

**Investigational Protocol for Swedish Match MRTTP Application**

**Table of Contents**

<b>I.</b>	<b>Background.....</b>	<b>2</b>
<b>II.</b>	<b>Research Objectives.....</b>	<b>3</b>
<b>III.</b>	<b>Intended Use of the Results.....</b>	<b>6</b>
<b>IV.</b>	<b>Sample Constraints.....</b>	<b>7</b>
<b>V.</b>	<b>Research Stimuli.....</b>	<b>7</b>
	a. Description.....	7
	b. Respondent Disclaimer.....	7
<b>VI.</b>	<b>Research Plan and Protocol.....</b>	<b>8</b>
	a. Research Objectives.....	8
	b. Research Provider.....	8
	c. Research Design.....	9
	i. Study Set-up.....	9
	ii. Cognitive Testing.....	9
	iii. Research Location.....	11
	iv. Sample Characteristics.....	11
	v. Rationale for a Monadic Research Design.....	15
	vi. Justification for Large Sample.....	16
	d. Research Flow.....	17
	e. Questionnaire Administration and Format.....	19
	f. Hypotheses.....	27
	g. Quantitative Analysis Procedures.....	28
	h. Key Strengths and Weaknesses of Study Design.....	29
<b>VII.</b>	<b>Appendices</b>	
	Appendix A: List of Warning Labels.....	30
	Appendix B: Research Stimuli.....	31
	Appendix C: Quantitative Questionnaire.....	67
	Appendix D: Test for the De-brief Protocol.....	99
	Appendix E: Discussion Guide for Cognitive Testing.....	103

**I. Background**

Swedish Match North America (Swedish Match) is a manufacturer and wholesale distributor of smokeless tobacco products, including Swedish Snus. Swedish Match intends to submit a modified risk tobacco product (“MRTP”) application requesting modifications to the health warnings currently mandated for smokeless tobacco products pursuant to Section 204 of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Act”) for its Swedish Snus smokeless tobacco product. Section 204 of the Tobacco Act requires smokeless tobacco products to bear one of the following labels:

1. WARNING: This product can cause mouth cancer.
2. WARNING: This product can cause gum disease and tooth loss.
3. WARNING: This product is not a safe alternative to cigarettes.
4. WARNING: Smokeless tobacco is addictive.

Based on extensive toxicology and epidemiology data compiled by Swedish Match, the company proposes to submit an MRTP application requesting that FDA authorize the removal of the mouth cancer, gum disease and tooth loss warning from its Snus labeling and the modification of the third warning to state that, “No tobacco product is safe, but this product [Swedish Snus] presents a substantially lower risk to health than cigarettes”. Swedish Match proposes to also include the addiction warning.

For FDA to issue an order permitting the introduction of an MRTP into commerce, the applicant must demonstrate, among other things, the effect that the MRTP may have on the population as a whole, including users and non-users of tobacco products. See FDCA 911(g)(2)(B)(iv). The applicant must also demonstrate that the public comprehends the information in the MRTP labeling and marketing and understands its relative significance. See FDCA 911(h)(1). FDA addressed the evidence necessary to demonstrate these effects in its March 2012 Draft Guidance for Industry on MRTP Applications (“Draft Guidance”).

To address the effect of an MRTP on tobacco use behavior among current tobacco users, the Draft Guidance recommends that applicants submit “human studies regarding.....consumer perception of the product, including its labeling, marketing and advertising.” See Draft Guidance at 19; see also FDCA 911(g)(4)(B).

The Draft Guidance further recommends that, to address the effect of the MRTP on tobacco use initiation among non-users, applicants should submit human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising, to provide evidence of the potential benefit or harm to non-users of tobacco products. See Draft Guidance at 20; see also FDCA 911(g)(4)(C).

Finally, the Draft Guidance addresses the data needed to evaluate the effect of marketing an MRTP on consumer understanding and perceptions pursuant to Section 911(h)(1) of the Act. In the Draft Guidance, FDA recommends that applicants submit human studies to assess consumers' ability to understand modified risk warning labels and their significance to consumers' beliefs about the health risks of using the MRTP relative to other tobacco products and cessation aids. See Draft Guidance at 20-21.

Prior to the enactment of the Tobacco Control Act, Swedish Match conducted extensive research among consumers and has gained a baseline understanding of the types of information likely to impact their beliefs about the health risks of a tobacco product. Notably, health warnings on product packaging are an important source of information. In addition, information from mainstream media (to a much more significant degree than claims made by manufacturers on labels, labeling and other marketing materials) are highly relevant to consumers. However, such information has little impact on consumer beliefs or behavior if a modified risk product contains government mandated warnings that contradict the modified risk information. Swedish Match's previous research findings are consistent with peer-reviewed research articles. See, e.g., Capella, M. L., C. R. Taylor, et al. (2012). "Tobacco harm reduction advertising in the presence of a government-mandated warning." Journal of Consumer Affairs 46(2): 235-259.

To address this dichotomy, Swedish Match intends to submit an MRTP application to modify the health warnings currently mandated for its Swedish Snus smokeless tobacco products. Swedish Match believes that this would represent an important first step in the development of appropriate messages about Swedish Snus.

## **II. Research Objectives**

In order to conduct research meeting the requirements set forth in FDA's Draft Guidance regarding sections 911(g)(4) and (h)(1) of the Act, the applicant must first develop the messages that it proposes to convey in the labeling, marketing and advertising of its MRTP.

In this study, Swedish Match intends to evaluate the following label modifications:

1. Removal of the statement "WARNING: This product can cause mouth cancer."
2. Removal of the statement "WARNING: This product can cause gum disease and tooth loss."

3. Replace the statement “WARNING: This product is not a safe alternative to cigarettes” with the statement “WARNING: No tobacco product is safe, but this product presents a substantially lower risk to health than cigarettes.”
4. Or, replace the statement “WARNING: This product is not a safe alternative to cigarettes” with the statement “WARNING: No tobacco product is safe, but this product presents a lower risk to health than cigarettes.”
5. Retain the statement “WARNING: Smokeless tobacco is addictive.”

This research is intended to assess the effects of these proposed modifications to the risk warning label on General snus packaging among current tobacco users and non-tobacco users. The study will assess the effect of the proposed modifications on their tobacco use behavior and understanding and perception of health risks associated with the product as a result of exposure to test and control warning labels. Specifically, pursuant to Subsection 911(g)(1)(B) and 911(g)(2)(B)vi of the FD&C Act and Section VI.A (page 16) of the Modified Risk Tobacco Product Application Draft Guidance. The proposed research is intended to address the following Key Areas of Investigation (See Draft Guidance at 16 – Section VI A):

1. The effect of marketing Swedish Snus with a modified warning label on tobacco use behavior among current tobacco users (Line 628);
2. The effect of marketing Swedish Snus with a modified warning label on tobacco use initiation behavior among non- users (both never users and former users) (Line 630);
3. The effect of marketing Swedish Snus with a modified warning label on consumer understanding and perceptions of the product (Swedish Snus) (Line 632);
4. The effect of marketing Swedish Snus with a modified warning label on the population as a whole (Line 634);
5. The effect of marketing Swedish Snus with a modified warning label on certain demographic groups, e.g., pregnant women, minorities and low-income households.

The investigation plan utilizes a quantitative methodology to evaluate responses to (primarily) close ended questions from statistically readable samples of respondents with a wide range of demographic and tobacco usage characteristics. Prior to deploying the quantitative survey, the survey instrument will go through cognitive testing to ensure that the questions are being interpreted as intended.

For the purpose of this study, a current tobacco user is an adult who uses any type of tobacco product on a daily basis. The research will also be conducted among

former tobacco users (former regular tobacco users and former occasional tobacco users) and non-tobacco users to understand the effect of the modified warning label on tobacco use behavior of non-users of tobacco products. Each respondent will fall in one of the following categories:

- I. Current Tobacco Users - Use any type of tobacco product on a daily basis (Q9, Column 1, Rows a-h)
- II. Non-Tobacco Users – A non-tobacco user can be one of the following:

- i. Former regular tobacco users –

Do not currently use any tobacco product (did not select column 1, 2 or 3 for any row a through g in Q9)

AND

Used at least one tobacco product regularly in the past (selected column 4 for any row a through g in Q9)

AND

Have not used a tobacco product during the past 12 months (selected column e through h in Q9a)

- ii. Former occasional tobacco users –

Do not currently use any tobacco product (did not select column 1, 2 or 3 for any rows a through g in Q9)

AND

Have not used any tobacco products regularly in the past (did not select column 4 for any rows a through g in Q9)

AND

Used at least one tobacco product occasionally in the past (selected column 5 for any rows a through g in Q9)

AND

Have not used a tobacco product during the past 12 months (selected column e through h in Q9a)

iii. Occasional triers –

Selected row 7 for one of more of the columns a-h in Q9

iv. Never user –

Did not select option ‘a’ in Q8

Each of the six warning labels will be shown to 1,100 current tobacco users and 1,100 non-tobacco users. No quota has been set within a cell of tobacco users or non-tobacco users.

**III. Intended Use of Research Results**

Based on the research objectives described above, we expect the research to:

1. *Provide diagnostic learning related to intended use of the tobacco product among current tobacco users and non-tobacco users*

The quantitative survey directly solicits ratings for each warning label for attributes such as intended effect on future tobacco use behavior. In addition, we will gather extensive baseline and diagnostic information on demographics, opinions, motivations, and tobacco usage and quitting behaviors (past, present, and intended). The large sample sizes among current tobacco users, former tobacco users, and non-users of tobacco products will potentially permit productive assessment of the effect of the tested warning labels based on a wide range of characteristics. The primary quantitative analyses will be bivariate and multivariate statistical comparisons of warning labels, while accounting for a wide range of potential correlated factors.

2. *Assess a warning label’s potential to produce unintended negative consequences to the population as a whole and subgroups of interest*

The quantitative survey will be the primary contributor to assessing whether a modified warning label adequately conveys the intended message in the population as a whole and among subgroups of interest, e.g., non-tobacco users, pregnant women, minorities and low-income households.

3. *Assess whether the proposed warning label is misleading.*

The flow of investigative questions is such that the quantitative research will be the primary contributor to addressing this goal.

**IV. Sample Constraints**

The research results will be used to assess the differential effective appeal of the tested warning labels among population subgroups, some of which may bear on the issue of net population effects. For example, an ideal warning label would be one that differentially appeals to tobacco users who are not likely to reduce their tobacco consumption absent an MRTP, while *not* differentially appealing to subgroups such as non-tobacco users or likely quitters.

Swedish Match strictly enforces an internal policy to never conduct research, including studies such as the one proposed here, among underage respondents because they are not within our target population and they present unique issues of consent. Therefore, even though minors are a key “controversial” population subgroup that has bearing on the assessment of overall net population effects, this proposed study does not include minors in the sampling frame. However, the sampling frame will include young adults (age 18-24 years old) or, in states with a higher statutory legal tobacco age (aged 19-24 years old).

We do not intend to oversample individuals identified by FDA as being at high risk for tobacco use (e.g., pregnant women, low income households or minorities) because the large sample size will be sufficient to reflect most subgroups with reasonable accuracy.

**V. Research Stimuli**

a. Description

The research stimuli for the quantitative research will be high resolution color images of 6 warning labels (4 existing warning labels and 2 proposed warning labels) on three different stock keeping units (SKU) of General snus cans – one each of General Nordic Mint, General Classic Blend and General Wintergreen. Each respondent will be shown 3 images of the same warning label on one screen. Each image consists of one warning label on top and side of a General round and non-round cans, respectively. The warning labels will cover at least 30% of the surface area of the can as mandated by Section 204 of the Tobacco Control Act.

A list of warning labels being tested is included in [Appendix A](#). The research stimuli images are shown in Appendix F.

b. Respondent Disclaimer

Each respondent in the test cell of the survey will, immediately after research participation, view a video disclaimer and sign a statement that explicitly states that the test cell warning label is a hypothetical, unproven research stimulus. This video disclaimer is designed to minimize any interpretation of the test warning label as either true government-approved warning label or a marketing effort by the product's manufacturer. The disclaimer video will go through cognitive testing along with the quantitative survey instrument (online quantitative questionnaire).

The text of the video disclaimer is shown in [Appendix D](#).

VI. Research Plan and Protocol

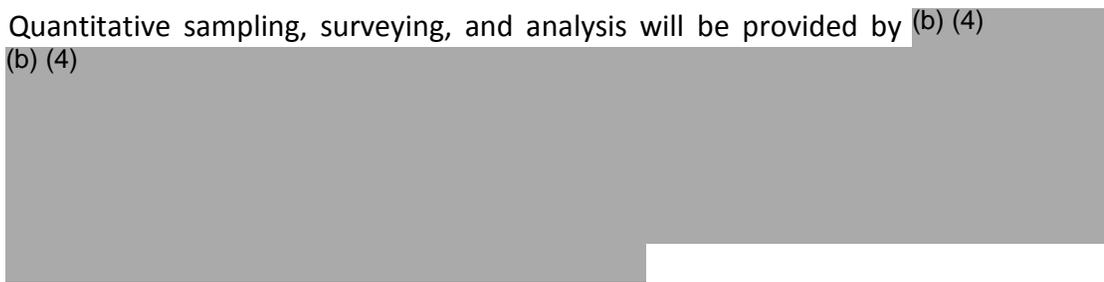
a. Research Objectives

The objective of the research is to quantitatively assess the effects of the proposed modified warning labels and existing warning labels on tobacco use behavior and understanding and perception of health risks associated with Swedish Snus, across various population subgroups, involving several tobacco transition states.

b. Research Provider

Quantitative sampling, surveying, and analysis will be provided by (b) (4)

(b) (4)

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(b) (4)

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(b) (4)

Internal research expertise is provided by Vijay Rajan, Director, Market Research at Swedish Match North America.

Vijay Rajan earned his Bachelor of Science degree from University of Bombay, a Master of Logistics Management from Maine Maritime University in Castine, ME and a Master of Marketing Research from University of Georgia in Athens, GA. Vijay Rajan has over 12 years of experience in market research in different industries including pharmaceuticals, consumer packaged goods and tobacco. Vijay Rajan has been in charge of market research at Swedish Match since December 2009.

c. Research Design

Cognitive Testing of the Survey Instrument

Prior to deploying the survey, the quantitative survey instrument (quantitative questionnaire) will go through cognitive testing among current tobacco users and non-tobacco users to ensure that the questions are being understood by potential respondents true to the intent of the questions. Cognitive testing of the survey instrument will take place in two phases. During the first phase of the research, the survey instrument will be tested with 14 consumers. The survey instrument will be then revised, as needed, based on the consumer feedback from the first phase of the research to ensure that the quantitative research questionnaires are being understood by the potential respondents to the true intent of the questions. (b) (4)

(b) (4)

(b) (4) . The survey will then be revised based on the results.

During the second phase of cognitive testing, the revised quantitative survey instrument will be tested again with a sample of 14 different consumers to understand if the consumer feedback from the first phase of cognitive testing resulted in better understanding of the quantitative survey instrument. (b) (4)

The sample composition for the two phases of cognitive testing is as follows:

	Per Testing Location	Tobacco Users	Non-tobacco User
<b>Gender</b>	(b) (4)		
(b) (4)			
<b>Ages</b>	(b) (4)		
(b) (4)			
<b>Household Income</b>	(b) (4)		
(b) (4)			
<b>Ethnicity</b>	(b) (4)		
(b) (4)			

The discussion guides for cognitive testing of the disclaimer video and quantitative survey instrument is shown in [Appendix E](#).

Quantitative Study Set-up

The quantitative research will be conducted as an online questionnaire via the vendor’s survey research platform. Participants will be recruited from the vendor’s consumer-based panel resources, where all potential respondents are members of a consumer research online panel who have opted to participate in research studies and have provided logistical and personal identification criteria in order to do so. Invitations will be distributed to participants via email and will include an HTML hyperlink that connects to the survey instrument.

On-line sampling has become a standard source of recruitment of the past 15 years. Some advantages of on-line recruitment include:

- I. Greater cost efficiencies permitting larger sample sizes
- II. Greater facility for age verification
- III. Low levels of intrusion for prospective respondents, since all have previously agreed to participate in marketing research surveys
- IV. Extensive pre-screening (since many data points will already exist about prospective respondents), permitting a more accurate tailoring of sample to desired quotas

- V. The increased use of mobile phones as the primary or sole household phone system continues to make random digit dialing increasingly more problematic as a recruiting methodology. Many maintain that on-line sampling now permits less bias in the eventual sample, especially with respect to younger respondents.

#### Quantitative Research Location

The survey will be national, with geographical quotas guided by 2010 Centers for Disease Control and Prevention Tobacco Fact Sheet - ([http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm)).

#### Sample Characteristics

Tobacco users and non-tobacco users will be split into six (6) cells of 1,100 subjects each for a total sample of 13,200 subjects: 6,600 each for current tobacco users and non-tobacco users. Each cell will test a single warning label.

Respondents who are at least 18 years of age will be allowed to take the survey. The sample will be balanced for gender, age, income (low-income households/non-low income households), ethnicity (minorities/non-minorities) and geography per the following criterion (guided by the Center for Disease Control Morbidity and Mortality Weekly Report Weekly/Vol. 60/ No. 35):

##### I. Gender

- i) Male – 57%
- ii) Female – 43%

##### II. Age

- i) 18-24 – 34%
- ii) 25-44 – 35%
- iii) 45+ – 32%

##### II. Income

- i) Low-income households (<45K annual income) – 48%
- ii) Non-low income households (>45K annual income) – 52%

##### III. Ethnicity

- i) Minorities – 30%

- ii) Non-minorities – 70%

#### IV. Geography

- i) Northeast – 26%
- ii) Midwest – 24%
- iii) South – 24%
- iv) West – 26%

Minorities, as a group, are defined as any survey respondent who is not of White/Caucasian descent. This research will analyze results for all racial/ethnic groups, excluding survey participants of White/Caucasian descent, as one group designated as “Minorities” to obtain a readable base for this subgroup.

Low-income households are defined as households that have annual income twice the poverty level (\$22,350 annual income for a family of four, per Social Security Administration Website <http://www.ssa.gov/policy/docs/statcomps/supplement/2011/3e.html#table3.e8>).

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

The following table shows the sample composition and margin of errors at 95% confidence interval for different subgroups mentioned above:

<b>Sample Size per Cell = 1,100</b>			<b>Margin of Error at CI 95%*</b>
<b>Subgroups</b>	<b>% of Cell Total</b>	<b>Counts</b>	<b>+/-</b>
<b>Gender</b>			
Males	57%	627	3.91
Females	43%	473	4.51
<b>Age</b>			
18-24	33%	363	5.14
25-44	35%	385	4.99
45+	32%	352	5.22
<b>Geography</b>			
Northeast	26%	286	5.79
Midwest	24%	264	6.03
South	24%	264	6.03
West	26%	286	5.79
<b>Ethnicity</b>			
Minorities	30%	330	5.39
Non-minorities	70%	770	3.53
<b>Income</b>			
Non-low income households (> \$45K annual household income)	52%	572	4.1
Low-income households (< \$45K annual household income)	48%	528	4.26

*\*Margin of error calculated on percentage, using a .5 planning percentage to insure the widest possible error range.*

Additional socio-demographic and behavioral attributes will be determined for each respondent for use during the survey and subsequent analysis phase. As recruiting within each cell of the quota structure will be essentially random, distributions of these ancillary attributes are expected to approximate those of the national population within each sample stratum.

Please note that for respondents in Alabama, Alaska, New Jersey, New York, and Utah, the minimum age to participate will be 19 (as opposed to 18 for the rest of the states) as per states' legal tobacco age.

There will be 12 unique quota cells defined by the participant's tobacco usage and the stimuli reviewed during the survey experience. Each of these sub-quotas will collect 1,100 completed interviews set to match the census criteria listed above (gender, age, region, ethnicity and income). The 12 cells are defined as follows:

<b>Test/Control Cells</b>	<b>Sample Size</b>	<b>Warning Label Shown</b>
Tobacco user Control Cell 1	1,100	WARNING: This product can cause mouth cancer
Non-tobacco user Control Cell 1	1,100	WARNING: This product can cause mouth cancer
Tobacco user Control Cell 2	1,100	WARNING: This product can cause gum disease and tooth loss
Non-tobacco user Control Cell 2	1,100	WARNING: This product can cause gum disease and tooth loss
Tobacco user Control Cell 3	1,100	WARNING: This product is not a safe alternative to cigarettes
Non-tobacco user Control Cell 3	1,100	WARNING: This product is not a safe alternative to cigarettes
Tobacco user Control Cell 4	1,100	WARNING: Smokeless tobacco is addictive
Non-tobacco user Control Cell 4	1,100	WARNING: Smokeless tobacco is addictive
Tobacco user Test Cell 5	1,100	WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes
Non-tobacco user Test Cell 5	1,100	WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes
Tobacco user Test Cell 6	1,100	WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes
Non-tobacco user Test Cell 6	1,100	WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes

Rationale for Monadic Research Design

Since the objective of the proposed research is only to understand the effect of marketing a Swedish Snus with a modified warning label and not to understand appropriate verbiage for such warning label, a quantitative research approach has been adopted. This research will allow us to determine, with statistical validity, the effects of marketing the product with existing and modified warning labels on tobacco use behavior and understanding and perception of Swedish Snus on current tobacco users and non-users of tobacco products.

Swedish Match believes that the most appropriate method to test the warning labels (both proposed and existing) is to use a monadic research design. Although using a sequential monadic design would help to lower the overall sample size and hence, the cost of the proposed research, such a design would most likely taint the likelihood to use and perception of individual health risks of the tobacco product (Swedish Snus) as a result of potential interactions between different warning labels shown to survey participants. A monadic design allows us to assess the effects of a particular warning label individually, without any undesirable lingering effects of seeing one particular warning label after another. A monadic design also best simulates the real-world scenario, as consumers will only see one warning label on a package of the product.

#### Justification for Large Sample Size

The proposed sample size of  $n=13,200$  (1,100 in each of 12 cells) is large compared to previous Swedish Match studies. Key justifications for the expanded sample size include:

- I. FDA's guidance requires the research to evidence the *absence* of certain characteristics (such as warning labels that are misleading or indicate negative effects among various population subgroups). As such, positions adopted from the research would take the form of multiple null hypotheses that are not rejected at stated probabilities of type I error. Due to this structure, Swedish Match sought to raise the power of statistical tests as much as feasible, in order to be as sensitive as possible in the identification of such negative effects. In short, if there is an undesirable effect of a particular warning label, Swedish Match wanted to maximize (within reason) the probability that this would be recognized.
- II. Swedish Match wanted to ensure that key non-quota subgroups within each cell would be sufficiently represented to permit statistically meaningful examinations. For example, with the proposed sample sizes, we would expect to see approximately 330 respondents designated as minorities (Black, non-Hispanic, Hispanic, AI/AN non-Hispanic, Asian non-Hispanic, Multiple race non-Hispanic) in each cell.

Since low-income household as a subgroup is of a particular interest to the FDA, a sample size of 1,100 per cell ensures that there will be approximately 528 respondents who could be designated to belong to a low-income household.

However we expect fewer than 17 pregnant women per cell. If pregnant women, as a subgroup, are another subgroup of interest to the FDA, we will set a quota of at least a 100 for pregnant women within each cell.

- III. Swedish Match wanted to comply with both the specific regulatory requirements, but also with the broad intent of the regulatory effort. We believe that an expanded sample size contributes to that goal.

There should be no legitimate concerns about potential “backdoor marketing” raised by the large sample size, not only because of the logical justifications of the expanded sample (above), but also due to the fact that if backdoor marketing *were* an objective, the proposed sample size would be markedly inadequate. Swedish Match considers that its highest likelihood of future snus sales will come from approximately 40 million smokers; it would not be reasonable for us to risk our credibility and reputation to address 13,200 individuals.

### Research Flow

The following provides a summary of the research flow. Further details of specific questions, wording, and logic will follow in the next sections.

1. Qualification screeners and introductory survey measures
  - I. Validation of gender, age, ethnicity, income and place of residence (U.S. Census regions)
  - II. Tobacco category involvement

This section serves as a validation of known respondent information and as the instrument to screen respondents for target sample criteria. Once these initial qualifications are met, the respondent will be allowed to continue with the survey.
2. Exploration of attitudes, awareness, and understanding
  - I. Gain understanding of respondent awareness of the different tobacco products, health risks and overall tobacco product usage
  - II. Collect and measure respondent feedback regarding their overall attitudes toward the tobacco category
  - III. Gain a preliminary assessment of consumer understanding of topics currently affecting the smoking category (e.g., public smoking bans, higher state taxes, change in package warnings)

This section establishes baselines for attitudes, awareness, and knowledge characteristics prior to the potential influence of exposure to the research stimuli on these factors.

3. Category participation and intention questions

- I. Question batteries designed to discern, identify and analyze similarities and differences pertaining to various relevant topics (category entry, cessation attempts, quitting history, future in category, etc.)

This section establishes usage and intention baselines prior to the potential influence of exposure to the research stimuli on these factors.

4. Exposure to test and control warning labels

- I. Survey participants in each cell will only be exposed to only one warning label.
- II. Collect quantitative, closed ended responses across the following metrics:

- I. Understanding of the warning labels

- II. Perception of health risks

- a. Perception of health risks of the tobacco product upon exposure to the warning label;
      - b. Perception of health risks of the tobacco product upon exposure to the warning label relative to other tobacco products, including those within the same class of products;
      - c. Consumer beliefs about the health risks of using the product relative to cessation aids; and
      - d. Consumer beliefs about the risks of using the product relative to quitting all tobacco use.

- III. Credibility of the warning label

- IV. Product usage – collect quantitative, closed ended responses on “Likelihood to use the product” for current tobacco users, including imminent quitters, and non-users of tobacco products (former and non-users of tobacco products):

- a. Likelihood that current tobacco user will start using the product;
      - b. Likelihood that current tobacco user will use the product in conjunction with other tobacco products;
      - c. Likelihood that tobacco user who may have otherwise quit smoking will instead use the product;
      - d. Likelihood that the user will use the product as intended or designed;

- e. The likelihood that non-user of tobacco products will initiate use of the tobacco product;
  - f. The likelihood that former tobacco users who adopt the tobacco product will switch to other tobacco products that present higher levels of individual health risk; and
  - g. The likelihood that former tobacco users will re-initiate use with the tobacco product.
- III. Each metric will be presented in the form of a 7-point scalar, anchored at each end and at the midpoints.

I. This questionnaire design will allow each respondent to provide feedback on the warning label assigned to that particular cell.

II. Ancillary demographic questions

This questionnaire design will allow each respondent to respond to additional profiling questions that will aid in characterizing the sample participants (e.g., employment, education level, household income, number of children in the household).

Questionnaire Administration and Format

Each respondent will be given a survey URL hyperlink that will connect the respondent to the online survey.

All questions except zip code will be presented in the form of a pick list or response buttons format to permit point-and-click answering. The zip code will be provided as a numeric open end question. The zip code provided by the survey participant will be used to determine his/her geographical categorization which, in turn will be used to balance the sample to the census regions.

The responses in each pick list or response button will be mutually exclusive and collectively exhaustive. The sequence of responses in the pick list will be rotated to avoid presentation order bias, unless there is a compelling reason to the contrary (e.g., the pick list being inherently ordinal in nature, such as “age”).

For the majority of questions, pick lists will be presented as fully detailed (i.e., each possible selection having its own unique description). An example of a fully detailed pick list is as follows:

[Q23]  
[Question type=single select grid]

## SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Thinking about the personal health risks associated with using snus compared to the personal health risks associated with using each of the following products, would you say that...

Columns

- a. Snus is much more harmful
- b. Snus is somewhat more harmful
- c. Snus is equally as harmful
- d. Snus is somewhat less harmful
- e. There is no personal health risk associated with using snus
- f. Don't know/not sure

Another key exception to the fully detailed format is the set of statement questions, which will be presented as 7-point scalars anchored at each. An example is as follows:

[Q55]

[Question type=radio button]

Show image of selected package

Having seen the warning label on the snus package, using the scale below, please indicate how easy or difficult is it to understand the **meaning** of the warning label on the package you just viewed.

Show the numbers in the answer choices

1. The meaning of the warning label is **very difficult** to understand
- 2.
- 3.
- 4.
- 5.
- 6.
7. The meaning of the warning label is **very easy** to understand

[Q23]

[Question type=single select grid]

Thinking about the personal health risks associated with using snus compared to the personal health risks associated with using each of the following products, would you say that...

Columns

- a. Snus is much more harmful

- b. Snus is somewhat more harmful
- c. Snus is equally as harmful
- d. Snus is somewhat less harmful
- e. There is no personal health risk associated with using snus
- f. Don't know/not sure

Rows- **Rotate- Only show those checked in Q8a (only show products aware of)**

Please note that in the above example, rows will be rotated but not the columns.

The above examples present the format for the “ease of understanding” and “perception of health risks of Swedish snus upon exposure to the warning label” metrics.

The other metrics are anchored as follows:

1) Perceived comparison of harm to quitting all tobacco

- a. Using snus is much more harmful to my health than if I quit using tobacco altogether
- b. Using snus is only somewhat more harmful to my health than if I quit using tobacco altogether
- c. Using snus poses no risk to my health – it's no different than if I quit using tobacco altogether
- d. Don't know/Not sure

2) Believability of warning label

- 1. The warning label is **not at all** believable
- 2.
- 3.
- 4.
- 5.
- 6.
- 7. The warning label is **extremely** believable

3) Likelihood to use based on information in warning label

- 1. I would **not at all** be likely to use snus
- 2.
- 3.
- 4.
- 5.
- 6.
- 7. I would be **extremely likely** to use snus

4) Likelihood of switching to other tobacco products instead of using snus

1. I definitely do **not** plan to start using this product again
- 2.
- 3.
- 4.
- 5.
- 6.
7. I definitely plan to start using this product again

5) Likelihood of using other tobacco products in addition to using snus

1. I would **not at all be likely** to use snus in addition to this product
- 2.
- 3.
- 4.
- 5.
- 6.
7. I would be **extremely likely** to use snus in addition to this product

Of particular interest are the questions that will categorize a respondent into the different “tobacco use” categories. We will therefore discuss these further.

The first of these questions presented to the potential respondent is:

[Q8]

[Question type= check boxes, rotate]

Do you **currently use, or have you ever used (even if only once or twice)** any of the following products?

- a. Tobacco product(s)
- b. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- c. Energy Drinks
- d. Liquor
- e. Beer
- f. None of the above **<mutuallyexclusive><anchor>**

If a potential respondent does not select “Tobacco product(s)” then that respondent is classified as a “non-user.”

The next question asks the respondents their awareness of different tobacco products. The responses from Q8a determine the list of products the respondents will see in Q9.

[Q8a]

[Question type= checkbox, min 1, rotate]

How you ever heard of the following tobacco products **before today**? Select all that apply.

- a) Cigarettes
- b) Snus (e.g. Camel snus, Marlboro snus, etc.)
- c) Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- d) Cigarillos
- e) Cigars
- f) Pipe Tobacco
- g) Loose Leaf chewing tobacco
- h) Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- i) E-cigarettes
- j) None of the above <mutuallyexclusive><anchor>

The next question is:

*Listed below are several different types of tobacco products. Please indicate how frequently you use each of these products.*

[Q9]

[Question type= single-select grid – randomize rows]

Listed below are several different types of tobacco products. Please indicate how frequently you use each of these products.

Columns:

1. I **currently use** this **daily**
2. I **currently use** this **at least once a week**
3. I **currently use** this **at least once a month**
4. I **currently use** this **less often than once a month**
5. I am a **former regular user** of this product (**previously used at least once a week**)
6. I am a **former occasional user** of this product (**previously used less often than once a week**)
7. I **tried** this product, but **didn't like it** and **never used it again**
8. I have **never** used this product

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Rows:

- a. Cigarettes **Hide if 'Tobacco products' is unchecked in Q8 OR cigarettes is unchecked in Q8a**
- b. Snus (e.g. Camel snus, Marlboro snus, etc.) **Hide if 'Tobacco products' is unchecked in Q8 OR snus is unchecked in Q8a**
- c. Moist Snuff (e.g. Copenhagen, Grizzly, etc.) **Hide if 'Tobacco products' is unchecked in Q8 OR moist snuff is unchecked in Q8a**
- d. Cigarillos **Hide if 'Tobacco products' is unchecked in Q8 OR cigarillos is unchecked in Q8a**
- e. Cigars **Hide if 'Tobacco products' is unchecked in Q8 OR cigars is unchecked in Q8a**
- f. Pipe Tobacco **Hide if 'Tobacco products' is unchecked in Q8 OR pipe tobacco is unchecked in Q8a**
- g. Loose Leaf chewing tobacco **Hide if 'Tobacco products' is unchecked in Q8 OR loose leaf chewing tobacco is unchecked in Q8a**
- h. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum) **Hide if 'Nicotine Replacement Products' is unchecked in Q8 OR nicotine replacement products is unchecked in Q8a**
- i. E-cigarettes **Hide if 'Tobacco products' is unchecked in Q8 OR e-cigarettes is unchecked in Q8a**

As mentioned earlier in the document, for the purpose of this study, a current tobacco user is an adult who uses any type of tobacco product on a daily basis. The research will also be conducted among former tobacco users (former regular tobacco users, former occasional tobacco users, and occasional triers) and non-tobacco users to understand the effect of the modified warning label on tobacco use behavior of non-users of tobacco products. Each respondent will fall in one of the following categories:

- I. Current Tobacco Users - Use any type of tobacco product on a daily basis (Q9, Column 1, Rows a-h)
- II. Non-Tobacco Users – A non-tobacco user can be one of the following:
  - i. Former regular tobacco users –  
  
Do not currently use any tobacco product (did not select column 1, 2 or 3 for any row a through h in Q9)  
  
AND  
  
Used at least one tobacco product regularly in the past (selected column 4 for any row a through i in Q9)

AND

Have not used a tobacco product during the past 12 months (selected column e through i in Q9a)

ii. Former occasional tobacco users –

Do not currently use any tobacco product (did not select column 1, 2 or 3 for any rows a through h in Q9)

AND

Have not used any tobacco products regularly in the past (did not select column 4 for any rows a through h in Q9)

AND

Used at least one tobacco product occasionally in the past (selected column 5 for any rows a through h in Q9)

AND

Have not used a tobacco product during the past 12 months (selected column e through i in Q9a)

v. Occasional triers –

Selected row 7 for one of more of the columns a-h in Q9

iii. Never user –

Did not select option 'a' in Q8

Note that the categories are not collectively exhaustive. We have defined the categories this way to strengthen potential contrasts and to minimize confounding effects of filtering by respondents:

- I. Potential respondents who currently use tobacco products less frequently than daily are not included in the 'current tobacco users' groups
- II. Potential respondents who have quit within the previous 12 months are not included in the sample

- III. Potential respondents who formerly used tobacco products less frequently than weekly are not included in the sample

The identification of imminent quitters is a critical key classification. This classification can be problematic due to the strong tendency of respondents to rationalize intentions (along the lines of “New Year’s Resolution Syndrome”). The primary determinant of this classification will be based on self-categorization as a result of the following question:

[Q28] Ask only for “Current Tobacco users”

[Question type=single select grid, rotate, required]

How likely are you to attempt to **quit** using the following product(s) **within the next month**?

Columns

- a. Definitely will attempt to quit
- b. Most likely will attempt to quit
- c. Possibly will attempt to quit
- d. Most likely will not attempt to quit
- e. Definitely will not attempt to quit

[Q30] Ask only for “Current Tobacco Users”

[Question type=single select grid, rotate, required]

How likely are you to attempt to **reduce** your use of the following product(s) **within the next month**?

- a. Definitely will attempt to reduce
- b. Most likely will attempt to reduce
- c. Possibly will attempt to reduce
- d. Most likely will not attempt to reduce
- e. Definitely will not attempt to reduce

If respondent selects a top 3-box answer in Q28 OR 30, set a hidden question to categorize them as a “likely quitter/reducer”. If they are not top 3-box in either question, set them as “Not a Likely quitter/reducer”. This is for analysis purposes only.

Visual examples of the on-line quantitative stimuli presentations described in detail in the original proposal include:

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4. If you compare the health effects of using snus with moist snuff, do you think that using snus is...

- Snus is more harmful than using moist snuff
- Snus is equally as harmful as using moist snuff
- Snus is somewhat less harmful than using moist snuff
- Snus is much less harmful than using moist snuff
- There is no risk associated with using snus

Next Question

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5. Smokers can have different motives for using snus or moist snuff. On a scale where 1 is "agree completely" and 5 is "do not agree at all", how would you agree to the following statements?

I use or have used snus or moist snuff...

	1- Agree completely	2	3- Neither agree nor disagree	4	5- Disagree completely
a) ... to reduce consumption of cigarettes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) ... to quit smoking completely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) ... as a complement to cigarettes where smoking is not allowed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Next Question

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6. We now would like you to look closely at these groups of statements regarding tobacco products and their impact on health. For each statement, please indicate, using the scale shown, on how Precise or Vague each statement is to you.

	1- The statement is Very Clear and easy to understand	2	3	4	5	6	7- The statement is Very Vague and difficult to understand
a) Statement 3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Statement 2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Statement 1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Next Question

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2. On a scale of 1 to 7 where 1 is "Very clear and easy to understand" and 7 is "Very vague and difficult to understand", how clear or vague is the warning label on the package you just viewed?

[Click here to review the package again.](#)

- 1 - The warning label is very clear and easy to understand
- 2
- 3
- 4
- 5
- 6
- 7 - The warning label is very vague and difficult to understand

Submit

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The complete questionnaire for the research is shown in [Appendix D](#).

### d. Hypotheses

Following alternative hypothesis will be tested from the results of this research:

- I. There are significant differences in understanding and perception of individual health risk between test and control cells for current tobacco users
- II. There are significant differences in understanding and perception of individual health risk between test and control cells for non-users of tobacco products
- III. There is significant difference in likelihood to use between test and control cells for current tobacco users
- IV. There is significant difference in likelihood to use between test and control cells for non-users of tobacco products
- V. There is significant difference in likelihood to switch to other tobacco products between test and control cells for current tobacco users
- VI. There is significant difference in likelihood to switch to other tobacco products between test and control cells for non-users of tobacco products
- VII. There is significant difference in likelihood to use other tobacco products in conjunction with the product (snus) between test and control cells for current tobacco users
- VIII. There is significant difference in likelihood to use other tobacco products in conjunction with the product (snus) between test and control cells for non-users of tobacco products
- IX. There is significant difference in likelihood to quit using tobacco products altogether when using the product (snus) between current tobacco users in test and control cells

- X. There is no trend in differences between any metric based on age (i.e., that would result in significant extrapolated inferences of undesirable effects among minors).

e. Quantitative Analysis Procedures

The primary analysis methodology will be a multivariate analysis of variance (MANOVA) to determine the presence of statistical differences and interactions among three factor sets:

- I. One warning label
- II. 13 metrics as described under Research Flow section on [page 14](#) of this protocol
- III. 3 subgroups

At the minimum the subgroups will include:

- I. Current tobacco users
  - a. Imminent quitter vs. non-imminent quitter
  - b. Attempted to quit in the past vs. never attempted to quit
- II. Non-tobacco users
  - a. Former regular tobacco users
  - b. Former occasional tobacco users
  - c. Never-users of tobacco

Further, within each subgroup statistically significant differences, at alpha level of .05 and 0.10, will be noted. Of particular interest will be metric comparisons across key subgroups and across varying levels of demographic and attitudinal covariates.

In addition to the core MANOVA analysis methodology, a variety of other analysis techniques may be used.

Examples of analyses that we will likely attempt include:

- a. Multivariate modeling to attempt to estimate each metric based on the broad range of gathered data on demographics, attitudes, and behaviors. These are intended to provide the most integrated evaluation of the relationships of metric values and the range of covariates collected. In all likelihood, these models will be either multiple regression models or logistic regression models, depending on the nature of the data.
- b. Predictive multivariate models that contain a significant own-coefficient or interaction-coefficients for age. These models, if forthcoming, could be used

to estimate key responses for hypothetical underage subjects without having to include underage respondents in the sample.

f. Key Strengths and Weaknesses of the Research Design

There are several potential strengths and weaknesses that relate to contextual aspects of the research. For example, the research expertise and category experience of the research provider are strengths of this research. This expertise will help mitigate the tendency inherent in socially unacceptable categories (such as tobacco use) for respondents to filter responses in a non-random manner to a higher degree than “normal,” which may increase systematic bias in certain responses.

Key strengths and weaknesses specifically of the research design include the following:

I. Key strengths

- a) Large sample sizes
- b) On-line survey methodology
- c) High degree of control of sample characteristics
- d) Depth of diagnostic information gathered

II. Key weaknesses

- a) Inherent nature of research objectives, which effectively require the demonstration of the absence of certain effects
- b) Small sample size for some of the subgroups such as, pregnant women

## **Appendix A**

### List of warning labels

#### Control Cells:

- I. WARNING: This product can cause mouth cancer
- II. WARNING: This product can cause gum disease and tooth loss
- III. WARNING: This Product is not a safe alternative to cigarettes
- IV. WARNING: Smokeless tobacco is addictive

#### Test Cells:

- I. WARNING: No tobacco product is safe, but this product presents a substantially lower risk to health than cigarettes
- II. WARNING: No tobacco product is safe, but this product presents a lower risk to health than cigarettes

**Appendix B:**

Current tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Current tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Current tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Non tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Non tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Non tobacco user control cell 1

WARNING: This product can cause mouth cancer.



Current tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Current tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Current tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Non tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Non tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Non tobacco user control cell 2

WARNING: This product can cause gum disease and tooth loss.



Current tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Current tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Current tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Non tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Non tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Non tobacco user control cell 3

WARNING: This product is not a safe alternative to cigarettes.



Current tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



Current tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



Non tobacco user control cell 4

WARNING: Smokeless tobacco is addictive.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents a substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 1

WARNING: No tobacco product is safe but this product presents substantially lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Current tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

Non tobacco user test cell 2

WARNING: No tobacco product is safe but this product presents lower risks to health than cigarettes.



## Appendix C

### Draft Questionnaire for the Research

#### Screeners

[Q1]

[Question type=statement]

Thanks for taking the time to participate in our survey. It will only take a few minutes to complete. All of your responses will be kept strictly confidential and will only be used for research purposes. Thank you in advance for your thoughtful input.

[Q2]

[Question type=radio button]

What is your gender?

- a. Male
- b. Female

[Q3]

[Question type=drop down]

In which state do you currently live?

- a. Alabama
- b. Alaska
- c. Arizona
- d. Arkansas
- e. California
- f. Colorado
- g. Connecticut
- h. Delaware
- i. District of Columbia
- j. Florida
- k. Georgia
- l. Hawaii
- m. Idaho
- n. Illinois
- o. Indiana
- p. Iowa
- q. Kansas
- r. Kentucky
- s. Louisiana
- t. Maine
- u. Maryland
- v. Massachusetts

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- w. Michigan
- x. Minnesota
- y. Mississippi
- z. Missouri
- aa. Montana
- bb. Nebraska
- cc. Nevada
- dd. New Hampshire
- ee. New Jersey
- ff. New Mexico
- gg. New York
- hh. North Carolina
- ii. North Dakota
- jj. Ohio
- kk. Oklahoma
- ll. Oregon
- mm. Pennsylvania
- nn. Rhode Island
- oo. South Carolina
- pp. South Dakota
- qq. Tennessee
- rr. Texas
- ss. Utah
- tt. Vermont
- uu. Virginia
- vv. Washington
- ww. West Virginia
- xx. Wisconsin
- yy. Wyoming
- zz. I do not live in the U.S. <Term Point>

[Q4]

[Question type= numeric open end max 5/min 5: Geography Tool]

What is your 5 digit zip code?

[Q5]

[Question type=drop down]

What is your age?

- a. Under 18 <Term Point>
- b. 18 <Term Point if Q# = Alabama, Alaska, New Jersey, Utah, New York>
- c. 19
- d. 20
- e. 21
- f. 22

g. 23  
h. 24  
i. 25  
j. 26  
k. 27  
l. 28  
m. 29  
n. 30  
o. 31  
p. 32  
q. 33  
r. 34  
s. 35  
t. 36  
u. 37  
v. 38  
w. 39  
x. 40  
y. 41  
z. 42  
aa. 43  
bb. 44  
cc. 45  
dd. 46  
ee. 47  
ff. 48  
gg. 49  
hh. 50  
ii. 51  
jj. 52  
kk. 53  
ll. 54  
mm. 55  
nn. 56  
oo. 57  
pp. 58  
qq. 59  
rr. 60  
ss. 61  
tt. 62  
uu. 63  
vv. 64

ww. 65+

[Q6]

[Question type=radio button]

What is your household income per year?

- a. Under \$22,000
- b. \$22,000 but less than \$34,999
- c. \$35,000 but less than \$44,999
- d. \$45,000 but less than \$59,999
- e. \$60,000 but less than \$74,999
- f. \$75,000 but less than \$99,999
- g. \$100,000 or more

[Q7]

[Question type=checkbox, min 1]

Which of the following would describe your race? Select all that apply.

- a. White
- b. Black or African American
- c. Asian
- d. American Indian or Alaska Native
- e. Native Hawaiian or Other Pacific Islander
- f. Other (please specify) <specify>

[Q7a]

[Question type=radio button]

How would you describe your ethnicity?

- a. Hispanic or Latino
- b. Not Hispanic or Latino

[Q8]

[Question type= check boxes, rotate]

Do you **currently use, or have you ever used (even if only once or twice)** any of the following products?

- g. Tobacco product(s)
- h. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- i. Energy Drinks
- j. Liquor
- k. Beer
- l. None of the above <mutuallyexclusive><anchor>

[Q8a]

[Question type= checkbox, min 1, rotate]

How you ever heard of the following tobacco products **before today**? Select all that apply.

- k) Cigarettes
- l) Snus (e.g. Camel snus, Marlboro snus, etc.)
- m) Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- n) Cigarillos
- o) Cigars
- p) Pipe Tobacco
- q) Loose Leaf chewing tobacco
- r) Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- s) E-cigarettes
- t) None of the above <mutuallyexclusive><anchor>

**If “a- Tobacco products and b- Nicotine Replacement Products” are both unchecked in Q8, skip to instructions before Q12**

[Q9]

[Question type= single-select grid – randomize rows]

Listed below are several different types of tobacco products. Please indicate how frequently you use each of these products.

Columns:

- 9. I **currently use** this **daily**
- 10. I **currently use** this **at least once a week**
- 11. I **currently use** this **at least once a month**
- 12. I **currently use** this **less often than once a month**
- 13. I am a **former regular user** of this product (**previously used at least once a week**)
- 14. I am a **former occasional user** of this product (**previously used less often than once a week**)
- 15. I **tried** this product, but **didn’t like it** and **never used it again**
- 16. I have **never** used this product

Rows:

- j. Cigarettes **Hide if ‘Tobacco products’ is unchecked in Q8 OR cigarettes is unchecked in Q8a**
- k. Snus (e.g. Camel snus, Marlboro snus, etc.) **Hide if ‘Tobacco products’ is unchecked in Q8 OR snus is unchecked in Q8a**

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- l. Moist Snuff (e.g. Copenhagen, Grizzly, etc.) Hide if 'Tobacco products' is unchecked in Q8 OR moist snuff is unchecked in Q8a
- m. Cigarillos Hide if 'Tobacco products' is unchecked in Q8 OR cigarillos is unchecked in Q8a
- n. Cigars Hide if 'Tobacco products' is unchecked in Q8 OR cigars is unchecked in Q8a
- o. Pipe Tobacco Hide if 'Tobacco products' is unchecked in Q8 OR pipe tobacco is unchecked in Q8a
- p. Loose Leaf chewing tobacco Hide if 'Tobacco products' is unchecked in Q8 OR loose leaf chewing tobacco is unchecked in Q8a
- q. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum) Hide if 'Nicotine Replacement Products' is unchecked in Q8 OR nicotine replacement products is unchecked in Q8a
- r. E-cigarettes Hide if 'Tobacco products' is unchecked in Q8 OR e-cigarettes is unchecked in Q8a

[Q9a] Only show if respondent **does not currently use** cigarettes, snus, moist snuff, cigarillos, cigars, pipe tobacco, loose leaf chewing tobacco or hookah (did not select columns 1-4 for any of these products), but is a former user of any of these same products (selected columns 5 or 6)

[Question type=radio button]

How long ago was the **last time** you used a tobacco product?

- a. Less than 1 month ago
- b. Between 1 and 2 months ago
- c. Between 3 and 6 months ago
- d. Between 7 and 12 months ago
- e. 1-2 years ago
- f. 3-4 years ago
- g. 5-10 years ago
- h. More than 10 years ago

Respondent qualifications fall as follows:

**Current Tobacco Users**= Currently use **any type** of tobacco Daily or At least once a week (Q9, Column 1-2, Rows a-h)

**Non-Tobacco Users** = one of the following:

**Former regular tobacco users** –

- Do not currently use any tobacco in Q9 (did not select column 1, 2, 3 or 4 for ANY rows a-h in Q9)
- AND Used at least one product regularly in the past (selected column 5 for ANY rows a-h in Q9)
- AND Have not used a tobacco product in the past 12 months (Q9a is answers e-h)

**Former occasional tobacco users** –

- Do not currently use any tobacco in Q9 (did not select column 1, 2, 3 or 4 for ANY rows a-h in Q9)
- AND Have not used any tobacco products regularly in the past (did NOT select column 5 for ANY rows a-h in Q9)
- AND Used at least one product occasionally in the past (selected column 6 for ANY rows a-h in Q9)
- AND Have not used a tobacco product in the past 12 months (Q9a is answers e-h)

**Triers only** –

- Do not currently use any tobacco in Q9 (did not select column 1, 2, 3 or 4 for ANY rows a-h in Q9)
- AND Are not former regular or occasional users of any tobacco in Q9 (did not select columns 5 or 6 for ANY rows a-h in Q9)
- AND selected column 7 for at least one row a-h in Q9

**Never used tobacco**- Did not check tobacco at Q8

We will have **one set of quotas for non-tobacco users (specific quotas will NOT be set to break out for former regular/occasional, triers or never used)**. However, we will at least track how many are in each group.

If respondent does not qualify for one of the above groups, terminate.

Category Usage/History

**Q12 REMOVED**

**If respondent did not check “Tobacco products” in Q8, go directly to Q21**

[Q13] Only show products currently using in Q9 (selected columns 1, 2, 3 or 4)

[Question type=checkbox, min 1, rotate]

And, what tobacco product do you use **most often**? (If you use more than one type of tobacco product with similar frequency, please choose all that apply.)

- a. Cigarettes
- b. Snus (e.g. Camel snus, Marlboro snus, etc.)
- c. Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- i. E-Cigarettes

[Q14] Only show products ever used in Q9 (selected columns 1-6)

[Question type=radio button, rotate]

Which tobacco product did you **first** start using?

- a. Cigarettes
- b. Snus (e.g. Camel snus, Marlboro snus, etc.)
- c. Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes

[Q15] Only show if respondent currently or previously smoked regularly in Q9 (columns 1 or 5 for cigarettes)

[Question type=drop down]

At what age did you start smoking cigarettes regularly?

**Only show ages equal to or less than their current age**

- a. Under 13
- b. 13
- c. 14
- d. 15

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

e.	16	
f.	17	
g.	18	
h.	19	
i.	20	
j.	21	
k.	22	
l.	23	
m.	24	
n.	25	
o.	26	
p.	27	
q.	28	
r.	29	
s.	30	
t.	31	
u.	32	
v.	33	
w.	34	
x.	35	
y.	36	
z.	37	
aa.	38	
bb.	39	
cc.	40	
dd.	41	
ee.	42	
ff.	43	
gg.	44	
hh.	45	
ii.	46	
jj.	47	
kk.	48	
ll.	49	
mm.	50	
nn.	51	
oo.	52	
pp.	53	
qq.	54	
rr.	55	
ss.	56	
tt.	57	

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

uu.	58
vv.	59
ww.	60
xx.	61
yy.	62
zz.	63
aaa.	64
bbb.	65+

[Q16] Only show if respondent currently or previously smoked in Q9 (columns 1 - 6 for cigarettes)

[Question type=radio button, rotate]

When you (if current smoker show “smoke”/if former smoker show “smoked”) approximately how many packs of cigarettes (if current smoker show “do you”/if former smoker show “did you”) smoke **in a typical week?**

- a. Less than half a pack
- b. More than half, but less than 1 pack
- c. 1 pack
- d. 2 packs
- e. 3 packs
- f. 4 packs
- g. 5 packs
- h. 6 packs
- i. 7 packs
- j. 8 packs
- k. 9 packs
- l. 10 packs
- m. 11 packs
- n. 12 packs
- o. 13 packs
- p. 14 packs
- q. 15 packs
- r. 16 packs
- s. 17 packs
- t. 18 packs
- u. 19 packs
- v. 20 packs
- w. 21+ packs

[Q17] Only show if respondent currently or previously smoked in Q9 (columns 1 - 6 for cigarettes)

[Question type=radio button, rotate]

Which flavor of cigarettes (if current smoker show “do you”/if former smoker show “did you”) **typically** smoke?

- a. Regular
- b. Menthol
- c. Other (specify)<specify><anchor>
- d. Don't know<anchor>

[Q18] Only show if respondents currently or previously used MS in Q9 (columns 1-6 for MS)

[Question type=drop down]

At what age did you start using moist snuff (e.g. Copenhagen, Grizzly, etc.)?

Only show ages equal to or less than their current age

- a. Under 13
- b. 13
- c. 14
- d. 15
- e. 16
- f. 17
- g. 18
- h. 19
- i. 20
- j. 21
- k. 22
- l. 23
- m. 24
- n. 25
- o. 26
- p. 27
- q. 28
- r. 29
- s. 30
- t. 31
- u. 32
- v. 33
- w. 34
- x. 35
- y. 36
- z. 37
- aa. 38

bb.	39
cc.	40
dd.	41
ee.	42
ff.	43
gg.	44
hh.	45
ii.	46
jj.	47
kk.	48
ll.	49
mm.	50
nn.	51
oo.	52
pp.	53
qq.	54
rr.	55
ss.	56
tt.	57
uu.	58
vv.	59
ww.	60
xx.	61
yy.	62
zz.	63
aaa.	64
bbb.	65+

[Q19]

[Question type=radio button, rotate] Only show if respondents currently or previously used snus in Q9 (columns 1-5 for moist snuff)

Approximately how many cans of moist snuff (if current MS user show "do you"/if former MS user show "did you") use **in a typical week**?

- a. Less than half a can
- b. More than half, but less than 1 can
- c. 1 can
- d. 2 cans
- e. 3 cans
- f. 4 cans
- g. 5 cans
- h. 6 cans

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- i. 7 cans
- j. 8 cans
- k. 9 cans
- l. 10 cans
- m. 11 cans
- n. 12 cans
- o. 13 cans
- p. 14 cans
- q. 15 cans
- r. 16 cans
- s. 17 cans
- t. 18 cans
- u. 19 cans
- v. 20 cans
- w. 21+ cans

[Q19a] Only show if respondents currently or previously used MS in Q9 (columns 1-6 for MS)

[Question type=radio button, rotate]

Which flavor of moist snuff (if current MS user show “do you”/if former MS user show “did you”)

**typically** use?

- a. Wintergreen
- b. Peach
- c. Natural
- d. Mint
- e. Cherry
- f. Straight
- g. Berry
- h. Apple
- i. Vanilla
- j. Other (specify)<specify><anchor>
- k. Don't know<anchor>

[Q20] Only show if respondents currently or previously used snus in Q9 (columns 1-6 for snus)

[Question type=drop down]

At what age did you start using snus (e.g. Camel snus, Marlboro snus, etc.)?

Only show ages equal to or less than their current age

- a. Under 13
- b. 13
- c. 14
- d. 15
- e. 16

f.	17	
g.	18	
h.	19	
i.	20	
j.	21	
k.	22	
l.	23	
m.	24	
n.	25	
o.	26	
p.	27	
q.	28	
r.	29	
s.	30	
t.	31	
u.	32	
v.	33	
w.	34	
x.	35	
y.	36	
z.	37	
aa.	38	
bb.	39	
cc.	40	
dd.	41	
ee.	42	
ff.	43	
gg.	44	
hh.	45	
ii.	46	
jj.	47	
kk.	48	
ll.	49	
mm.	50	
nn.	51	
oo.	52	
pp.	53	
qq.	54	
rr.	55	
ss.	56	
tt.	57	
uu.	58	

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

vv.	59
ww.	60
xx.	61
yy.	62
zz.	63
aaa.	64
bbb.	65+

[Q21] Only show if respondents currently or previously used snus in Q9 (columns 1-6 for snus)

[Question type=radio button, rotate]

Approximately how many cans of snus (if current snus user show “do you”/if former snus user show “did you”) use **in a typical week**?

- a. Less than half a can
- b. More than half, but less than 1 can
- c. 1 can
- d. 2 cans
- e. 3 cans
- f. 4 cans
- g. 5 cans
- h. 6 cans
- i. 7 cans
- j. 8 cans
- k. 9 cans
- l. 10 cans
- m. 11 cans
- n. 12 cans
- o. 13 cans
- p. 14 cans
- q. 15 cans
- r. 16 cans
- s. 17 cans
- t. 18 cans
- u. 19 cans
- v. 20 cans
- w. 21+ cans

[Q21a] Only show if respondents currently or previously used snus in Q9 (columns 1-6 for snus)

[Question type=radio button]

Which flavor of snus (if current snus user show “do you”/if former snus user show “did you”) **typically** use?

## SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- a. Mint (any type of mint variation)
- b. Other (anything that is not some type of mint flavor)(specify)<specify>

### Current Tobacco Health Opinions

[Q22]

[Question type=statement]

Please let us know your opinion of the tobacco and nicotine products specified in the following questions.

If you used snus every day, how would you rate the risks that snus posed to your health? Please use the scale below when providing your answer.

1. There is no health risk associated with using snus
- 2.
- 3.
- 4.
- 5.
- 6.
7. Using snus poses every day extremely harmful health risks
8. Don't know/Not sure

[Q23]

[Question type=single select grid]

Thinking about the personal health risks associated with using snus compared to the personal health risks associated with using each of the following products, would you say that...

### Columns

- g. Snus is much more harmful
- h. Snus is somewhat more harmful
- i. Snus is equally as harmful
- j. Snus is somewhat less harmful
- k. There is no personal health risk associated with using snus
- l. Don't know/not sure

Rows- **Rotate- Only show those checked in Q8a (only show products aware of)**

Cigarettes

Moist snuff

Cigarillos

Cigars

Pipe Tobacco

Loose Leaf chewing tobacco

E-Cigarettes

Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q24]

[Question type=radio button]

Which of the following statements best describes how you feel about the impact that using snus would have on your personal health risks?

- a. Using snus is much more harmful to my health than if I quit using tobacco altogether
- b. Using snus is only somewhat more harmful to my health than if I quit using tobacco altogether
- c. Using snus poses no risk to my health – it's no different than if I quit using tobacco altogether
- d. Don't know/Not sure

Rotate the order of Q25-Q25d to reduce bias

[Q25]

[Question type=single select grid]

Do you think that the following increase the risk for any type of cancer?

Columns:

- a. Yes
- b. No
- c. Do not know

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q25a]

[Question type=single select grid]

Do you think that the following increase the risk for lung cancer?

Columns:

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- a. Yes
- b. No
- c. Do not know

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q25b]

[Question type=single select grid]

Do you think that the following increase the risk for lung disease? By lung disease, we mean diseases like emphysema, COPD/chronic bronchitis and asthma.

Columns:

- a. Yes
- b. No
- c. Do not know

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q25c]

[Question type=single select grid]

Do you think that the following increase the risk for mouth cancer?

Columns:

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- a. Yes
- b. No
- c. Do not know

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q25d]

[Question type=single select grid]

Do you think that the following increase the risk for heart disease? By heart disease, we mean diseases like clogged arteries/artery disease, angina, heart attack or high blood pressure.

Columns:

- a. Yes
- b. No
- c. Do not know

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

NO Q26

[Q27]

[Question type=checkboxes, min 1, rotate]

## SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

[If respondent is current or former tobacco user, show: Which of the following impacted or influenced your tobacco usage habits in any way (e.g. changed tobacco products/brands, reduced or quit a tobacco consumption, avoided using tobacco, etc.)? ]

[If respondent is tobacco trier or never user, show: Which of the following impacted or influenced your reasons for **not using** tobacco regularly or occasionally? ]

Please check all that apply.

- a. Public bans on smoking in different areas
- b. Taxes on tobacco products
- c. Changes in warnings on tobacco product packages
- d. Information in the news or other media
- e. Warnings from the FDA (other than package warnings)
- f. Advice from your doctor/physician
- g. **Information** from a friend or family member
- h. **Influence/pressure** from family members or friends
- i. A personal health issue
- j. Fear of the impact of tobacco on the body
- k. Overall price of tobacco
- l. Change in taste/preference
- m. Advertisements
- n. Lifestyle change
- o. Other (please specify) <specify><anchor>
- p. None of the above <mutuallyexclusive><anchor>

[Q28] Ask only for "Current Tobacco users"

[Question type=single select grid, rotate, required]

How likely are you to attempt to **quit** using the following product(s) **within the next month?**

Columns

- f. Definitely will attempt to quit
- g. Most likely will attempt to quit
- h. Possibly will attempt to quit
- i. Most likely will not attempt to quit
- j. Definitely will not attempt to quit

Rows- Rotate – Only show those currently using in Q9 (columns 1-4)

- a. Cigarettes
- b. Snus (e.g. Camel snus, Marlboro snus, etc.)
- c. Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- d. Cigarillos
- e. Cigars

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco

NO Q29

[Q30] Ask only for “Current Tobacco Users”

[Question type=single select grid, rotate, required]

How likely are you to attempt to **reduce** your use of the following product(s) **within the next month**?

- f. Definitely will attempt to reduce
- g. Most likely will attempt to reduce
- h. Possibly will attempt to reduce
- i. Most likely will not attempt to reduce
- j. Definitely will not attempt to reduce

Rows- Rotate – Only show those currently using in Q9 (columns 1-4)

- a. Cigarettes
- b. Snus (e.g. Camel snus, Marlboro snus, etc.)
- c. Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco

If respondent selects a top 3 box answer in any row in Q28 OR 30, set a hidden question to categorize them as an “Imminent quitter/reducer”. If they are **not** top 3 box in **either** question, set them as “Not an Imminent quitter/reducer”. This is for analysis purposes only.

NO Q31-52

## WARNING LABEL EVALUATION

[Q53]

[Question type=statement]

You will now be presented with images of a package for a tobacco product called snus. Please review the package images closely, including the warning label. Afterwards, we will ask you a few questions about the product.

Respondents will be assigned to see 1 of 5 potential snus packages. 4 packages will have current warning labels (control) and 1 will have the test warning label. Each of the 5 cells must be balanced to reflect the total quota breakdown established for current and non-tobacco users for age, gender, region, income and ethnicity.

[Q54]

[Question type=statement]

Please review the image of the can below closely and then click "Next Question" whenever you are ready.

Expose respondents to randomly selected package

[Q55]

[Question type=radio button]

Show image of selected package

Having seen the warning label on the snus package, using the scale below, please indicate how easy or difficult is it to understand the meaning of the warning label on the package you just viewed.

Show the numbers in the answer choices

8. The meaning of the warning label is very difficult to understand
- 9.
- 10.
- 11.
- 12.
- 13.
14. The meaning of the warning label is very easy to understand

[Q55a]

[Question type=radio button]

Show image of selected package

Having seen the warning label on the snus package, using the scale below, please indicate how clear or vague is the meaning of the claim in the warning label of the package you just viewed.

Show the numbers in the answer choices

1. The description on the warning label is **very vague**
- 2.
- 3.
- 4.
- 5.
- 6.
7. The description on the warning label is **very clear**

[Q56]

[Question type=radio button]

Show image of selected package

After viewing the information in the warning label, how does the information you saw on the warning label **directly influence** your likelihood to use snus? Please indicate your likelihood to use this product using the scale below.

Show numbers in the scale

1. I would **not at all** be likely to use snus
- 2.
- 3.
- 4.
- 5.
- 6.
7. I would be **extremely likely** to use snus

If respondent selects rating of 1, 2 or 3, skip to Q61

[Q57] (Ask only current tobacco users who do NOT use snus – did not select Row b, columns 1-4 in Q9)

[Question type=single select grid]

Show image of selected package

After viewing the information in the warning label, how does the information you saw on the warning label **directly influence** your likelihood to use snus in addition to the following tobacco products? Please indicate your likelihood to use this product using the scale below.

Click here to review the images again. ([hyperlink to package image](#))

Show numbers in the scale

Columns

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

8. I would **not at all be likely** to use snus in addition to this product
- 9.
- 10.
- 11.
- 12.
- 13.
14. I would be **extremely likely** to use snus in addition to this product

Rows – Rotate- Only show those currently using in Q9 (Columns 1, 2, 3 or 4)

- a. Cigarettes
- b. Moist Snuff (e.g. Copenhagen, Grizzly, etc.)
- c. Cigarillos
- d. Cigars
- e. Pipe Tobacco
- f. Loose Leaf chewing tobacco
- g. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- h. E-cigarettes

[Q58] (Ask only current tobacco users who selected 4, 5, 6 or 7 in Q57 for any row)

[Question type=radio button]

Show image of selected package

You indicated that based on the information in the warning label, you would be likely to use snus in addition to the following products. What kind of an impact would snus usage have on your current use of the following tobacco products?

Columns

- a. I would use snus to reduce my usage of this product
- b. I would use snus to quit using this product
- c. I would use snus in addition to this product but it would not impact the amount of this product that I currently use
- d. Don't know/Not sure <Not Rotated>

Rows – Rotate- Only show those rated as 4, 5, 6 or 7 in Q57

- a. Cigarettes
- b. Moist Snuff
- c. Cigarillos
- d. Cigars
- e. Pipe Tobacco
- f. Loose Leaf chewing tobacco

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- g. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- h. E-cigarettes

[Q59] (Ask only Former tobacco users (regular or occasional) who do NOT currently use snus – did not select Row b, column 1-4 in Q9)

[Question type=single select grid]

Show image of selected package

How does the information you saw in the warning label **directly impact** your plan to start using the following tobacco products again? Please provide an answer using the scale below.

Columns Show the numbers in the columns

1. I definitely do **not** plan to start using this product again
- 2.
- 3.
- 4.
- 5.
- 6.
7. I definitely plan to start using this product again

Rows – Rotate- Only show those formerly used in Q9 (Columns 5 or 6)

- a. Cigarettes
- b. Moist Snuff
- c. Cigarillos
- d. Cigars
- e. Pipe Tobacco
- f. Loose Leaf chewing tobacco
- g. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- h. E-cigarettes

[Q60] (Ask only TRIERS or NEVER USERS)

[Question type=single select grid]

Show image of selected package

How does the information you saw on the warning label **directly impact** your plan to start using the following tobacco products? Please provide an answer using the scale below.

Columns Show the numbers in the columns

1. I definitely do **not** plan to start using this product

- 2.
- 3.
- 4.
- 5.
- 6.
7. I definitely plan to start using this product

Rows – Rotate

- a. Cigarettes
- b. Moist Snuff
- c. Cigarillos
- d. Cigars
- e. Pipe Tobacco
- f. Loose Leaf chewing tobacco
- g. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)
- h. E-cigarettes

[Q61]

[Question type=radio button]

Show image of selected package

How does the information you saw on the warning label **directly impact** how motivated you are to buy snus?

Show the numbers in the answer choices

1. Definitely would **discourage me** from purchasing snus
- 2.
- 3.
- 4.
- 5.
- 6.
7. Definitely would **motivate me** to purchase snus

NO Q62

[Q63]

[Question type= radio button]

Show image of selected package

How believable is the warning label on this package of snus?

Show the numbers in the answer choices

Columns:

1. The warning label is not at all believable
- 2.
- 3.
- 4.
- 5.
- 6.
7. The warning label is extremely believable

[Q64]

[Question type=radio button]

Show image of selected package

How does the information you saw on the warning label directly influence your perception of the risk that using snus every day would pose to your health? Please use the scale below.

1. There is no health risk associated with using snus
- 2.
- 3.
- 4.
- 5.
- 6.
7. Using snus poses every day extremely harmful health risks
8. Don't know/Not sure

[Q65]

[Question type=single select grid]

Show image of selected package

How does the information you saw on the warning label directly influence your perception of the personal health risks associated with using snus compared to the personal health risks posed by the tobacco products below?

Columns

- a. Snus is much more harmful
- b. Snus is somewhat more harmful
- c. Snus is equally as harmful
- d. Snus is somewhat less harmful
- e. There is no health risk associated with using snus
- f. Don't know/Not sure

Rows- Rotate Only show those checked in Q8a (only show products aware of)

- a. Cigarettes
- b. Moist snuff
- c. Cigarillos
- d. Cigars
- e. Pipe Tobacco
- f. Loose Leaf chewing tobacco
- g. E-Cigarettes
- h. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q66]

[Question type=radio button]

Show image of selected package

Now that you have seen the information in the warning label, which of the following statements best describes the impact you think using Snus would have on your personal health risks?

- a. Using snus is much more harmful to my health than if I quit using tobacco altogether
- b. Using snus is only somewhat more harmful to my health than if I quit using tobacco altogether
- c. Using snus poses no risk to my health – it's no different than if I quit using tobacco altogether
- d. Don't know/Not sure

Rotate the order of Q66a-Q66e to reduce bias

[Q66a]

[Question type=single select grid]

Show image of selected package

After viewing the information in the warning label, do you think that the following increase the risk for any type of cancer?

Columns:

- a. Yes
- b. No
- c. Don't know/not sure

Rows- Rotate

- a. Cigarettes

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q66b]

[Question type=single select grid]

Show image of selected package

After viewing the information in the warning label, do you think that the following increase the risk for lung cancer?

Columns:

- a. Yes
- b. No
- c. Don't know/not sure

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q66c]

[Question type=single select grid]

Show image of selected package

After viewing the information in the warning label, do you think that the following increase the risk for lung disease? By lung disease, we mean diseases like emphysema, COPD/chronic bronchitis and asthma.

Columns:

- a. Yes

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- b. No
- c. Don't know/not sure

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q66d]

[Question type=single select grid]

Show image of selected package

After viewing the information in the warning label, do you think that the following increase the risk for mouth cancer?

Columns:

- a. Yes
- b. No
- c. Don't know/not sure

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

[Q66e]

[Question type=single select grid]

Show image of selected package

## SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

After viewing the information in the warning label, do you think that the following increase the risk for heart disease? By heart disease, we mean diseases like clogged arteries/artery disease, angina, heart attack or high blood pressure.

Columns:

- a. Yes
- b. No
- c. Don't know/not sure

Rows- Rotate

- a. Cigarettes
- b. Moist snuff
- c. Snus
- d. Cigarillos
- e. Cigars
- f. Pipe Tobacco
- g. Loose Leaf chewing tobacco
- h. E-Cigarettes
- i. Nicotine Replacement Products (i.e. nicotine patches, nicotine gum)

Demographics

[Q67]

[Question type=checkboxes]

Do you diagnosed with and /or are being treated for any of the following medical conditions? Select all that apply.

- a. Clogged Arteries
- b. Coronary Artery Disease
- c. Carotid Artery Disease
- d. Peripheral Artery Disease
- e. Stable/ Unstable/ Crescendo angina
- f. Heart Attack / myocardial infarction / coronary
- g. Asthma
- h. High blood pressure
- i. High cholesterol
- j. COPD/chronic bronchitis
- k. Emphysema
- l. Lung cancer
- m. Oral cancer (gum, lip or throat)
- n. Gum disease (aside from cancer)
- o. Tooth loss/dental issues
- p. Other type of cardiac condition not listed here (specify) <specify><anchor>
- q. Other type of lung/pulmonary condition not listed here (specify) <specify><anchor>
- r. Other type of cancer not listed here (specify) <specify><anchor>
- s. None of the above <mutuallyexclusive><anchor>

[Q68]

[Question type=radio button]

What is your marital status?

- a. Married/living with partner
- b. Single/never married
- c. Separated or divorced
- d. Widowed
- e. Prefer not to answer

[Q69] Only show to females

[Question type=radio button]

Are you currently pregnant?

SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- a. Yes, in my first trimester
- b. Yes, in my second trimester
- c. Yes, in my third trimester
- d. No, I am not pregnant

[Q70] Only show to females who are not currently pregnant (selected “d” in previous question)

[Question type=radio button]

Were you pregnant in the past 12 months?

- a. Yes
- b. No

[Q71]

[Question type=radio button]

How many children under the age of 18 do you currently have living with you in your home?

- a. 0
- b. 1
- c. 2
- d. 3
- e. 4
- f. 5+

[Q72]

[Question type=radio button]

Which best describes your current employment status?

- a. Employed full time
- b. Employed part time
- c. Unemployed
- d. Retired

[Q73]

[Question type=radio button]

Which of the following categories includes (if employed full or part time in previous question show “your occupation”/if unemployed or retired, show “your most recent occupation”)?

- a. Professional (lawyer, doctor, teacher, etc.)
- b. Executive/managerial
- c. Sales/administrative
- d. Information services
- e. Technical

## SWEDISH MATCH PREMARKET CONSUMER PERCEPTION SURVEY PROTOCOL

- f. Skilled craftsman/tradesman
- g. Laborer
- h. Skilled worker (plumber, electrician, construction, etc.)
- i. Other (specify)

[Q74]

[Question type=radio button]

What is the highest level of education you have completed?

- a. Some high school
- b. Graduated high school
- c. Completed trade school
- d. Some college coursework
- e. Two year college degree
- f. Four year college degree
- g. Some post-graduate coursework
- h. Post-graduate degree
- i. Prefer not to answer

[Q75]

[Question type=video]

As a final step for this research and in order to successfully complete this survey, please watch the video below. Please make sure you watch it in its entirety before continuing. The video is 1 minute long.

[Show FDA Disclaimer video here.](#)

[Q76]

[Question type=radio button]

In order to complete your participation in this survey, please certify that you have watched the video just presented to you in its entirety.

- a. Yes- I certify that I was able to watch the video in its entirety.
- b. No- I cannot certify that I watched this video. **(Respondent will not be included in the data set if this option is selected)**

## **Appendix D**

Debriefing Disclaimer Text:

### **Dr. John or Jane Doe speaks:**

Hello, my name is Dr. John or Jane Doe of ABC Medical Institution.

You need to know that none of the claims made as part of this study have been validated or approved by any regulators of smokeless tobacco products, including Snus.

Further, all smokeless tobacco products referenced in this study must carry one of the following warnings:

1. This product can cause mouth cancer
2. This product can cause gum disease and tooth loss
3. This product is not a safe alternative to cigarettes
4. Smokeless tobacco is addictive.

I emphasize that the information you have just examined has not been substantiated by the FDA.

### **Narrator concludes:**

Thank you for your time and attention.

## Appendix E

### Draft Discussion Guide for Quantitative Survey Instrument and Disclaimer Video

The goal of this study is to understand the thought process of respondents as they move through the length of the survey. Using both pre-scripted and unscripted questioning, we will uncover and eliminate any points of confusion, or elements that could be misinterpreted in any way.

There will be a two-part interview process. One to be administered once the client feels the survey is “consumer ready”. This will give us a baseline to work from in terms of how the questions, terms used and answer choices are perceived. After the first round of interviews is complete, the questionnaire will be refined to reflect the feedback collected thus far.

Following a strategic revision process, a second round of interviews will be conducted to determine if any initial sticking points have been successfully identified and removed, thereby allowing us to draft a final version that is likely to yield the most accurate and valuable results.

- The questionnaire will be evaluated by section, as follows...
  - Screeners
  - Category/Usage History (if applicable)
  - Current Tobacco Health Opinions
  - Warning Label Evaluation
  - Demographics

Participants will be asked to “think aloud” as they answer each question. They will not be interrupted, but the moderator will record detailed respondent reactions to be discussed after each individual section above is complete.

Note that there are a few basic questions that will be used repeatedly throughout this process, but the most valuable probes are likely to surface “on the fly” as feedback varies from participant to participant.

Ideally, this research should be conducted using the programmed survey that will most closely mimic the true participant experience.

## **PARTICIPANT INTRODUCTION**

Thank you so much for taking the time to speak with us today. We have a very important mission for you, as your thoughts and opinions are extremely valuable to us.

We are going to take an online survey together. As you go from question to question, I am going to ask you to read each one aloud, and to tell me what you're thinking as you choose your answer. We would like to know how you feel about the questions themselves, the answer choices given, and the words/phrasing used. We are also interested in any comments you may have regarding instructions for answering questions and the overall 'flow' of the survey. After you complete each section of questions, we will talk about each one together before moving on.

*NOTE: This process will not have to be done for every question, as there are many that are clear, straightforward and the foundation of nearly every survey (i.e. age, gender, state of residence, other demographic questions, etc.).*

*In addition, many unscripted questions will be asked during the interview process that are tailored to each individual participant and their unique perceptions/responses. Client-requested probes will also be added for individual questions as the project progresses.*

## **BASIC GUIDE – INDIVIDUAL QUESTIONS**

- Describe for me what you think the question is asking you.
  - [Tell participant if need be, the goal of the question] Knowing what we are trying to get at here, is this question worded appropriately? How would you change it to make it better?
- Tell me what made you choose the answer you did.
  - What does your answer mean to you?
  - NOTE: Here we will discover if the participant felt the answer choices were comprehensive.
- How do you feel about the answer choices given?
  - Are you able to answer in a way that reflects your true feelings?
  - What would your *ideal* answer to this question be?
    - How can we alter the options given to reflect this?
  - How do you feel about the number of choices given?
    - Probe: Too many/too few.
  - Any point where you feel forced to choose an answer that isn't reflective of your feelings and opinions?
    - What can we do to fix this?
- Are there any words or phrases used in either the question itself or the answer choices provided that are unclear or unfamiliar to you?
  - How can we fix each point of confusion? (Go through each one individually if warranted).

- Are there additional questions you believe should be asked in this section?
  - Probe: Likelihood to start using tobacco products again BEFORE seeing the warning labels.
- Are there questions you believe should be removed from this section?
- Are there questions you believe should be modified in this section?

### **BASIC GUIDE – SURVEY AS A WHOLE**

- As we move from section to section, is the transition to a new topic clear? What could we do to prepare you for the next group of questions?
  - Probe: Provide a brief introduction that describes the types of questions you are about to receive.
- How do you feel about the length of the survey?
- Any place where you would have stopped taking it, and why?
- What could we do to ensure you complete the entire survey, giving it your FULL attention?
  - Probe: Allow you to complete the survey in more than one sitting.
  - Probe: Provide a detailed introduction upfront explaining what the research is being used for.
- How do you feel about the warning labels that you saw and evaluated?
  - What is it telling you?
    - How easy or hard it is to understand?
  - Describe any points of concern you may have after seeing the warning labels.
    - What can be done to prevent these from occurring?
  - What do you think of the way it looks?
    - Where on the package should it be placed to ensure you see it?
  - How does it impact your likelihood to use the product and why?
    - How does it make you feel about using this type of tobacco product?
      - Probe: Safer using, others TBD.
    - [IF NOT CURRENTLY USING] What impact does it have on you starting to use a product like this again and why?

### **FDA DISCLAIMER VIDEO**

- How do you feel about the FDA disclaimer video that you watched at the end of the survey?
  - What do you think the purpose of the video is?
    - What is it telling you? What does this message mean to you?
    - How easy or hard it is to understand?
  - What do you think of the video in terms of:
    - The way it looks
    - The information that is presented

- The way in which the information is presented
  - Impact of “live delivery” vs. voice over w/picture
- How do you feel about the person who presented the information in the video?
  - Probe:
    - Credibility
    - Trust
  - How it makes you feel when watching it
- After seeing this video, would you have changed your answers to the questions asked earlier regarding the warning label that was not approved by the FDA? [Note: Review answers to the non-FDA approved warning label at this time to remind participant and determine if responses would be altered in any way]
- What does having the FDA “stamp of approval” mean to you?
  - How does it impact your feelings about the product discussed in this survey?
  - How does it impact your likelihood to buy the product discussed in this survey?
- Do you believe the claims of this warning label if not granted FDA approval? What makes you say that?
- What would make you feel better about this warning label if it does not receive FDA approval?
  - Probe: Level/extent of testing by the company making the claim/any evidence to support it
- How does it make you feel that you were not made aware when evaluating this version of the warning label that it does not currently have the endorsement of the FDA?
- Would you like to have been given the opportunity to rate this label twice – once before knowing it’s not FDA approved, and once after? Why/why not?
- [Note: Describe to participant the full intent of the disclaimer video and what it is designed to do here] Knowing what we are trying to achieve with this video, how could we improve upon it?