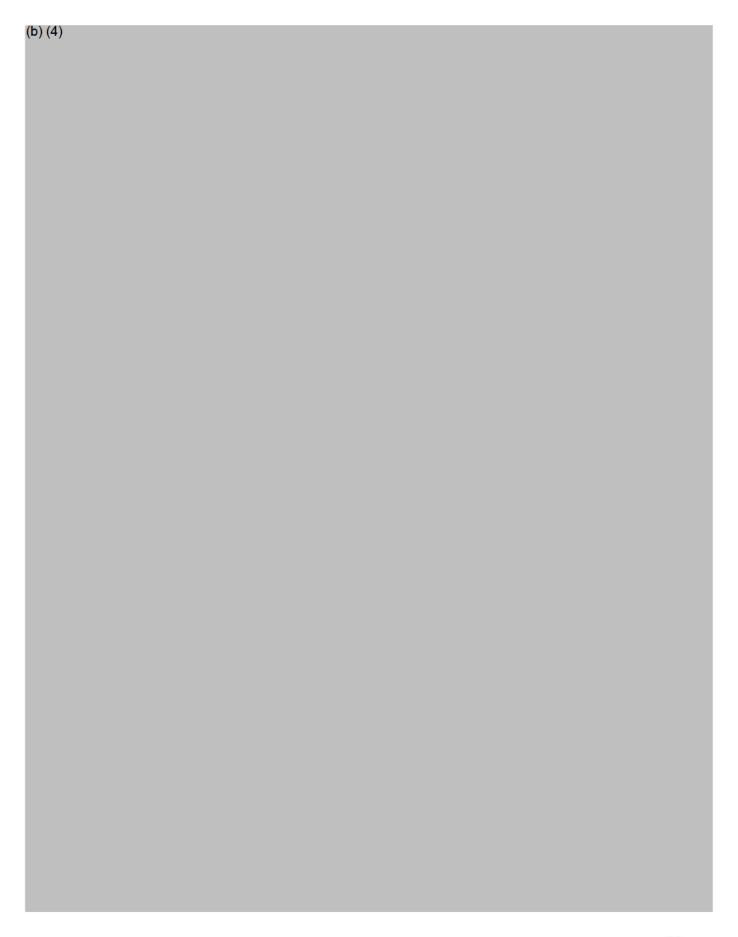
(b) (4)		

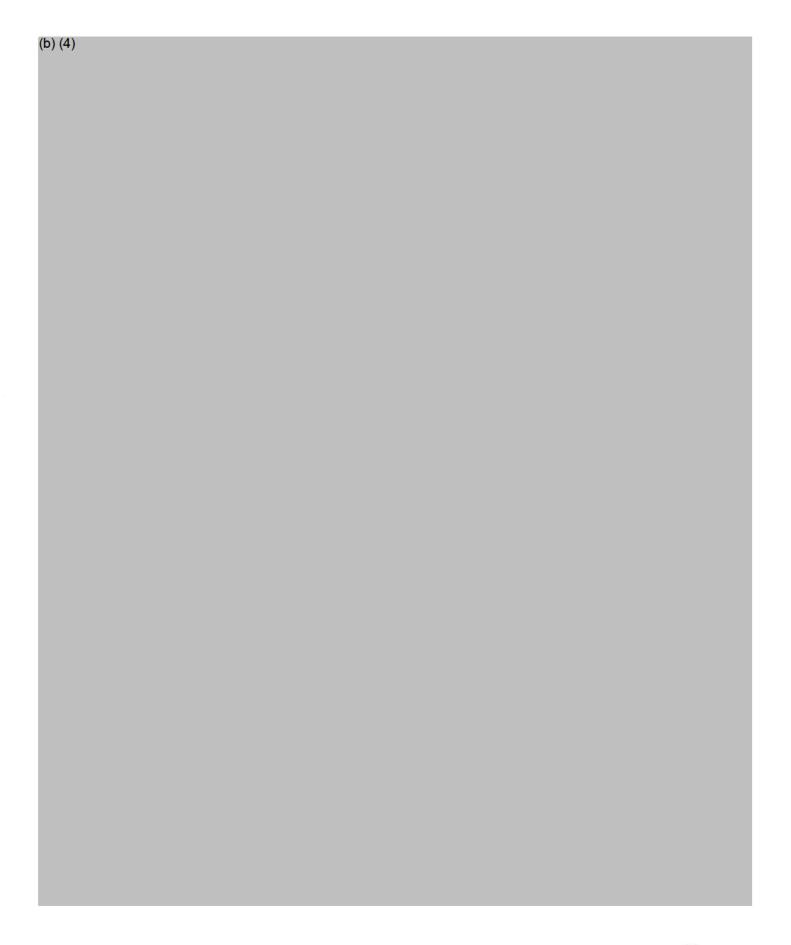


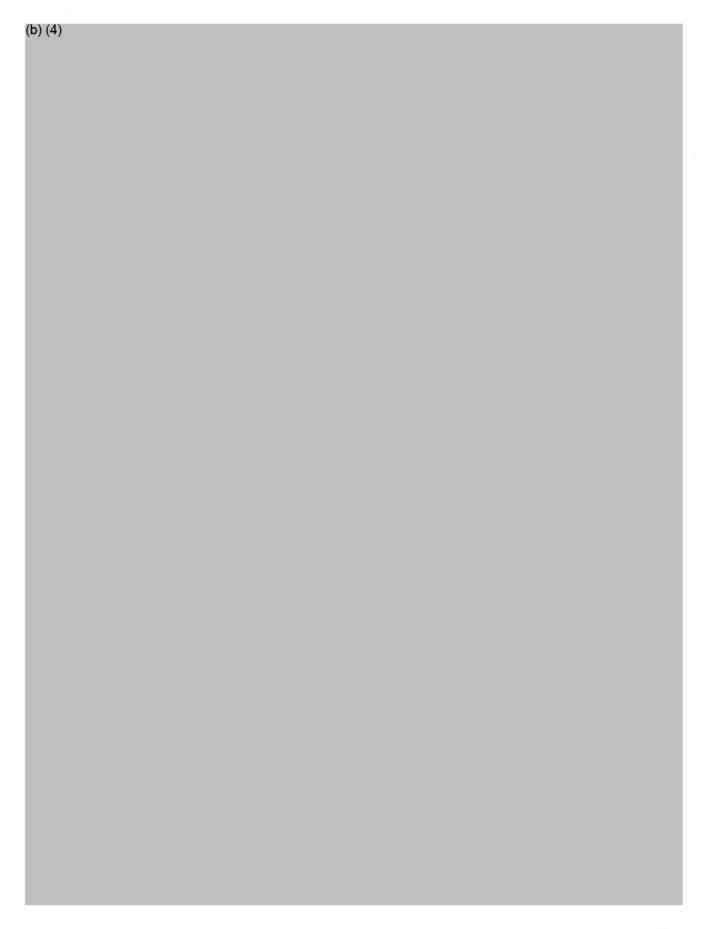


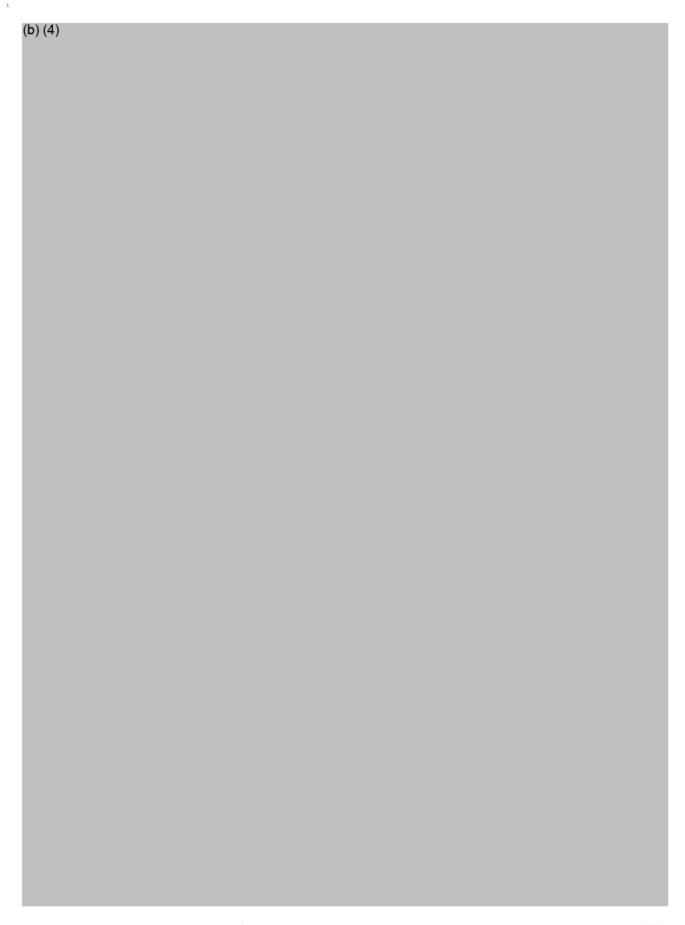
(b) (4)	

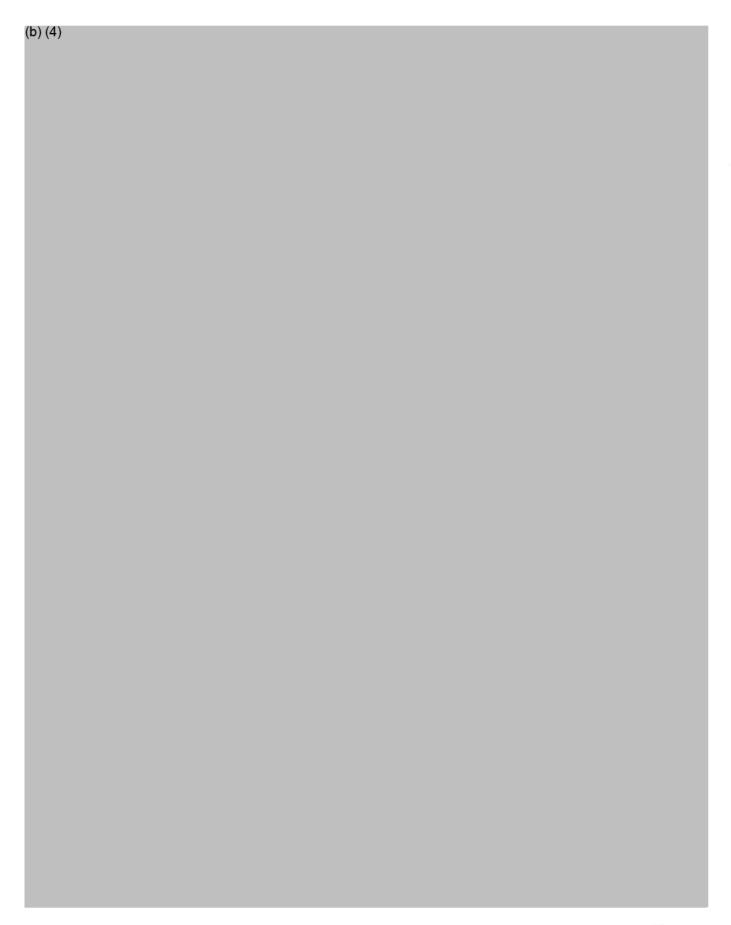
(b) (4)		

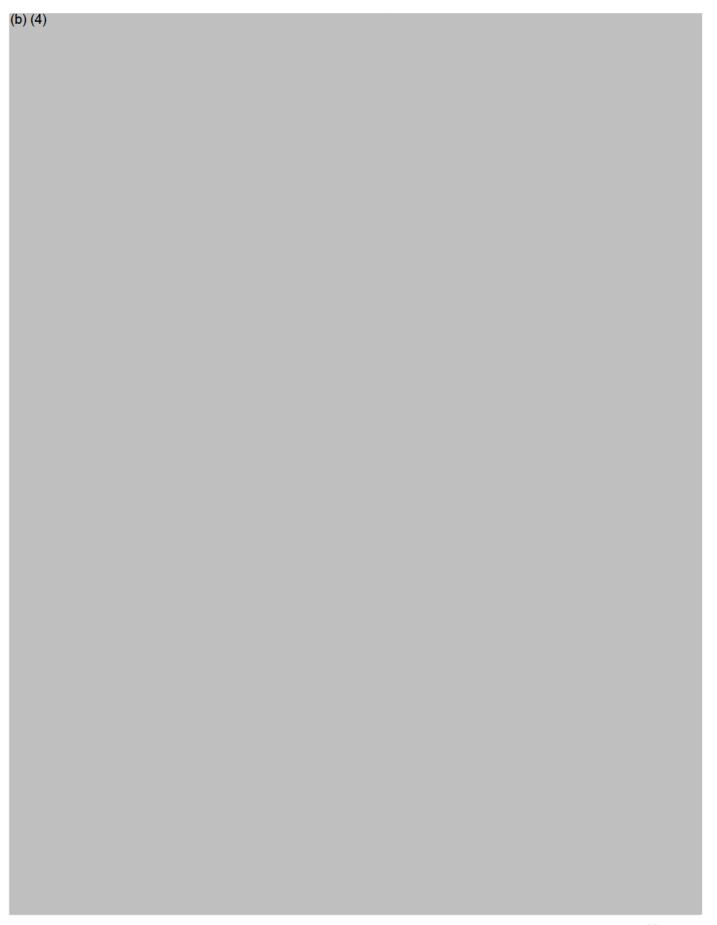








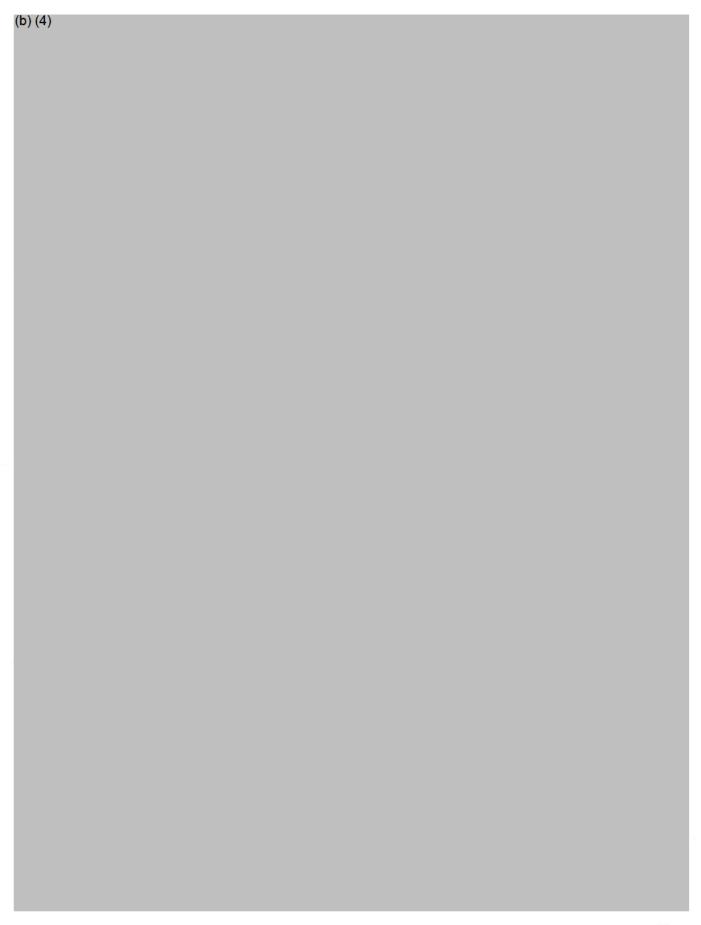




(b) (4)	

(b) (4)	

(b) (4)		



(b) (4)	

Attachment I: New Tobacco Product "Attractiveness" Study:

An Algorithm to Predict Usage of New Tobacco Products Prior to Market Launch

Methodological Report

January 29, 2013

Prepared for: RAI Services Company

Prepared By:

NAXION

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Research conducted on behalf of RAIS's Regulatory Oversight Department in anticipation of potential FDA requirements. Research shall only be used and/or disseminated for compliance-related activities.

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1. STUDY BACKGROUND AND OBJECTIVES

1.1 Study Background

Under its new mandate to regulate the impact of tobacco on public health, the FDA requires manufacturers of tobacco products to demonstrate, prior to the launch of any new tobacco product, that the market entry of the new product will not increase "net harm" to the population by increasing net tobacco prevalence. The first step of this evaluation requires an independent and reliable projection of product use — overall and within key subpopulations.

1.2 Study Objectives

To provide the FDA with projected usage estimates for a tobacco product *before* it is launched, RAI Services Company commissioned research to create a ratings conversion algorithm. The algorithm converts 10-point survey rating data, measuring "likelihood of purchase with intent to try," to projectable estimates of actual purchase for trial.

(b) (4)		

2. STUDY DESIGN

2.1 Sample Design

(b) (4)		

2.2 Survey Content/Pretest Process

In Wave 1, the following data were collected:*

- (1) **Demographics (age, gender, race/ethnicity and education):** to ensure that key consumer groups are represented and that results can be weighted appropriately so that they are representative of the universe of consumers
- (2) **Current and past use of tobacco products**: to classify respondents into behavioral status groups (current vs. former vs. never regular user of tobacco, and user of smoked vs. non-smoked vs. both product types)
- (3) Anticipated use of tobacco products nine months in the future: to permit analysis of additional key sub-groups (those intending/not intending to quit tobacco use)
- (4) Presentation of information about Marlboro Special Blend cigarettes, followed by a rating of likelihood of purchase with intent to try to provide the foundation for a projected use model

In Wave 2, the following data were collected:

- (1) **Current (at the time of Wave 2) use of tobacco products**: to permit comparisons of predicted vs. actual tobacco use behavior (anticipated vs. actual continuing, quitting, starting, and re-starting tobacco use behavior)
- (2) Purchase of Marlboro Special Blend for personal trial at any point in the previous nine months: to provide required input to the model
- (3) **On-going use of Marlboro Special Blend:** to provide insights regarding post-trial persistence with the product

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See Section 6 of this report for survey instruments

2.3 Data Collection Timelines

The research consisted of two survey waves with the same respondents, structured as "pre-launch/post-launch" data collection to compare *predicted* future product use in Wave 1 with *reported usage* in Wave 2.

Wave 1 was conducted from December 23, 2009 until 9am on January 6, 2010, to ensure field closed before consumers could have purchased or tried Marlboro Special Blend, which was expected to be launched on January 6, 2010. The Wave 2 follow-up survey was conducted approximately nine months later (September 16, 2010 through October 5, 2010).

2.4 Distribution of Completed Interviews

For the initial fielding day, the invitations were issued to reach the first day goal of five percent completion in all quota groups, as a quality control check. After the successful "slow start," invitations were issued every second or third day with the goal of reaching an additional 15-20% of the total goal in each quota group. This approach permitted control of the flow of survey invitations based on demographic and/or tobacco use, to account for differential response rates.

For Wave 1, a total of 15,393 consumers completed the survey. All Wave 1 respondents were eligible for, and invited to participate in, Wave 2.

Table 1: Unweighted Sample Distribution
- Demographics by Tobacco Status -

	Tobacco Status			
	Current Regular User	Former Regular User	Never Regular User	
(n) =	5,545	4,328	5,520	
Northeast	994	806	1,047	
Midwest	1,384	987	1,207	
South	1,989	1,530	1,890	
West	1,178	1,005	1,376	
18-30	1,207	594	1,544	
31-50	2,800	1,530	2,296	
51-75	1,538	2,204	1,680	
Male	3,179	2,224	2,474	
Female	2,366	2,104	3,046	
Hispanic	650	370	876	
Non-Hispanic White	3,886	3,205	3,459	
Non-Hispanic Black	619	483	706	
Non-Hispanic Asian/Other	424	307	508	
High School (or less)	1,124	509	876	
Some College	3,662	2,876	3,362	
Bachelor's Plus	759	943	1,282	

3. NON-RESPONSE ANALYSIS AND WEIGHTING

3.1 Analysis of Potential Non-Response Bias

Of the 15,393 people interviewed in Wave 1, a total of 8,328 responded to the second survey, a 54% recontact rate. This level of attrition was anticipated at the start of the research.

Wave 2 responders were compared to non-responders to determine if any bias was introduced through sample attrition. As shown below in Table 2a, the unweighted samples are almost identical with respect to tobacco status, suggesting that no bias was introduced.

Table 2a: Unweighted Sample Distribution
- Tobacco Behavior Status by Wave 2 Participation Status -

	Total Wave 1	Completed Wave 2	Did Not Complete Wave 2
(n) =	15,393	8,328	7,065
Tobacco Status:			
Current Regular User	36%	34%	38%
Cigarette	(78%)	(78%)	(78%)
Cigar/Cigarillo	(20%)	(20%)	(21%)
Snuff or snus	(16%)	(16%)	(17%)
Chewing Tobacco	(14%)	(14%)	(15%)
Pipe	(5%)	(5%)	(5%)
Former Regular User	28%	29%	27%
Cigarette	(94%)	(95%)	(94%)
Cigar/Cigarillo	(15%)	(14%)	(15%)
Snuff or snus	(4%)	(4%)	(5%)
Chewing Tobacco	(6%)	(6%)	(7%)
Pipe	(8%)	(9%)	(7%)
Never Regular User	36%	37%	35%

Wave 2 responders and non-responder were also compared with respect to demographics. As shown in Table 2b below, the unweighted demographic data are similar for both groups—the key differences being a slightly higher rate of attrition among respondents age 18-30 and non-Hispanic Whites, which required a minor weighting adjustment to rebalance.

Table 2b: Unweighted Sample Distribution
- Demographics by Wave 2 Participation Status -

	Total Wave 1	Completed Wave 2	Did Not Complete Wave 2
(n) =	15,393	8,328	7,065
Region:			
Northeast	19%	19%	18%
Midwest	23%	24%	22%
South	35%	34%	37%
West	23%	23%	23%
Age:			
18-30	22%	18%	26%
31-50	43%	42%	45%
51-75	35%	40%	29%
Gender:			
Male	51%	52%	51%
Female	49%	48%	49%
Race/Ethnicity:			
Hispanic	12%	10%	15%
Non-Hispanic White	68%	72%	64%
Non-Hispanic Black	12%	11%	13%
Non-Hispanic Other	8%	7%	8%
Education:			
Up to High School	16%	16%	16%
Some College	41%	39%	42%
Bachelor's Degree	24%	25%	23%
More than a Bachelor's Degree	19%	20%	19%

Table 2c below provides the unweighted distribution of ratings for "likelihood of purchasing Marlboro Special Blend with intent to try" (Wave 1 responses). The distribution of Wave 1

ratings were similar for individuals who did and did not respond in Wave 2, further minimizing concern about non-response bias.

Table 2c: Unweighted Rating Distribution
- Purchase Intent Ratings by Wave 2 Participation Status -

	Total Wave 1	Completed Wave 2	Did Not Complete Wave 2
(n) =	15,393	8,328	7,065
Definitely Would Not Purchase ▶ 1	62%	63%	60%
2	4%	5%	5%
3	3%	3%	4%
4	2%	2%	2%
5	5%	5%	5%
6	4%	4%	4%
7	4%	4%	4%
8	5%	5%	5%
9	3%	3%	3%
Definitely Would Purchase ► 10	8%	7%	8%

3.2 Weighting

(b) (4)

Step 1. Development of Base Weights

(b) (4)

Table 3: Population Estimates
- Population Counts by Region, Tobacco Status and Age -

		AGE		
		18-30	31-50	51-75
	Current Regular User	1,535,299	2,669,602	1,737,684
Northeast	Former regular User	628,455	2,287,085	3,879,997
	Never Regular User	6,188,629	8,856,635	6,845,356
	Current Regular User	2,666,523	4,346,810	2,812,432
Midwest	Former Regular User	1,145,679	2,741,039	4,859,317
	Never Regular User	7,535,954	10,642,870	8,109,569
	Current Regular User	4,071,618	6,657,492	4,736,665
South	Former Regular User	1,464,386	4,068,533	7,673,351
	Never Regular User	14,508,307	20,487,904	15,422,969
West	Current Regular User	2,194,904	3,179,379	2,196,272
VVEST	Former Regular User	1,022,016	2,861,253	4,883,656

^{*} The following sources were used to develop all population counts: Census website (http://www.census.gov/); the March 2010 Annual Social and Economic Supplement to the Current Population Survey; and the Tobacco Use Supplement to the Current Population Survey (from May 2006, August 2006, and January 2007)

Never Regular User 10,365,597 14,180,452 9,633,430

Step 2. Raking

(b) (4)		

^{*} See "Practical Considerations in Raking Survey Data" by Michael P. Battaglia, David Izrael, David C. Hoaglin, and Martin R. Frankel, Survey Practice, June 2009

Table 4a: Weighted Tobacco Use Distribution
- Tobacco Status by Wave -

	Total Wave 1	Completed Wave 2
(n)*	= 15,393	8,328
Tobacco Status:		
Current Regular User	19%	19%
Cigarette	(83%)	(83%)
Cigar/Cigarillo	(18%)	(18%)
Snuff or snus	(14%)	(14%)
Chewing Tobacco	(11%)	(11%)
Pipe	(4%)	(4%)
Former Regular User	18%	18%
Cigarette	(94%)	(94%)
Cigar/Cigarillo	(14%)	(15%)
Snuff or snus	(5%)	(5%)
Chewing Tobacco	(7%)	(6%)
Pipe	(9%)	(9%)
Never Regular User	63%	63%

 $[\]ensuremath{^{^{*}}}$ Unweighted sample sizes (on which the weighted data are based) are shown.

Table 4b: Weighted Sample Distribution
- Demographics by Wave -

	Total Wave 1	Completed Wave 2
(n)* =	15,393	8,328
Region:		
Northeast	17%	17%
Midwest	21%	21%
South	38%	38%
West	24%	24%
Age:		
18-30	25%	25%
31-50	40%	40%
51-75	35%	35%
Gender:		
Male	49%	49%
Female	51%	51%
Race/Ethnicity:		
Hispanic	15%	15%
Non-Hispanic White	67%	67%
Non-Hispanic Black	12%	12%
Non-Hispanic Other	6%	6%
Education:		
Up to High School	44%	44%
Some College	29%	29%
Bachelor's Degree	18%	18%
More than a Bachelor's Degree	9%	9%

 $[\]ensuremath{^{\ast}}$ Unweighted sample sizes (on which the weighted data are based) are shown.

Table 4c: Weighted Rating Distribution
- Purchase Intent Ratings by Wave -

	Total Wave 1	Completed Wave 2
(n)* =	15,393	8,328
Definitely Would Not Purchase ► 1	72%	72%
2	4%	4%
3	2%	2%
4	2%	2%
5	4%	4%
6	3%	3%
7	2%	2%
8	3%	3%
9	2%	2%
Definitely Would Purchase ► 10	6%	6%
Mean Rating	2.5	2.5

 $^{^{}st}$ Unweighted sample sizes (on which the weighted data are based) are shown.

4. ANALYSIS PLAN/ALGORITHM DEVELOPMENT (b) (4)

4.2 Algorithm Development

(b) (4)



The following table lists the model coefficients for demographic groups that were significant predictors of trial:

Table 6: Logistic Regression Results for Key Sub-groups

Model Inputs:	Parameter/ Coefficient	Std. Err.	Wald Chi- Square	pr > ChiSq
Intercept	-6.4986	0.3319	383.2863	<.0001
Raw Rating Score (1-10)	0.3367	0.0315	114.5716	<.0001
Current Regular Tobacco User	1.7425	0.3509	24.662	<.0001
Current Regular Tobacco User Age 18-30	0.843	0.2718	9.6185	0.0019
Current Regular Tobacco User Age 31-50	0.5153	0.228	5.1084	0.0238
Former Regular Tobacco User Age 18-30	1.6292	0.5775	7.9578	0.0048
Former Regular Tobacco User Age 31-50	1.9444	0.4161	21.8334	<.0001

(b) (4)		
Tables 7a and 7b (below) show (b) (4)		

^{*} Tobacco usage status, age, race/ethnicity, gender, education level, and region sub-groups

Table 7a: Model Estimates vs. Actual Weighted Purchase Rates
- For Key Demographic Sub-Groups -

	Model Estimate	95% Confidence Interval	Actual
Total	2.8%	2.0% - 4.0%	2.8%
Region:			
Northeast	2.5%	1.8% - 3.6%	2.0%
Midwest	3.1%	2.2% - 4.4%	3.3%
South	3.0%	2.1% - 4.2%	3.1%
West	2.4%	1.7% - 3.5%	2.4%
Age:			
18 - 30	3.5%	2.4% - 5.1%	3.5%
31 - 50	3.4%	2.5% - 4.7%	3.6%
51 - 75	1.6%	1.1% - 2.4%	1.4%
Gender:			
Male	3.1%	2.2% - 4.4%	3.0%
Female	2.5%	1.8% - 3.6%	2.6%
Race/Ethnicity:			
Hispanic	2.4%	1.7% - 3.5%	3.0%
Non-Hispanic White	3.2%	2.2% - 4.4%	3.2%
Non-Hispanic Black	1.5%	1.0% - 2.3%	.9%
Non-Hispanic Other	2.5%	1.7% - 3.5%	1.9%
Education:			
Up to High School	3.7%	2.7% - 5.1%	3.7%
Some College	2.7%	1.9% - 3.9%	2.9%
Bachelor's Degree	1.7%	1.1% - 2.5%	1.4%
More than a Bachelor's Degree	1.1%	0.7% - 1.8%	1.3%

Table 7b: Model Estimates vs. Actual Weighted Purchase Rates
- For Key Tobacco Use Groups -

	Model Estimate	95% Confidence Interval	Actual
Total	2.8%		2.8%
Tobacco Status: Current Regular Tobacco User	11.7%	8.8% - 15.3%	11.7%
Plan to continue tobacco use (84%)	12.1%		12.3%
Plan to quit use of all tobacco (16%)	9.6%		8.4%
Former Regular Tobacco User	2.0%	1.1% - 3.7%	2.1%
Never Regular Tobacco User	0.4%	0.2% - 0.7%	0.4%

(b) (4)

Data suggest that Marlboro Special Blend appeal is greatest among Current Regular Tobacco Users, particularly those tobacco users who expected to still be using some type of tobacco use nine months later (84% of all Current Regular Tobacco Users).

Probabilities of Marlboro Special Blend use by Former and Never Regular Users suggest that availability of Marlboro Special Blend is *unlikely* to have a significant impact on rates of initiation or recidivism:

- Estimated use by those two groups appears to be well within the historically observed bounds of initiation and recidivism rates
- These same rates of initiation and recidivism are likely to be observed even without introduction of Marlboro Special Blend. Most Former and Never regular users who became "Tobacco Users" over the nine-month period did not purchase Marlboro Special Blend for trial (see Table 7c below).
- Furthermore, virtually all (1.9% of the 2.1%) "Former Regular Tobacco Users" who purchased the Marlboro Special Blend product for trial tried at least one other cigarette brand over the 9-month period of the study, and all of those initiating tobacco tried at least one other cigarette brand (see Table 7c below).

• Finally, these rates are likely to represent *maximum* use (i.e., trial rather than repeat or regular use). Only a subset of consumers who tried the product continued to use it** (see Table 7c below).

Table 7c: Weighted Self-reported Trial, Recidivism, Initiation,
And Repeated Use Rates

	Wave I "Current Regular Tobacco User"	Wave I "Former Regular Tobacco User"	Wave I "Never Regular Tobacco User"
(n)* =	2,864	2,438	3,039
% Classified as "Tobacco User" in Wave II	88.6%	16.3%	6.5%
% Purchased Marlboro Special Blend (trial)	11.7%	2.1%	.4%
% Purchased at least one other cigarette brand <i>in</i> addition to Marlboro Special Blend	11.3%	1.9%	.4%
% Continued use** of Marlboro Special Blend	7.1%	1.2%	.2%

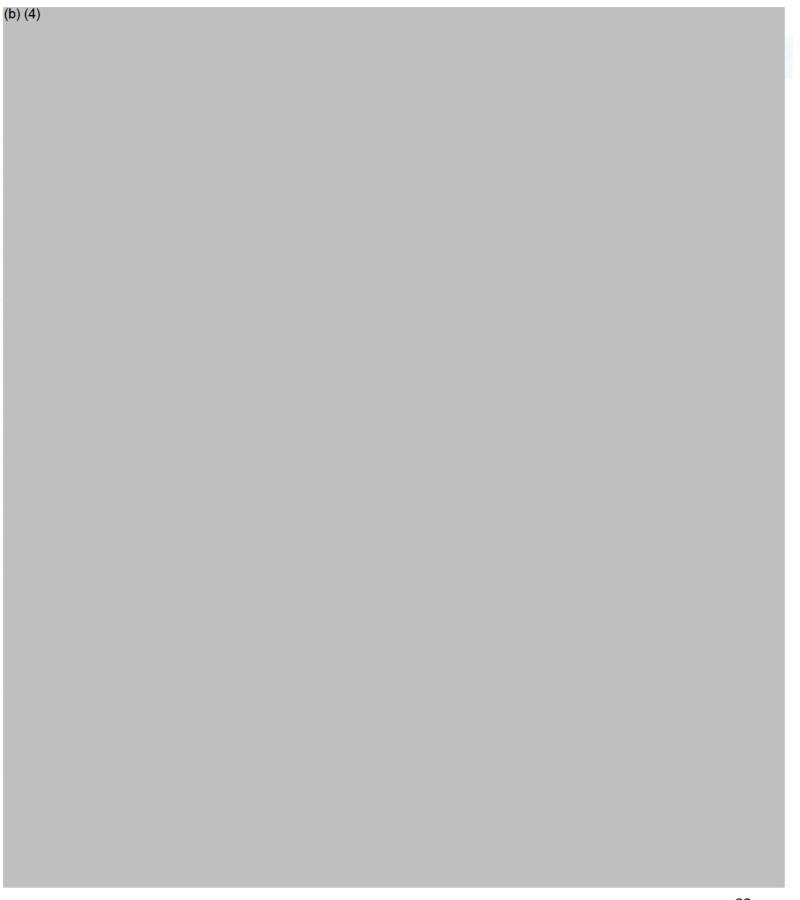
^{*} Unweighted sample sizes (on which the weighted data are based) are shown.

^{**} Continued use is defined as "currently purchase for regular or occasional use" at time of the Wave II survey.

5. MODEL VALIDATION AND IMPLICATIONS

5.1 Model Validation		
(b) (4)		

(b) (4)



6. SURVEY INSTRUMENTS

Wave 1: Product Usage Survey

- Final Screener -

Thank you for visiting our survey site to answer a few qualifying questions. This survey is strictly for research purposes only. It is our policy to keep all survey responses anonymous.

All questions on each screen must be answered before you move to the next screen, so please be sure you have answered every question before trying to move forward. On the next few screens you will be asked a few questions to see if you qualify for this study. If you qualify, the survey itself should take less than 5 minutes to complete.

PROGRAMMER: INSERT STANDARD INSTRUCTION SCREEN

FIELD OPS: RECRUIT RESPONDENTS FROM eRewards PANEL; HAVE RECRUITERS DRAW SAMPLE...

- 4) ACCORDING TO MINIMUM PURCHASE AGE IN STATE (SEE S7 INSTRUCTIONS)
- 5) ACCORDING TO QUOTA (SEE FINAL PAGE OF SURVEY)

In this survey we are interested in the opinions of people who have been, or are, regular users of certain products, as well as people who have never used them.

S1a. Would you consider yourself to be – or to have been at any time in the past – a "regular user" of any of the following products? We leave it to you to define regular use.

Select "yes" or "no" for each row.

	Yes I am – or was – a regular user	No, have never been a regular user
Beer or malt-based beverages?	0	0
Bottled water (still or carbonated)?	0	0
Nutritional supplements/vitamins?	0	0
Tobacco products?	0	0

PROGRAMMER:

2) DISPLAY ROWS IN RANDOM ORDER

Select one response for each row.

	Current Non-user	Current Occasional User	Current Regular User
Beer or malt-based beverages?	0	0	0
Bottled water (still or carbonated)?	0	0	0
Nutritional supplements/vitamins?	0	0	0
Tobacco products?	0	0	0

PROGRAMMER:

2) DISPLAY ONLY ROWS ANSWERED AS "Yes" IN S1a, IN SAME ORDER AS IN S1a

CL	AS	SI	FY	A	S:
----	----	----	----	---	----

A) Curren	t Regular Toba	cco User: S1k	"Tobacco	product" IS	"Infrequent"	or "Regular"	(col 2 or 3)
-----------	----------------	---------------	----------	-------------	--------------	--------------	--------------

Former Regular Tobacco User:	S1b "Tobacco	product" IS "Non	1-user" AND S1a	"Tobacco product	t" IS "Yes"
------------------------------	--------------	------------------	-----------------	------------------	-------------

C)	Never Regular Tobacco User:	S1a "Tobacco product" IS "No"

S2.	What is your current age?			
DROCE	ANANAED.	Years		

PROGRAMMER:

- 3. RANGE IS 10-99
- 4. IF < 18 OR IF > 75, TERMINATE NOW
- S3. What is your gender?

Male	0
Female	0

What is the highest grade you have completed in school? (Select one) S4.

High school or less	0
Some college or technical/vocational training	0
Four years of college (Bachelor's degree)	0
More than Bachelor's degree	0

CEo	Da vau sansidan	tourself to b	a of Hispania	Latina a	" Cuaniah	!-!-
S5a.	Do you consider	yoursell to b	e of Hispanic,	Latino, o	r spanisn	origin:

Yes	0
No	0

S5b. What do you consider to be your race? (Select all that apply)

White	
African American / Black	
Asian	
Other	

PROGRAMMER:

2. DISPLAY S5a AND S5b ON SAME SCREEN

S6. Which of the following best describes your total <u>household</u> income?

Under \$25,000	0
\$25,000 to \$49,999	0
\$50,000 to \$74,999	0
\$75,000 to \$99,999	0
\$100,000 or more	0

S7. In what state do you currently reside?

[SHOW POP UP LIST OF STATES]

- 1. IF STATE IS ALABAMA, ALASKA, NEW JERSEY OR UTAH AND S2= 18, TERMINATE NOW (minimum age for tobacco purchase in these states is 19)
- 2. IF STATE IS IOWA OR MASSACHUSETTS, TERMINATE AT END OF SCREENER

S8. Earlier you indicated that you [currently use tobacco products./have used tobacco products on a "regular basis" in the past, but that you no longer do.] Which of the following types of tobacco products [do you currently use/did you use regularly]? (Select all that apply)

Cigarette	
Cigar/cigarillos	
Pipe	
Chewing tobacco	
Snuff or snus	

PROGRAMMER:

- 4. ASK IF CLASSIFIED AS "Current" or "Former" Regular Tobacco User
- 5. IF S1b "Tobacco product" IS "Infrequent" OR "Regular," USE FIRST TEXT IN BRACKETS, ELSE USE 2ND TEXT
- 6. CHECK QUOTAS, BUT DO NOT TERMINATE ANY RESPONDENT OF ELIGIBLE AGE WHO SELECTS ROW 4 OR 5 (Chewing tobacco, snuff or snus) IN S8

"You have qualified for our survey, and we'd like to invite you to participate. The survey will require less than five minutes to complete, and we ask for your undivided attention once you begin it. If you do not have five minutes right now, please click "stop," and return any time during the next 24 hours when you have an <u>uninterrupted</u> five minutes."

Wave 1: Product Usage Survey

- Final Survey -

1a. Earlier you indicated that you used to use tobacco products on a "regular basis," but that you no longer do. When did you <u>stop</u> using the following types of tobacco products?

Select one column for each product shown below.

	Less than 6 months ago	6 months to 1 year ago	Over 1, but less than 2 years ago	Over 2, but less than 5 years ago	More than 5 years ago
Cigarette	0	0	Ö	0	0
Cigar/cigarillos	0	0	0	0	0
Pipe	0	0	0	0	0
Chewing tobacco	0	0	0	0	0
Snuff or snus	0	0	0	0	0

PROGRAMMER:

- 1. ASK IF CLASSIFIED AS "Former" Regular Tobacco User
- 2. SHOW ONLY PRODUCTS SELECTED IN S8
- 1b. Earlier you indicated that currently use tobacco products. About how long have you been using the following types of tobacco products? *Select one column for each product shown below.*

	Less than 6 months	6 months to 1 year	Over 1, but less than 2 years	Over 2, but less than 5 years	More than 5 years
Cigarette	0	0	0	0	0
Cigar/cigarillos	0	0	0	0	0
Pipe	0	0	0	0	0
Chewing tobacco	0	0	0	0	0
Snuff or snus	0	0 '	0	0	0

- 1. ASK IF CLASSIFIED AS "Current" Regular Tobacco User
- 2. SHOW ONLY PRODUCTS SELECTED IN S8

2.	Now please think ahead to nine months from now. Based on your experience, product preference, and
	goals, do you expect that you will be using the following types of products nine months from now?

Select "yes" or "no" for each row.

	Yes	No
Cigarette	0	0
Cigar/cigarillos	0	0
Pipe	0	0
Chewing tobacco	0	0
Snuff or snus	0	0

The final section of this survey focuses on a new tobacco product. Please note that <u>everyone</u> is asked <u>all</u> of the questions in this survey, regardless of the products they currently use or their in-going expectations about future use.

Please take your time and read the information closely so that you will be able to answer the questions that follow.

Please carefully read the profiles below. Take as much time as you need.

(b) (4)

3. Assuming the product were available today, how likely would you be to purchase the Marlboro Special Blend product so that you could try it?

Definitely Would <u>Not</u> Purchase it (to Try) ₩					Definitely Wou Purchase It (to Ti				
1	2	3	4	5	6	7	8	9	10
0	0	0	0	0	0	0	0	0	0

4. If you decided to try the Marlboro Special Blend product and found that you liked it enough to continue using it, please predict as best you can how you would imagine using it. *Select one row.*

I would imagine that I would use the new product	
<u>In place of</u> some or all of my use of my current brand(s) (<u>no</u> net increase in tobacco use)	0
<u>In addition to</u> my use of my current brand(s) (leading to some potential increase in tobacco use)	0

PROGRAMMER:

3. ASK IF "CLASSIFIED AS CURRENT REGULAR USER" AND Q3 > 1

Earlier you indicated that you do not currently use tobacco products. Please note that the goal of this survey is only to assess how interesting the new tobacco product is to people from many different backgrounds, and it is **not** intended to encourage you or anyone else to start using tobacco products.

- Individuals should consider the conclusions of the U.S. Surgeon General, the Centers for Disease control, and other public health and medical officials when making decisions regarding smoking.
- The best course of action for tobacco users concerned about their health is to quit. Adults who continue to use tobacco products should consider the reductions of risks for serious diseases associated with moving from cigarettes to the use of smoke-free tobacco or nicotine products.
- Minors should never use tobacco products and adults who do not use or have quit using tobacco products should not start.
- Adults who smoke should avoid exposing minors to secondhand smoke, and adult smokers should comply with rules and regulations designed to respect the rights of other adults.

PROGRAMMER:

1. DISPLAY IF CLASSIFIED AS Never Regular Tobacco User OR AS Former Regular Tobacco User

THANK YOU SCREEN

	QUOTAS:
(b) (4)	

Wave 2: Product Usage Survey

- Final Screener -

Thank you for visiting our survey site. This survey is strictly for research purposes only. It is our policy to keep all survey responses anonymous.

All questions on each screen must be answered before you move to the next screen, so please be sure you have answered every question before trying to move forward.

PROGRAMMER: INSERT STANDARD INSTRUCTION SCREEN
FIELD OPS: ALL RESPONDENTS SHOULD BE FROM eRewards PANEL – ONLY RESPONDENTS WHO COMPLETED
THE SURVEY IN DECEMBER 2009/JANUARY 2010 ARE ELIGIBLE FOR SCREENING

[NOTE: Q0 DESCRIPTORS WILL NOT BE RE-ASKED IN WAVE II, SO FOR DUE-DILIGENCE WE ARE ASKING RESPONDENTS TO VALIDATE THAT THEY ARE THE PERSON WHO ANSWERED IN WAVE I]

So. We are trying to re-contact individuals who completed one of our surveys through eRewards in late December 2009 or in early January 2010.

Someone connected with this e-mail address completed the survey, and at that time indicated that **[he/she]** was:

- A [S2] year old [S3]
- [S5a "Yes" = Of/"No" = Not of] Hispanic, Latino, or Spanish origin
- Who completed [S4 with lower-case first letter]

Are you this person?

Yes	0
No	0

PROGRAMMER:

- 1. e.g.: A 53 year old male
 - Of Hispanic, Latino, or Spanish origin

Who completed some college or technical/vocational training

- 2. REPLACE "he/she" WITH "he" IF S3 IS "male," AND WITH "she" IF S3 IS "female"
- 3. IF SO IS "No, TERMINATE NOW

[NOTE: S1 IS IDENTICAL TO THE QUESTION IN WAVE I; ASKED TO CAPTURE CHANGES IN CLASSIFICATION WHICH MAY BE A NECESSARY INPUT TO THE MODEL]

S1. Focusing only on the present, how would you <u>currently</u> describe yourself, relative to each of the following categories? We leave it to you to define regular use.

Note that your answers to this question do not need to match those in the prior survey – we are asking this question again because we recognize that your status may have changed since then. Please select one response for each row.

	Current Non-user	Current Occasional User	Current Regular User
Beer or malt-based beverages?	0	0	0
Bottled water (still or carbonated)?	0	0	0
Nutritional supplements/vitamins?	0	0	0
Tobacco products?	0	0	0

PROGRAMMER:

3) DISPLAY ROWS IN RANDOM ORDER

CLASSIFY AS:

A) Current Tobacco User: S1b "Tobacco product" IS "Occasional" or "Regular" (col 2 or 3)

B) Current Non Tobacco User: S1b "Tobacco product" IS "Non-user"

[NOTE: S2 "purchase for personal use" LANGUAGE MIRRORS WAVE I "LIKELIHOOD" SCALE; NECESSARY MODEL INPUT. NOTE THAT WE ASK THIS QUESTION OF ALL RESPONDENTS; "NON-USER" IS REALLY "NON-REGULAR" USER, AND COULD HAVE PURCHASED FOR SHORT-TERM OR SINGLE PERSONAL USE]

S2. When, if ever, was the <u>most recent time that you purchased</u> the following products for personal use (either regular *or* occasional use)? *Select one column for each product shown below.*

Some time this calendar year (between January 1, 2010 and today)		Some time in 2009	Some time <u>before</u> 2009 (and NOT since then)	Have not purchased any of this product for personal use
Beer or malt-based beverages?	0 4	0	0	0
Bottled water (still or carbonated)?	0	0	0	0
Nutritional supplements/vitamins?	0	0	0	0
Tobacco products?	0	0	0	0

PROGRAMMER:

1. IF "Tobacco products" IS COL 2, 3, OR 4 (Some time in 2009 or earlier), TERMINATE NOW

[&]quot;You have qualified for our survey, and we'd like to invite you to participate. The survey will require less than five minutes to complete, and we ask for your undivided attention once you begin it. If you do not have five minutes right now, please click "stop," and return any time during the next 24 hours when you have an <u>uninterrupted</u> five minutes."

Wave 2: Product Usage Survey

- Final Survey -

[NOTE: THE ONLY RESPONDENTS ENTERING THE SURVEY ARE THOSE WHO PURCHASED TOBACCO <u>IN SOME FORM</u> OVER THE PAST 9 MONTHS. Q1 AND Q2 IDENTIFY THOSE WHO PURCHASED CIGARETTES IN THE PAST 9 MONTHS.]

1.	Which of the following types of tobacco products have you ever purchased for personal use (either
	regular or occasional use)? (Select all that apply)

Cigarette	
Cigar/cigarillos	
Pipe	
Chewing tobacco	
Snuff or snus	

PROGRAMMER:

1. ASK ALL

2. When, if ever, was the <u>most recent time that you purchased</u> the following types of tobacco products for personal use? *Select one column for each product shown below.*

	Some time this calendar year (between January 1, 2010 and today)	Some time in 2009	Some time <u>before</u> 2009 (and NOT since then)	Have not purchased any of this type of tobacco for personal use
Cigarette	0	0	0	0
Cigar/cigarillos	0	0	0	0
Pipe	0	0	0	0
Chewing tobacco	0	0	0	0
Snuff or snus	0	0	0	0

- 1. SHOW ONLY PRODUCTS SELECTED IN 1
- 2. IF "Cigarette" IS COL 2, 3, OR 4 (2009 OR EARLIER), SKIP TO FINAL "WARNING" SCREEN (POST Q6) AND CHECK LOGIC FOR DISPLAY

[Q3 PROVIDES THE BASIS FOR Q4 AND Q5 MARLBORO SPECIAL BLEND DRILL-DOWN. Q3/Q4 IDENTIFY RESPS WHO HAVE EVER PURCHASED MARLBORO SPECIAL BLEND; Q5 IDENTIFIES RESPS WHO CURRENTLY PURCHASE MARLBORO SPECIAL BLEND]

3. [Even though you no longer use cigarettes,] Which of the following cigarette brands have you purchased for personal use in the past nine months (since January 1, 2010)? Select "yes" or "no" for each row.

Have you purchased	Yes	No
American Spirit?	0	0
Basic?	0	0
Benson and Hedges (B&H)?	0	0
Camel?	0	0
Capri?	0	0
Carlton?	0	0
Doral?	0	0
Dunhill?	0	0
Eclipse?	0	0
GPC?	0	0
Kent?	0	0
Kool?	0	0
Lucky Strike?	0	0
Marlboro?	0	0
Merit?	0	0
Misty Slims?	0	0
Newport?	0	0
Pall Mall?	0	0
Parliament?	0	0
Salem?	0	0
USA Gold?	0	0
Vantage?	0	0
Virginia Slims?	0	0
Winston?	0	0

- 1. ASK IF Q2 "Cigarette" IS COL 1 (PAST 9 MONTHS)
- 2. INSERT TEXT THAT IS IN BRACKETS IF CURRENTLY CLASSIFIED AS "Current Non Tobacco User"

4. [Again, even though you no longer use cigarettes,] Which of the following Marlboro cigarette products have you <u>purchased</u> for personal use <u>in the past nine months</u> (since January 1, 2010)?

Select "yes" or "no" for each of the following Marlboro products.

In the past 9 months, have you purchased Marlboro	Yes	No
Red Pack (Full Flavor)	0	0
Red Label (Medium)	0	0
Gold Pack (formerly Lights)	0	0
Silver Pack (formerly Ultra Lights)	0	0
Blend No. 27	0	0
Virginia Blend	0	0
Special Blend Red	0	0
Special Blend Gold	0	0
Menthol	0	0
Menthol Blue Pack (formerly Milds)	0	0
Menthol Gold Pack (formerly Lights)	0	0
Menthol Silver Pack (formerly Ultra Lights)	0	0
Menthol Blend No. 54	0	0
Menthol Smooth	0	0

- 1. ASK IF Q3 "Marlboro" IS "Yes"
- 2. INSERT TEXT THAT IS IN BRACKETS IF CURRENTLY CLASSIFIED AS "Current Non Tobacco User"
- 3. DISPLAY PICTURES OF RELEVANT PRODUCTS IN EACH ROW
- 4. DISPLAY MESSAGE IF NO ROW IS "Yes" "Earlier you indicated that you have purchased a Marlboro cigarette product in the past nine months. Please review your answers to this question, selecting the Marlboro product that you purchased, or click the "Back" button to revise your earlier answer.

5. Which, if any, of the following types of Marlboro cigarette products do you <u>currently</u> purchase on an occasional *or* on a regular basis?

Select "yes" or "no" for each of the following Marlboro products.

Do you currently purchase Marlboro	Yes	No	
Red Pack (Full Flavor)	0	0	1
Red Label (Medium)	0	0	2
Gold Pack (formerly Lights)	0	0	3
Silver Pack (formerly Ultra Lights)	0	0	4
Blend No. 27	0	0	5
Virginia Blend	0	0	6
Special Blend Red	0	0	7
Special Blend Gold	0	0	8
Menthol	0	0	9
Menthol Blue Pack (formerly Milds)	0	0	10
Menthol Gold Pack (formerly Lights)	0	0	11
Menthol Silver Pack (formerly Ultra Lights)	0	0	12
Menthol Blend No. 54	0	0	13
Menthol Smooth	0	0	14

- 1. ASK IF "Current Tobacco User" AND Q3 "Marlboro" IS "Yes"
- 2. DISPLAY PICTURES OF RELEVANT PRODUCTS IN EACH ROW
- 3. DISPLAY ONLY ROWS SELECTED AS "Yes" IN Q4

[Q6 IS INTENDED TO HELP US UNDERSTAND TYPE OF SPECIAL BLEND USE - REPLACEMENT VS. ADDITION]

6. Please think back to the point in time just before you started using Marlboro Special Blend. Relative to that point in time would you say that you use Marlboro Special Blend... Select one row.

<u>In place of</u> some or all of your use of the tobacco products you used at that time $(\underline{no} \text{ net increase in tobacco use})$	
<u>In addition to</u> your use of the tobacco products you used at that time (leading to some increase in tobacco use)	

PROGRAMMER:

1. ASK IF CLASSIFIED AS "Current Tobacco User" AND Q5 "Marlboro Spec. Blend" (ROW 7 OR 8) IS "Yes"

Earlier you indicated that you do not currently use tobacco products. Please note that the goal of this survey is only to understand use of tobacco product among people from many different backgrounds, and it is <u>not</u> intended to encourage you or anyone else to start using tobacco products.

- Individuals should consider the conclusions of the U.S. Surgeon General, the Centers for Disease control, and other public health and medical officials when making decisions regarding smoking.
- The best course of action for tobacco users concerned about their health is to quit. Adults who continue to use tobacco products should consider the reductions of risks for serious diseases associated with moving from cigarettes to the use of smoke-free tobacco or nicotine products.
- Minors should never use tobacco products and adults who do not use or have quit using tobacco products should not start.
- Adults who smoke should avoid exposing minors to secondhand smoke, and adult smokers should comply with rules and regulations designed to respect the rights of other adults.

PROGRAMMER:

1. DISPLAY IF CLASSIFIED AS "Current Non Tobacco User"

THANK YOU SCREEN

	WAVE 1 QUOTAS:
(b) (4)	

7. WEIGHTING TARGETS WEIGHTING TARGETS BY CELL

(b) (4)