DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

April 19, 2017

MEETING MINUTES

Swedish Match North America, Inc.
Attention: Gerard Roerty, Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Number (STN): TC0002213

Dear Mr. Roerty:

Please refer to the March 22, 2017 meeting held to discuss your Modified Risk Tobacco Product Applications (MRTPA) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following products:

STN	TOBACCO PRODUCT NAME
MR0000020	General Loose
MR0000021	General Dry Mint Portion Original Mini
MR0000022	General Portion Original Large
MR0000024	General Classic Blend Portion White Large – 12 ct
MR0000025	General Mint Portion White Large
MR0000027	General Nordic Mint Portion White Large – 12 ct
MR0000028	General Portion White Large
MR0000029	General Wintergreen Portion White Large

A copy of the official minutes is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions please contact Shireen Ahmad, Regulatory Health Project Manager, at (240) 402-0435.

Sincerely,

Benjamin Apelberg -S

Digitally signed by Benjamin Apelberg -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000588076, cn=Benjamin Apelberg -S
Date: 2017.04.19 11:23:27 -04'00'

Benjamin Apelberg, PhD, MHS
Director
Division of Population Health Science
Office of Science
Center for Tobacco Products

Enclosure: Meeting Minutes

MEETING MINUTES

FDA Submission Tracking Number:	TC0002213
Meeting Minutes Issue Date:	April 19, 2017
Meeting Date and Time:	March 22, 2017 at 1:30 PM EST
Meeting Format:	Face-to-face
Meeting Category:	MRTP
Applicant Name:	Swedish Match North America, Inc.
Meeting Requestor:	Gerry Roerty, Vice President, General Counsel & Secretary
Product Name:	General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large – 12 ct, General Mint Portion White Large, General Nordic Mint Portion White Large – 12 ct, General Portion White Large, and General Wintergreen Portion White Large
Received Meeting Information Package:	January 17, 2017
Preliminary Reponses Sent:	March 20, 2017

I. MEETING ATTENDEES

See section VI

II. BACKGROUND

On December 14, 2016, FDA sent a Response letter and Denial letters for MR0000020-22, MR0000024-25, and MR0000027-29. On January 9, 2017, Swedish Match North America, Inc. (SMNA) submitted a meeting request to discuss the Response letter and Denial letters. The company indicated it is inclined to amend these MRTP applications with different claims, but before doing so, wanted some clarification on the path forward. On January 17, 2017, Swedish Match North America, Inc. submitted an amendment to the meeting request, which included meeting objectives, agenda, questions, and participants. On February 3, 2017, Swedish Match North America, Inc. submitted an amendment to the meeting request, which included a sampling of different types of claims for discussion at the meeting.

III. OBJECTIVES

The meeting information package containing objectives, agenda, specific questions, and meeting attendees was received on January 17, 2017. As described in the meeting information package, the following objectives and outcomes were expected by Swedish Match North America, Inc. attendees:

1. The fundamental objective from the proposed meeting is to have a better understanding of the process for submitting revised MRTPAs, with different claims,

for the General snus products. The new claims would not include removal of the existing warning labels; rather the Company is considering proposing relative risk-based communication messages that are informed by the existing science and Center for Tobacco Products (CTP) regulatory decisions; and

2. A specific meeting objective is to determine if, and to what degree, CTP is willing to interact with SMNA in developing and implementing a consumer perception research program designed to test the relative risk-based claims in the revised MRTPAs. SMNA understands the company must propose new claims and communication messages, and develop a survey and complementary tools to fully test the claims/messages. However, we believe the process will be most efficient if there is first, agreement on the claims/messages to be tested; and second, acceptance of the testing methods proposed by SMNA.

IV. DISCUSSION

General FDA Response

Pre-submission meetings can provide feedback on the types of studies and data/information sources that could be used in an application. Whether or not the data that is submitted in support of your application is sufficient to support a marketing authorization is always a review issue.

Based on our preliminary review of the materials you submitted, we have the following initial comments. The comments are not indicative of all the issues that may be identified during review of a complete submission of an amendment to your MRTPA.

Question 1

SMNA assumes that CTP used a precautionary, rather than a weight of evidence based approach in making the MRTPA partial decision. However, if the MRTPs were revised, with different claims, not to include removal of the existing warning labels, would CTP employ more of a weight of evidence approach in making decisions?

FDA Response

FDA does not understand and therefore does not agree with your characterization of FDA's review. As described in the TPL review, in reviewing SMNA's modified risk tobacco product applications (MRTPAs), FDA evaluated your specific requests by considering all of the relevant evidence, including: information submitted in your applications; the recommendations from the Tobacco Products Science Advisory Committee; comments, data, and information submitted to FDA; and other scientific information identified by the Agency, including from the peer-reviewed, published literature. FDA conducted a scientific review of all these materials, including an evaluation of the strength and quality of the underlying studies. FDA then evaluated whether, as a matter of science, there was sufficient data and information to demonstrate

that the standards for issuing a modified risk order were met with respect to SMNA's specific requests.

In particular, SMNA requested to remove the mouth cancer and gum disease warnings currently required for all smokeless tobacco products. FDA determined that this is a request to market your products with implied modified risk claims that, unlike other smokeless tobacco products, the eight General Snus products cannot cause gum disease or tooth loss and cannot cause mouth cancer. In evaluating the scientific substantiation of these proposed claims, FDA weighed the strength and quality of the epidemiological, clinical, and nonclinical evidence available to the agency. FDA uses the same approach to evaluate any explicit or implicit claim that an applicant is requesting in an MRTPA, whether or not the request involves the removal of an existing warning.

Because FDA evaluates the scientific substantiation for the specific claims an applicant proposes in their application, there can be a distinction in terms of the evidence required based on the nature of the claim. If an applicant proposes an implicit or explicit claim that a product does not or cannot cause a disease, FDA will consider not only evidence regarding the observable relationship between the product and disease in well-conducted epidemiological and/or clinical studies, but also evidence regarding any biologically plausible mechanisms by which the product would be expected to increase the risk of such disease. As a result, in general, FDA thinks that, in most cases, comparative risk claims would be easier to substantiate than a claim regarding the non-existence of a causal relationship. In addition, we remind you that even if a proposed claim is scientifically substantiated, FDA would still need to determine whether the rest of the statutory criteria for issuing a modified risk order were met.

Additional Discussion

Swedish Match North America, Inc. accepted FDA's response.

Question 2

SMNA is considering a claim/message comparing General snus to cigarettes; for example stating that General snus, unlike cigarettes, does not cause lung cancer. Is it reasonable to assume that CTP will take a weight of evidence approach in assessing such a claim? Or would CTP require evidence proving that General snus cannot cause lung cancer?

FDA Response

As described in response to Question 1, FDA will evaluate whether all of the relevant evidence provides scientific substantiation for the explicit or implicit claim that an applicant proposes. FDA thinks that it would be very difficult to demonstrate the non-existence of a causal relationship, which is what is being explicitly proposed with the statement that "General snus, unlike cigarettes, does not cause lung cancer". FDA agrees that there is evidence demonstrating exclusive use of smokeless tobacco and snus use

presents substantially lower health risks of lung cancer as compared to the use of cigarettes. However, as described above, the evaluation of a claim about the absence of risk would also take into account evidence related to biological mechanisms by which the product would be expected to increase disease risk. While the products submitted in these MRTPAs do in fact have lower levels of HPHCs, including the tobacco-specific nitrosamines (TSNAs) NNN and NNK, as compared to cigarettes and many other oral tobacco products, the levels present in these products nonetheless still retain increased risk of systemic cancer to snus users compared to non-users. In the absence of evidence establishing a threshold dose that does not raise these concerns, we think that it would be very difficult to substantiate a claim related to the absolute elimination of risk of any cancer. FDA will not prejudge any claim without first evaluating the supporting evidence. However, based on the evidence known to FDA at this time, (and as further described in the response to Question 6), FDA recommends that you pursue claims related to reduced, and not the absence of, carcinogenic risk.

Additional Discussion

Swedish Match North America, Inc. accepted FDA's response.

Question 3

SMNA intends to develop science based claims/messages for the revised MRTPAs, which would be informed by the General snus PMTA TPL; is this an appropriate approach?

FDA Response

Yes. It would be an appropriate approach to use both the PMTA and MRTPA TPLs to inform the development of science-based claims and messages for the amended MRTP applications. Some of the conclusions from the PMTA and MRTPA TPLs related to the General Snus products that were the subject of these applications include:

- "…while resting on certain assumptions about manner of use, there is evidence to support that use of the eight General Snus products as compared to smoking cigarettes would significantly reduce harm and the risk of certain tobacco-related diseases to individual tobacco users (i.e., lung cancer and COPD)." (MRTPA TPL, p. 23)
- "When used as exclusively instead of combusted tobacco products, these products offer lower risk of developing respiratory diseases (i.e., chronic obstructive pulmonary disease (COPD), emphysema, chronic bronchitis) and cancers (such as oral, esophageal, and lung) than smokers." (PMTA TPL, p. 7)
- "When used as exclusively instead of other smokeless tobacco products or cigarettes on the US market, these products offer potential for reductions in oral cancer risk." (PMTA TPL, p. 6)

In one of the slides you submitted as background material for the meeting, you note that you believe the language in the PMTA TPL review provides evidence to support a claim

related to the quantification of cancer risk reduction due to General Snus use. FDA cautions against using quantitative toxicological risk estimates in the PMTA TPL to support a claim quantifying the risk reduction associated with switching from cigarette smoking to snus use. In the scientific review of SMNA's PMTA for General Snus products, a 38-92% reduction in the excess lifetime cancer risk was estimated for use of General Snus products when compared to other smokeless tobacco products on the US market. This reduction was due to the considerably lower levels of NNN in General Snus products compared to most smokeless tobacco products on the US market and the assertion that NNN is presumed to be a principal driver of carcinogenic risk in smokeless tobacco. Assuming similar use patterns between snus and other smokeless tobacco products, a comparison of excess cancer risk based on NNN oral exposure is reasonable.

FDA does not think a risk comparison can be made between cigarettes and General Snus products based solely on NNN levels due to the differences in other HPHCs and routes of exposure. While NNN is a powerful oral cavity carcinogen, it cannot be presumed to be the main driver of carcinogenic risk to cigarette smokers. Moreover, NNN oral exposure differs between smokers and smokeless tobacco users; intractable variables affecting NNN exposure in the oral cavity from cigarette smoke include ventilation and smoking topography. For these reasons, a claim of related to a specific, quantitative reduction in risk of tobacco-related cancer compared to cigarettes, based on oral exposure to NNN alone, would not be appropriate.

Regarding the approach for construction of the claims/messages, we note that they should be crafted in a manner that is most likely to be (a) understandable to consumers and (b) expected to affect behavior in ways that would benefit the health of individuals and the population as a whole.

Additional Discussion

Swedish Match North America, Inc. accepted FDA's response.

Question 4

SMNA's envisions a comprehensive messaging strategy that will largely focus on outside the label advertising and would provide information to consumers concerning the risk differences between the General snus products and other tobacco products; is this an appropriate approach?

FDA Response

From your question, we are not clear if, by "outside the label", you mean outside the warning label, but otherwise displayed on the product's label, or, alternatively, if you mean messaging that appears on advertising/marketing materials *rather than* on the product label. However, either of these approaches may be appropriate.

It is important that the modified risk information communicated to consumers be understandable and lead them to make decisions about using the MRTP that would benefit the population as a whole. As such, a consumer perception study designed to assess consumer reactions to the modified risk information will be most informative to FDA's evaluation of the MRTPA to the extent that (1) the stimuli tested reflect, and are representative of, what will be implemented in the marketing of the product and (2) the modified risk information statements are tested verbatim.

As you plan and design a consumer perception study, we encourage you to consider and describe how the materials and information tested relate to your overall marketing strategy. Also, providing a description of the proposed messaging strategy and marketing plan will help FDA to better understand how the MRTP information tested will ultimately be presented to consumers, which will aid FDA's evaluation of the adequacy of the study.

Additional Discussion

Swedish Match North America, Inc. accepted FDA's response.

Question 5

SMNA believes it is in the best interest of the public health that the type of information cited in the PMTA TPL be effectively communicated to adult tobacco consumers in a timely fashion. Thus, the Company anticipates an expedited decision-making process for the revised and resubmitted MRTPAs, with a decision approximately 180 days following final submittal of the revised MRTPAs; is this a reasonable expectation?

FDA Response

The determination of whether a product with a particular modified risk statement (claim) meets the standards for issuing an order under Section 911 requires that FDA perform a rigorous review of all of the relevant evidence. We will work as expeditiously as possible to review the amendment and make a determination. In order to facilitate the review process, FDA recommends that SMNA organize the amendment by listing each deficiency in the December 14th, 2016 letter from FDA, clearly describing how each of these deficiencies is addressed, and providing links to the relevant information and data in your amendment.

Additional Discussion

SMNA requested clarification on which deficiencies FDA was referring to in the response. FDA indicated that the response is in reference to the specific items listed as deficiencies in the Response Letter sent on December 14, 2016.

Question 6

The following is a sampling of different types of messages that the sponsor is considering. Please provide any general feedback on the appropriateness of these types of messages, given FDA's review of the MRTPAs.

- Exclusive use of General snus instead of cigarettes will substantially reduce your risk of tobacco related diseases.
- This product does not cause lung cancer or COPD/asthma/emphysema/chronic bronchitis.
- If you switch completely from cigarettes to General snus, you reduce risk of tobacco-related cancer by (more than) 90%.
- Exclusive use of this product instead of smoking substantially reduces your risk of most smoking/tobacco-related cancers including mouth and lung cancer.
    - If you switch completely from cigarettes to this product, you substantially reduce your risk of mouth and lung cancer.
    - Exclusive use of this product instead of smoking greatly reduces your risk of heart disease and stroke.
    - If you switch completely from cigarettes to this product, you substantially reduce risk your risk of heart disease, stroke, COPD, mouth cancer, and lung cancer.

FDA Response

Based on the information FDA has reviewed to date, FDA thinks there is compelling evidence to support a potential claim(s) regarding lower risks of certain diseases associated with General snus use compared with cigarette smoking (and some other smokeless tobacco products). In particular, FDA agrees that the available evidence demonstrates that exclusive use of these products, compared to cigarette smoking, poses lower risks of various diseases, such as lung cancer, COPD, and mouth cancer. Thus, among the list of claims proposed by SMNA, those that compare the risks of specific diseases between exclusive use of your products and cigarette smoking (i.e., the final bullet, and its three sub-bullets, in SMNA's proposed list) may be the most appropriate.

If SMNA pursues any of these claims, the specific language used to communicate this information should be carefully developed and tested to assess consumer comprehension and perceptions. The language used to communicate risk should be precise. For example, in the proposed claims, it should be made clear whether the comparison is smoking, in general, or cigarette smoking, in particular. In addition, the claims related to switching should make it clear that the comparison is with continuing to smoke cigarettes. FDA also urges caution when using qualitative descriptors such as "substantially" and "greatly" to describe reduction in risk. For example, the magnitude of difference in relative risks between snus users and cigarette smokers is greater for some disease categories (e.g., COPD, mouth cancer, and lung cancer) than others (e.g., heart disease),

thus making it difficult to support the use of "substantial" when describing risk reduction in all of these disease categories. If you use qualitative descriptors in your claims, it would be helpful to operationalize (i.e., provide a definition for the term and/or a specific metric by which to assess the term) and support their inclusion. This is particularly important when considering claims related to the magnitude of risk reduction resulting from switching products, since this is likely to be dependent on lifetime smoking history and has not been regularly assessed in long-term studies of snus users. An alternative approach would be to develop a claim that compares the risks of two products (e.g., exclusive use of this product poses lower risk of heart disease than cigarette smoking).

As noted above, FDA will not prejudge any claim without first evaluating the supporting evidence. However, based on current scientific evidence known to FDA at this time, FDA would not recommend pursuing a claim that these products do not cause a specific type of cancer (e.g., lung cancer), because it would be very difficult to support the absolute statement that there is no carcinogenic risk associated with the use of General snus, particularly in the absence of a mode of action that defines a threshold for the carcinogens present in the product. As described in the response to Question 2, the products submitted in these MRTPAs do, in fact, have lower levels of smokeless tobacco HPHCs, including NNN and NNK, as compared to cigarettes and many other oral tobacco products. Nonetheless, the levels present in these proposed MRTPs still retain increased cancer risk to snus users compared to non-users. In the absence of data that support a dose threshold below which the carcinogenicity of a compound can be shown not to occur, it is standard toxicological practice to assume a linear relationship between the dose of a carcinogen and the increased cancer incidence it induces. This assumption is particularly applicable to carcinogens that directly interact with DNA, such as the TSNAs. Therefore, based on scientific evidence of which we are aware, we think it would be very difficult to substantiate an absolute claim related to the absence of carcinogenic risk associated with the use of these products.

If SMNA pursues a claim that quantifies the reduced risk of complete switching from cigarette smoking to snus use (e.g., 90% lower risk of tobacco-related cancer), quantitative evidence to support the claim would be necessary. FDA is not aware of studies that have directly measured the reduction in tobacco-related cancer risk associated with switching from cigarettes to snus in comparison to continuing to smoke cigarettes. Even if a specific magnitude of risk reduction could be substantiated for smokers, on average, it is unlikely that the same estimate would apply both to smokers with a brief lifetime history of smoking and those who, for example, have smoked daily for decades.

These recommendations are based on the evidence FDA has previously reviewed as part of SMNA's MRTPAs. In the context of the evaluation of an amended application, FDA cannot prejudge which of these claims, if any, would support issuance of a modified risk order for these products.

The appropriateness of a given claim in terms of consumer perception and understanding should be determined based on empirical evidence, wherein the claim is evaluated in the context in which it will appear. In general, when designing modified risk statements, we

recommend you consider the following to make the statements easier for consumers to interpret and reduce potential misinterpretation: (1) write the statements at an appropriate reading level; and (2) provide information that is more specific, rather than general. In addition, FDA recommends you test multiple versions of potential claims in your consumer perception study.

One potential challenge in designing a study to evaluate consumer perception and understanding is the number of possible experimental factors, each of which may have multiple levels. For example, testing could include: multiple versions of claims, variations of marketing materials (including different types of materials, different content, or both), and product variations (e.g., SKUs that vary by flavor and size). It may not be feasible or necessary to include every factor, or to test every level of each factor alone or in combination (e.g., in a fully crossed factorial design). Thus, prioritizing among these factors may be necessary to design a study that is feasible, while still providing information that can be informative to the application. Therefore, in designing your study, we encourage you to explain how the specific study design provides adequate information to evaluate the products in your application (e.g., that the information can be generalized to all SKUs and/or marketing materials). For example, a scientific rationale for generalizing the results from one SKU to other SKUs should be provided, as appropriate, if you are not testing the effect of the modified risk information for each SKU separately. Finally, we would expect that all stimuli showing product packaging and/or advertising display the currently mandated warnings. We recommend you include all four mandated warnings (e.g., rotating them randomly on stimuli), as this reflects the context in which consumers would encounter the MRTPs in the marketplace.

As you further refine and develop proposed claims, we recommend that you submit your consumer study protocol including statistical analysis plan to FDA for review. FDA will evaluate the methods proposed to address the research aims of the study and provide substantive review and comment in advance of embarking on the study. However, we remind you that FDA assessment of data directly evaluating consumer reactions to specific claims is a MRTPA review issue.

If you wish to submit a protocol in advance, the following would be helpful to include:

- Detailed description of study design and hypotheses, including indications of which hypotheses are primary and which are secondary, which will inform power analyses.
- Detailed description of study methods including: recruitment materials and procedures; study sample (inclusion/exclusion criteria); study procedures; stimuli; a description of all study measures, including their source and any information related to their validity; and all relevant study instruments.
- Detailed statistical analysis plan, including power analysis.

In addition, this background information could be helpful to us in evaluating your study design:

- Description of your overall marketing plan
- Description of any formative work done that led to the current study (e.g., development and selection of claims)

Additional Discussion

SMNA communicated that they interpreted FDA's response to this question to mean that they should not use the term "substantially" in their claims. FDA clarified that this was not FDA's position. FDA communicated that since the term "substantially" is a subjective, qualitative descriptor, it would be helpful for the company to characterize how they define the term and how consumers interpret it or any other descriptors used in communicating modified risk information.

SMNA also communicated that they interpreted FDA's response to this question and Question 2 to mean that FDA would not authorize a modified risk tobacco product with a claim describing the absence of a causal association. FDA clarified that FDA would not pre-judge a specific claim, but reiterated to SMNA that the MRTP pathway requires the evaluation of a specific product with specific modified risk information that would be communicated to consumers. This evaluation is dependent on the specific modified risk information that an applicant is proposing to communicate. FDA re-iterated that based on the currently available information, it thinks it would be difficult to substantiate statements that communicate the absence of a causal relationship, especially regarding cancer, when the product contains known carcinogens, even if they are at lower levels than other products.

SMNA inquired whether they should pursue a general claim instead of or in addition to specific claims. FDA reiterated that deciding which claims to pursue is up to SMNA, but suggested that more specific claims may be easier to substantiate and less likely to result in consumer misunderstanding or misperception because they may leave less room for interpretation. FDA also indicated that it would be valuable to test different claims and language in the consumer perception studies. It would be beneficial to conduct formative, qualitative research to craft the specific language. Quantitative testing would provide information about how modifications in language impact the way people understand and respond to claims.

SMNA asked for clarification of FDA's feedback on the design of a consumer perception study. SMNA asked how they might demonstrate that the results of a study including one of their SKUs can be extrapolated to one of their other (non-tested) SKUs. FDA noted that one way to extrapolate would be to conduct a pre-test on a few of the SKUs and demonstrate that the findings across SKUs are similar. This could be used to build a scientific rationale for generalizing across these and other SKUs. SMNA also asked what FDA meant when recommending that "the stimuli tested reflect … what will be implemented in the marketing of the product." For example, if modified risk information will be provided to consumers in a magazine print advertisement, should SMNA provide study particants with a hard copy of a magazine with the print advertisement inside? FDA clarified that the stimuli should reflect the verbatim modified risk information in the context of the advertisement, but the advertisement need not be presented to participants inside an actual magazine. For example, study participants could view the advertisement in another format, such as on a computer screen.

SMNA also inquired whether they could request multiple claims in their amended applications and FDA confirmed that they could.

ADDITIONAL FDA COMMENTS

FDA would like to clarify that there are multiple inquiries that FDA undertakes when assessing an MRTP application. One type of inquiry is claim substantiation, in which FDA assesses whether the scientific evidence demonstrates that the claim is scientifically accurate. As described at the meeting, for claims with subjective qualifiers such as "substantially", it would be helpful for the applicant to characterize how this term is defined for the purposes of substantiating the claim. FDA notes that the TPL review of the SMNA MRTPAs concluded that, with respect to claim substantiation, exclusive use of these products does pose substantially lower risks to health than cigarette smoking for certain major causes of tobacco-related disease, including lung cancer and COPD.

Another inquiry related to MRTPA assessment is how the marketing of the product with the proposed claims impacts consumers' perception, understanding, comprehension, behavior, and the health of the population as a whole. In this context, it is important to study the proposed claims verbatim and in the appropriate context in order to assess how consumers interpret the modified risk information, including the term "substantially" or any other descriptors used in communicating the information.

During the meeting, SMNA went through several presentations, including one on SMNA's proposed consumer research plan. While in the meeting, FDA suggested that it would provide some feedback on SMNA's consumer research plan presentation, given that SMNA noted that the information in that presentation was preliminary, at this time FDA thinks it would be more helpful to provide a summary of high-level guidelines for consideration when conducting consumer perception research. These are provided as an addendum to the meeting minutes. FDA reiterates that, while not a "collaborator" on SMNA's research studies, it is committed to providing timely, constructive feedback and advice, including on scientific research protocols and any specific questions that SMNA may have on its consumer research plan presentation.

V. ACTION ITEMS

No action items capture for this meeting

VI. ATTACHMENTS

Meeting Attendees

FDA Attendees

Shireen Ahmad, MS, Regulatory Health Project Manager, Division of Regulatory Project Management (DRPM), Branch IV, Office of Science (OS)

Ben Apelberg, PhD, MHS, Director, Division of Population Health Science (DPHS), OS
Rosanna Beltre, MPH, Program Analyst, Policy Team, OS
Kimberly Benson, PhD, Director, Nonclinical Science (DNCS), Immediate Office (IO), OS
James Bowling, Regulatory Counsel, Division of Enforcement and Manufacturing (DEM), Office of Compliance and Enforcement (OCE)
Cindy Chang, PhD, MPH, Epidemiologist, DPHS, OS
Ii-Lun Chen, PhD, Director, Individual Health Science (DIHS), IO, OS
Priscilla Callahan-Lyon, MD, Deputy Director, Division of Individual Health Science (DIHS)
Jessica Greenbaum, General Counsel, Office of Chief Counsel (OCC), Office of the Commissioner (OC)
Sheila Healy, PhD, Toxicology Reviewer, DNCS, OS
Matthew Holman, PhD, Director, Office of Science
Sarah Johnson, PhD, Social Scientist, DPHS, OS
Diana Kaneva, General Counsel, OCC, OC
David Keith, Division Director, DEM, OCE
Deirdre Kittner, PhD, MPH, Deputy Director, DPHS, OS
Jao Lacorte, MD, Medical Officer, DIHS, OS
LCDR Marvin Mitchell, Team Lead, DRPM, Branch IV, OS
Alexander Persoskie, PhD, Social Scientist, DPHS, OS
LCDR Lana Rossiter, PhD, Acting Chief, DRPM, Branch IV, OS
Hans Rosenfeldt, PhD, Deputy Director, DNCS, OS

Swedish Match North America, Inc. Attendees:

Lars Dalhgren, Chief Executive Officer and President, Stockholm, Sweden
Richard Flaherty, President, Richmond, VA
Fredrik Peyron, Sr. Vice President for Regulatory Affairs and Group Communications, Stockholm, Sweden
David Price, Vice President of Marketing, Richmond, VA
Gerry Roerty, Vice President and General Counsel, Richmond, VA
Lars-Erik Rutqvist, Sr. Vice President for Scientific Affairs, Stockholm, Sweden
Steve Seiferheld, Director of Marketing Research, Richmond, VA
Jim Solyst, Vice President, Federal Regulatory Affairs, Severna Park, MD

VII. ADDENDUM – General Principles for Consideration in the Design of a Tobacco Product Perception and Intention Study

Below is a summary of high-level guidelines for consideration when designing a "tobacco product perception and intention study" (TPPIS). Here, we use TPPIS to refer to studies designed to assess constructs such as: participants' perceptions of tobacco products; their intentions to use those products; and/or their understanding of information about those products (e.g., labeling, claims).

Overall approach

There are many valid approaches to conducting TPPISs, and we recommend you conduct such studies using an approach that is appropriate to support your submission and maximizes scientific rigor. Study personnel involved in the design, implementation, and analysis of the TPPIS should have formal training and experience in conducting social or behavioral science research and have the ability to conduct quantitative research.

If you plan to use the results of the study as support for an application for more than one product, it is important to either include each product in your study, or provide a rationale for why the study results generalize to products that were not included in the study.

Developing Aims and Hypotheses

FDA recommends aims be developed prior to conducting a TPPIS and be clearly linked to the overall rationale for specific requests in the MRTPAs. We recommend you classify aims as primary and secondary, which will inform power analysis and sample size estimation. When studies seek support for the null hypothesis (i.e., there are no differences between groups), it is especially important to have documented that the measures chosen for the study are valid measures of the constructs being investigated, and that the study is sufficiently statistically powered to detect differences should they exist.

Study Design Considerations

In an experimental study, in at least one condition participants would be exposed to the target stimuli and at least one condition should be an appropriate control (e.g., the same stimulus but without the modified risk claims). In an experimental study, participants should be randomly assigned to conditions.

Manipulation Checks

FDA recommends that TPPISs using experimental designs include a manipulation check, which determines whether the experimental manipulation (i.e., exposure to stimulus) was noticed by the participants, as intended. A manipulation check is important for evaluating internal validity of the study, and can help determine whether a lack of difference between conditions was due to the participants failing to notice the manipulation. There are a number of ways to implement a

manipulation check. For instance, investigators may ask participants to recall (via free response) what they have just seen. Or, participants may be asked to select the target (e.g., claim) from a list of options.

Survey-Based Designs

FDA recommends that you use best practices in survey design (including survey-based experimental designs) when creating quantitative surveys for TPPISs. Consider the following:

- present information to participants written at a reading level appropriate for those with less than a high school education;
- include definitions of terms that participants may not be familiar with or are likely to be misunderstood by participants;
- for questions referring to tobacco products other than cigarettes, include images of the product when possible;
- consistently place the most affirmative response options at either the beginning or the end of the response scale throughout the survey (e.g., both *Definitely Yes* and *Strongly Agree* should consistently be at the beginning or the end of the list of response options across all questions);
- avoid including instructions or questions that contain information that influences a participant's ability to answer subsequent questions, other than when defining unfamiliar terms;
- attempt to order questions in a way that minimizes order effects, or the impact of previous questions or tasks on how people respond to subsequent questions, and effects. For example, investigators should consider the proximity of the stimulus exposure to the primary outcome questions, as the effect of the stimulus may fade over time. As another example, investigators should be mindful of the impact of any study tasks (instructions or measures) that precede stimulus exposure and how they may affect participants' processing of the stimulus.

FDA recommends you engage in the following before finalizing the survey:

- Conduct cognitive testing to determine any potential problems with how participants understand, interpret, and answer each survey question, including questions or response options which may be confusing or misinterpreted, and the presence of order effects. Refine the survey based on results of this testing and conducting additional rounds of testing on subsequent drafts as necessary (see OMB Statistical Policy Directive No. 2 Addendum: Standards and Guidelines for Cognitive Interviews).
- Pre-test a draft of the survey to identify and correct any remaining potential problems with how participants answer each survey question before conducting the full study.

Stimuli

FDA recommends that TPPISs test the effect of the stimulus exactly as it is proposed in the application and as you propose to market it. For example, if packaging and advertisements for the product type are required by a government statute to display rotating warning labels in the marketplace, FDA recommends that the packaging or advertising stimuli in the study include variants reflecting each required warning label.

If the product depicted in the stimuli differs from the product in the application, you should provide a scientific rationale for generalizing the results of the study to the proposed product. FDA recommends that you provide a scientific rationale for generalizing the results concerning one version to understanding the effects of another version.

Stimuli should be presented to participants in such a way that all information is visible and legible to participants. FDA recommends that you consider the implications of a study's mode of administration (e.g., online vs. in-person) for ensuring that the stimuli presented are clearly visible and legible. For example, studies conducted online should either ensure that participants using devices with small screens can appropriately view the stimuli, or require participants to use a computer or other device with a screen of sufficient size to adequately view the stimuli.

Measures

FDA recommends you select measures established as valid in peer-reviewed literature whenever possible and adapt them for your study. It is also acceptable to select and adapt measures that are widely used in the peer-reviewed literature, even if their validity has not been directly studied. Additionally, you may develop new measures. FDA recommends the following guidelines for writing, selecting, and adapting measures of psychosocial constructs.

Adapting Measures from Peer-Reviewed Scientific Literature

FDA recommends that you adapt measures of tobacco product perceptions, understanding, and intentions to refer to the exact product that is the subject of the study or application. For example, a TPPIS concerning a cigarette product should ask participants about their intentions to smoke the specific brand and sub-brand of cigarettes rather than their intentions to smoke cigarettes in general. Adapting measures in this way maximizes FDA's ability to draw conclusions about the tobacco product that is the subject of the application based on the findings of your study.

General Recommendations for Writing or Adapting Measures

FDA recommends the following when writing new measures or adapting existing measures for a TPPIS:

- Assure that each question is direct, specific, and unambiguous. Each question should address a single issue. Avoid double-barreled questions that combine two or more questions into one question;

- Use questions that ask participants about their perceptions and intentions directly. Avoid asking participants about the extent to which they have been influenced by the stimuli;
- Avoid including leading questions and language in the question stem that could bias responses;
- Avoid providing double-barreled response scales that include more than one dimension per question. For example, the midpoint of a response scale ranging from *Strongly Disagree* to *Strongly Agree* should not assess a separate dimension, other than agreement.
- Use equal numbers of positive and negative response options on rating scales;
- Distinguish 'undecided' or 'don't know' response options from 'neutral' by placing 'undecided' or 'don't know' options separate from the scale (if applicable);
- Include a sufficient number of response categories to be able to sensitively detect any potential misperceptions.

Outcomes

FDA recommends you identify and prioritize outcomes based on the objectives of your TPPIS. The following are a list of outcomes that FDA generally recommends you assess in your TPPIS:

Tobacco Product Perceptions

We use "tobacco product perceptions" as an umbrella term to refer to the cluster of related but distinct psychological constructs, including: beliefs, attitudes, judgments, and expectancies. Because there is a broad range of product perceptions that could be assessed, FDA recommends you prioritize assessing the perceptions most informative to the population health impact of marketing your proposed MRTP. In general, we recommend you assess the following perceptions:

- Perceptions about absolute health risks of the MRTP.
- Perceptions about the health risks of using the MRTP relative to:
  - other products in the same class;
  - cessation aids or nicotine replacement therapy;
  - quitting all tobacco use;
  - using the comparison product (i.e., the product your application argues is more harmful and that people should switch from)
  - dual use of the MRTP and the comparison product (i.e., incomplete switching from the comparison product to the MRTP).

For the above measures, the health risks assessed would include risk of specific tobacco-related diseases, such as the principal diseases associated with use of the MRTP, as well as any specific risks or diseases mentioned in the modified risk claim itself.

Intentions to Use

FDA recommends that TPPIS assess behavioral intentions. For example, this could include intended behaviors ranging from product purchase, trial, use, or discontinuing use. FDA recommends you define and measure the behavioral intention of interest based on the research question and in consultation with the scientific literature to identify measures that are established as valid whenever possible.

A well-conducted TPPIS would assess a range of measures of intention related to product use, including the extent to which:

- tobacco users intend to switch completely to using the MRTP;
- tobacco users intend to use the MRTP in conjunction with other tobacco products;
- tobacco users opt to use the MRTP rather than cease tobacco use altogether; and
- nonusers, including never users and former users, intend to initiate or relapse tobacco use with the MRTP.

Understanding

FDA recommends TPPIS assess participant understanding of the modified risk information, such as: the extent to which participants understand the information about risk, its significance in the context of one's health, and the conditions of using the product that are required to achieve reduced risk. Measures of understanding might assess potential unintended consequences related to the modified risk information presented, for example, the extent to which consumers may believe that they can achieve reduced risk even if they do not use the product as intended; and the extent to which consumers infer benefits of the product (e.g., additional risks reduced) that the product does not actually confer.

Study Sample

Users and Non-Users of Tobacco Products

To evaluate the potential population health impact of marketing a product, studies should include current users of tobacco products as well as people who do not currently use tobacco products (both former and never users). When identifying which user and nonuser groups to include in a study, you should consider both intended and unintended users of the product.

Once these groups have been selected, careful consideration should be given to determine the most appropriate operational definitions. When selecting definitions for user and non-user groups, FDA recommends you:

- consult relevant scientific literature;
- consider how age group (e.g., youth vs. adults) and tobacco product class (e.g., cigarettes) may affect how product use states, such as current use, are defined (e.g., use of a threshold for lifetime use); and
- select definitions appropriate for your particular research questions and study design.

In all cases, FDA recommends clear articulation of how you are defining user and non-user groups and providing a scientific rationale for these definitions.

Populations particularly likely to be affected

FDA recommends that you identify and oversample subpopulations that are especially likely to be affected by the marketing of the tobacco product being studied. These subpopulations may include both:

- individuals to whom you plan to market the product (i.e., intended users); and
- individuals who you do not intend to use the proposed modified risk tobacco product but who nonetheless may be more likely to use the tobacco product based on demographic or other characteristics (e.g., young adult non-users).

Sample Size and Power

FDA recommends that you provide a justification for the sample size, based on the following guidelines:

- If the study is quantitative with primary hypotheses, you should conduct statistical power analyses to determine the sample size needed to detect the hypothesized effect size(s). FDA recommends that you provide the following information when reporting power analyses:
  - the statistical computations used to determine sample sizes, specifying the number of primary hypotheses or research questions, the associated type I error probabilities, and the statistical power, and how the sampling design was considered in the power analysis;
  - the statistical tests planned for analyses, the expected effect sizes for which the study was powered; and
  - a description of how study design and sampling plan were accounted for in the power analysis.
- If additional analyses are conducted on secondary hypotheses, you should consider that any lack of observed effects may be due to insufficient statistical power. You should also consider this when interpreting the results of quantitative exploratory studies.
- FDA recommends that you develop a sampling plan to ensure that you can detect small effect size differences between subpopulations particularly likely to be affected by the marketing of your product and the general population.

Human Subjects' Protection

FDA recommends you submit your TPPIS for Institutional Review Board (IRB) review. An IRB reviews the risks and benefits of research involving humans to protect them from physical or psychological harm. Most research institutions have their own IRBs, and independent IRBs review research conducted by entities that are not affiliated with such institutions.

We recommend investigators develop a plan for effectively debriefing participants at the conclusion of the study to mitigate any lingering effects that study participation may have had on study participants.

Analysis

FDA recommends you develop an analysis plan before the data are collected. The analysis plan should follow from the research aims and hypotheses. Developing an analysis plan beforehand helps to prevent bias and promote transparency. Several additional recommendations for reducing bias and providing transparency are described below.

For quantitative studies, FDA recommends that you include the following in the analysis plan:

- Power analyses for primary outcomes to ensure the sample size is suitable for the planned analytical approach (see "Sample Size and Power" Section above).
- Description for how data will be cleaned and assessed for meeting statistical assumptions of the chosen data analytic technique.
- Description of planned primary and secondary analyses.
- Description of covariates you plan to include, and a justification for including them (or a justification for not using covariates).
- Description of plan for handling missing data.
- Description of weighting procedures and rationale for how they were determined (or a justification for not using them);
- Description and justification for how you dealt with Type I error with multiple comparisons.

The analysis plan should direct the analysis after data collection. If any deviation from the analysis plan is required based on unforeseen circumstances, this deviation should be well documented and include a clear explanation of why the deviation was necessary and rationale for the new approach. The choice to deviate should be reported with the results, and include the explanation and rationale for the new approach.

VIII. Handouts/Presentations

MARCH 22, 2017

SWEDISH MATCH MRTPA MEETING WITH CTP OFFICE OF SCIENCE

JIM SOLYST

OVERVIEW OF AGENDA

Three presentations:

- **Review of the MRTPA Science and Basis for Preliminary Claims/Messages**
  - **Lars-Erik Rutqvist, Sr. VP for Scientific Affairs, Swedish Match AB**

- **Market Dynamics within Tobacco Category**
  - **David Price, VP for Marketing, Swedish Match North America**

- **Consumer Research for a Revised MRTPA**
  - **Steve Seiferheld, Director, Marketing Research, Swedish Match North America**

SWEDISH MATCH REACTION TO THE DECEMBER 14, 2017 PARTIAL DECISION

- Stand by the decision to request removal of the existing mouth cancer and tooth loss/gum disease warning labels.
- But we accept the partial decision for now and we want to move forward.
- In correspondence with Swedish Match, CTP stated that the applications could be amended in several ways: "for example by changing the proposed claims, supplementing the evidence, and conducting new studies…"
- We are only interested in changing the claims and only providing new studies that are directly related to the new claims.

SWEDISH MATCH PROPOSED PATH FORWARD

- For a revised MRTPA, the goal is to develop claims/messages that are scientifically accurate and resonate with adult tobacco consumers.
- We started with the science; and each claim/message is based on the findings from a credible study, or usually several studies.
- CTP decision documents were particularly significant in the development of possible claims/messages; most notably the PMTA Technical Project Lead document.
- Will design and conduct a consumer intent study to test the proposed claims/messages. The consumer intent study will essentially be a refined version of the study conducted for the initial MRTPA.
- The Company's capabilities and understanding of what is necessary has increased significantly since we prepared the initial consumer perception study.

GOAL OF THIS MEETING

- Feedback regarding the preliminary claims/messages;
  - Are the claims/messages presented in the February 3, 2017 letter scientifically sound?
  - Narrow down the list, allowing Swedish Match to select claims/messages to be tested.
- Provide CTP OS an overview of the Swedish Match approach to conducting consumer perception studies and receive preliminary feedback.
- Determine a process for ongoing communication to ensure a timely and efficient path forward.
- Discuss a timeframe for Swedish Match to conduct the necessary consumer perception studies and submit revised MRTPAs.

THE SWEDISH MATCH MRTPA FOR GENERAL SNUS

CTP MEETING, MARCH 22, 2017

LARS E. RUTQVIST, M.D., PH. D.

“WHY ARE WE DOING THIS ?”

- **Promotion of tobacco harm reduction through communication of truthful, science-based information to the public about the risk differential between Swedish snus manufactured according to the Gothiatek® standard and cigarettes**
  - Tobacco consumers are interested in less risky products
  - Swedish Match is currently unable to publicly communicate the available science about snus because it might be construed as unauthorized health claims
  - Current warnings lack a solid, scientific evidence base and can be misleading,
  - Public not well informed about “continuum of risk” & risk differential between low-nitrosamine, smokeless products such as Swedish snus and cigarettes
  - These circumstances work against tobacco harm reduction & promotes dual use/smoking maintenance
  - Section 911 is the only regulatory pathway to address these issues

SNUS MRTPA: POSSIBLE PATH FORWARD

- We believe that the FDA took a precautionary approach in making the Dec 14, 2016 decisions
- Had the approach been based on “weight of evidence” and/or quantitative risk assessments, the decisions may have been different
- Nonetheless, we accept the situation for now, and we want to move forward along the lines suggested in CTP’s Dec 14 communications

POSSIBLE PATH FORWARD, CONT'D

- **CTP has stated that the applications could be amended in several ways:**
  - **"for example, by changing the proposed claims, supplementing the evidence, and conducting new studies…"**
- **We don't believe that provision of new toxicological data or human health evidence is likely to be sufficient to overcome the partial decision nor FDA's apparent inclination to reject our request to remove/change the mouth cancer or "not safe alternative…" warnings**
- **We believe a possible way forward could be to (1) change the claims, (2) put them in a context outside of the current health warnings, and (3) provide new, premarket evidence related to these claims**

We need CTP's feed-back on this proposed path forward, the new claims & our ideas on how to rigorously test them in a premarket setting

POSSIBLE HEALTH CLAIMS FOR SNUS (OUTSIDE OF CURRENT WARNINGS)

- **Guiding principles for the development of health claims**
  - **Consistent with available, epidemiological evidence**
    - Cancer, cardiovascular disease
  - **Language in the PMTA Technical Project Lead Report**
    - Quantification of cancer risk reduction
  - **Consistent with generally accepted pathogenetic pathways in the absence of epidemiological confirmation**
    - COPD
- **Proposed health claims should also be comprehensible, resonate with adult tobacco consumers, and not be misleading or have unintended consequences**
  - None of them have yet been tested in a premarket setting
- **Feed back from CTP needed on which of these claims are most useful for the protection of public health and have the ability to effectively communicate with the public**

PROPOSED HEALTH CLAIMS

1. **If you switch completely from cigarettes to General snus/this product , you reduce your risk of tobacco-related cancer by more than 90%**
2. **Exclusive use of General snus/this product instead of smoking greatly reduces your risk of heart disease and stroke**
3. **Exclusive use of General snus/this product instead of cigarettes will substantially reduce your risk of tobacco-related disease**
4. **Exclusive use of General snus/this product instead of smoking substantially reduces your risk of both mouth cancer and lung cancer**
5. **If you switch completely from cigarettes to General snus/this product, you substantially reduce your risk of heart disease, stroke, COPD, mouth cancer, and lung cancer**
6. **General snus/this product does not cause lung cancer or COPD (e. g. chronic bronchitis, emphysema, asthma)**

- None of these statements include a disclaimer about other relevant risks as this can be considered covered by the current warnings
- Inconsistent to require that an MRTP should carry more elaborate health warnings that other products from the same category

CURRENT WARNINGS MAY COUNTERBALANCE THE HEALTH CLAIMS

The proposed health claims may be interpreted as inconsistent or confusing when viewed together with the currently mandated warnings

- **"If you switch completely from cigarettes to General snus, you reduce your risk of tobacco-related cancer by more than 90%"**
- **"Exclusive use of General snus instead of smoking substantially reduces your risk of both mouth cancer and lung cancer"**
- **"WARNING: THIS PRODUCT CAN CAUSE MOUTH CANCER"**

- **"If you switch completely from cigarettes to General snus, you substantially reduce your risk of heart disease, stroke, COPD, mouth cancer, and lung cancer"**
- **"Exclusive use of General snus instead of cigarettes will substantially reduce your risk of tobacco-related disease"**
- **"WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES"**

RATIONALE FOR A CHANGE OF THE CURRENT WARNINGS

- **Modifying the existing warning statements would be an important first step to address the public's misconceptions about products such as Swedish snus**
- **The warnings constitute the U.S. Government's most distinctly communicated and widely distributed evaluation of a product's health profile**
- **Although it can be argued that the current warnings are not factually incorrect, they do not acknowledge the risk differential that exists between Swedish snus and cigarettes, and may be interpreted to contradict the concept tobacco harm reduction (the concept that underpins section 911)**
- **Current warnings may counterbalance any health claims/risk reduction messages from a manufacturer**

COMMENTS ON THE MRTPA TPL REVIEW (MOUTH CANCER WARNING)

- **”Omission of this warning from a subset of smokeless tobacco products indicates that, unlike other smokeless tobacco products, the eight General snus products *cannot* cause mouth cancer”**
  - We disagree with this premise
  - More reasonable interpretation is that for these eight General products the risk has been demonstrated to be non-existent or at least so small that a warning is unwarranted
  - Proving a negative is scientifically impossible in human health research
- **”General snus contains NNN & NNK which are carcinogenic, therefore they pose an increased risk of mouth cancer”**
  - Statement not based on a quantitative risk assessment
  - U.S. Supreme Court, 1980: Industrial Union Department, ALF-CIO v. American Petroleum Institute (448 U.S. 607)
    - Emphasizes an obligation for government agencies involved in the control of toxic substances to conduct a rational risk assessment
    - A quantitative risk assessment should be conducted in order to define the level of risk
    - “Safe" in this context should not be defined as risk-free

COMMENTS ON THE MRTPA TPL REVIEW (MOUTH CANCER WARNING), CONT'D

- **FDA response not based on a weight of evidence approach**
  - **Latest meta-analysis of all available seven mouth cancer studies:**
    - All subjects: RR 0.97 (95% C.I.: 0.68-1.37) (Lee PN, 2013)
    - This meta-analysis estimate includes the Roosaar et al. study (RR 3.1, 95% C.I.: 1.5-6.6)
    - Unreasonable to cite an outlier as evidence of an effect when the totality of the evidence shows no effect
- **"No treshold for NNN carcinogenicity. Therefore, no evidence that snus "cannot" cause oral cancer**
  - Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk. M7(R1) Addendum to ICH M7. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER), May 2015
  - Section 7.2.2: "The existence of mechanisms leading to a dose response that is non-linear or has a practical threshold is increasingly recognized…"
  - We believe that the negative epidemiological findings (Lee PN, 2013) [1] together with quantitative, toxicological considerations related to formation of DNA-adducts from nitrosamines (Nilsson R, 2011)[1] indicate that the low levels of nitrosamines in Swedish snus are below what can be described as a "practical threshold"

1. Lee P N, Harm Reduction Journal. 2013, 10:36
2. Nilsson, R.. Regul Toxicol Pharmacol. 2011

COMMENTS ON THE MRTPA TPL REVIEW (" …NOT A SAFE ALTERNATIVE TO CIGARETTES")

- **"Snus may reduce the risk of some, but not all, tobacco-related diseases…"**
  - "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"
  - Proposed warning does not imply reductions of all tobacco-related diseases
    - The MRTPA clearly demonstrated substantial risk reductions among individual users for those diseases that contribute >90% of the excess mortality among smokers
  - In rational risk management, "safe" should not be defined as equivalent to "no risk"
    - U.S. Supreme Court, 1980: Industrial Union Department, ALF-CIO v. American Petroleum Institute (448 U.S. 607)

- **The current "not a safe alternative" represents an inappropriate and confusing message for a product deemed to be an MRTP**
  - Does not acknowledge the concepts of "continuum of risk" or "tobacco harm reduction"
  - Support current public misconceptions

COMMENTS ON THE DENIAL OF REMOVING THE "GUM DISEASE & TOOTH LOSS" WARNING

- **Current warning lacks a convincing, scientific evidence base**
  - Evidence base for snus-oral health not as solid as that for snus-oral cancer
- **"..little biologically plausible reason…that outcomes (with snus) would differ from…use of other smokeless tobacco products"**
  - Compelling scientific rationale for snus having different oral effects than some other STP:s on the US market
  - Chemical analysis section of the MRTPA provides a rationale: high pH, no added sugar
- **Not based on a weight of evidence approach to evaluating the available studies (IOM, Bradford-Hill guidelines)**
  - Larger and more recent studies adjusting for oral hygiene show no association for gum disease and tooth loss
- **"Given the evidence that snuff-induced lesions develops in almost all regular snus users, we cannot conclude that there is a biologically plausible mechanism by which these products cannot cause gum disease and tooth loss"**
  - "Snus lesions" constitute a marker of snus use, not a "gum disease"
  - Proving a negative ("cannot cause") is impossible in human health research

- THANK YOU -

MARKET DYNAMICS WITHIN TOBACCO CATEGORY

MARCH 22, 2017

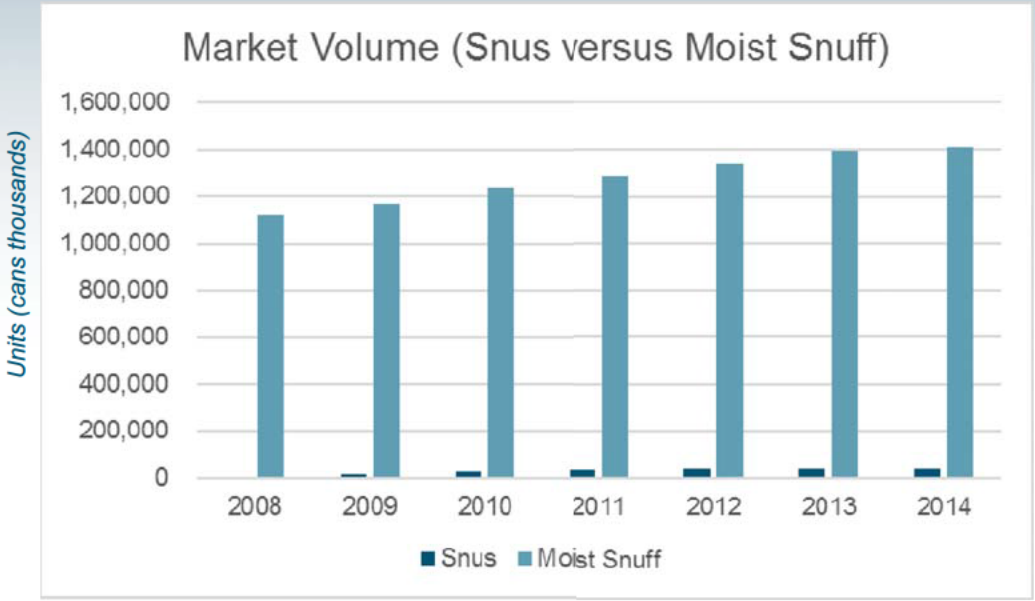
David Price
Vice President Marketing
david.price@swedishmatch.com

CONTENTS:

- HISTORY OF SNUS IN U.S. MARKET
- PRODUCT FORM USAGE AND ADOPTION
- PERCEIVED RISK BY PRODUCT FORM

HISTORY OF SNUS IN U.S. MARKET

MARKET DEVELOPMENT OF SNUS VERSUS OTHER TOBACCO FORMS



	Pounds Sold	Dollar Sales	Estimated Volume	Advertisng and Promotional Expenditures
2008	170,527	$ 9,148,659	5,147,985	$ 58,763,000
2009	482,909	$ 49,807,528	14,578,385	$ 106,415,000
2010	818,913	$ 81,786,519	24,721,902	$ 57,394,000
2011	1,052,675	$ 77,999,446	31,778,868	$ 13,703,000
2012	1,291,182	$ 99,104,325	38,979,079	$ 55,593,000
2013	1,192,881	$ 84,594,698	36,011,502	$ 51,163,000
2014	1,230,967	$ 93,040,562	37,161,268	$ 47,392,000

Estimated volume assumes per unit equals (.53 ounces)

- In 2009, reported Advertising and Promotional Expenditures of $106.4 million within Snus category.^
- The expenditure (2009) represents 37% of the total spend of the Moist Snuff category.
- The (7) year average spend within Snus category equals $57.4 million compared to Moist Snuff of $345.4 million (17%)
- Snus category volume in 2014 represents 2.6% of moist snuff.
- In 2014, cigarette reported volume represents 12.7 billion packs.^^

Swedish Match.

^ Source: FTC: Federal Trade Commission Smokeless Tobacco Report for 2014 (issued 2016)
^^ FTC: Federal Trade Commission Cigarette Report for 2014 (issued 2016)

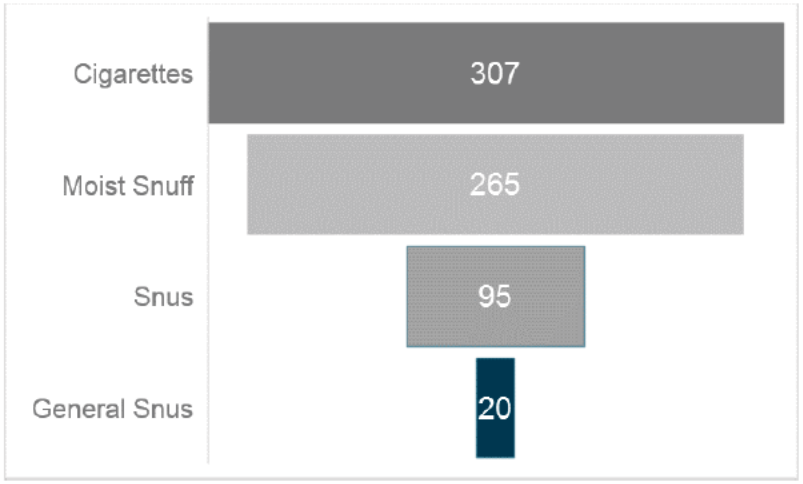
HISTORY OF SNUS IN U.S. MARKET

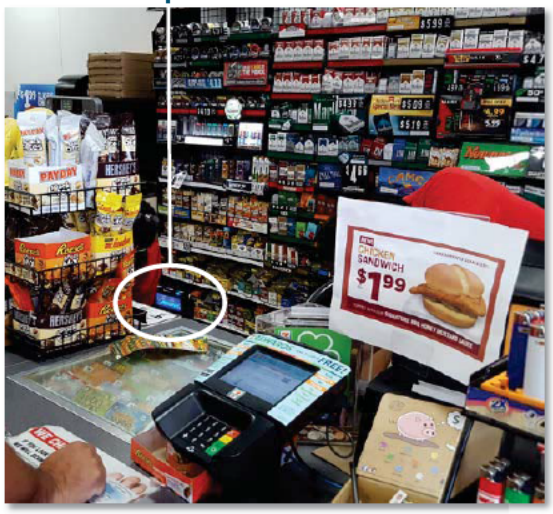
RETAIL ENVIRONMENT: SNUS PLACEMENT VERSUS OTHER TOBACCO FORMS

- Cigarettes are in distribution in approximately 307 thousand retail outlets, with Convenience stores being the primary outlet (56%/ 172 thousand).^
- Smokeless tobacco, including moist snuff and Chewing tobacco are sold in approximately 265 thousand outlets (86% of cigarette retail locations).
- Snus is in distribution in approximately 95 thousand outlets.

- Within retail, depending on brand, snus is located in either the cigarette, moist snuff or an independent location.
- Placement and visibility of General Snus offerings are non-uniform.

RETAIL OUTLETS BY PRODUCT TYPE (thousands)





^ Source: Nielsen, TD link December 2016

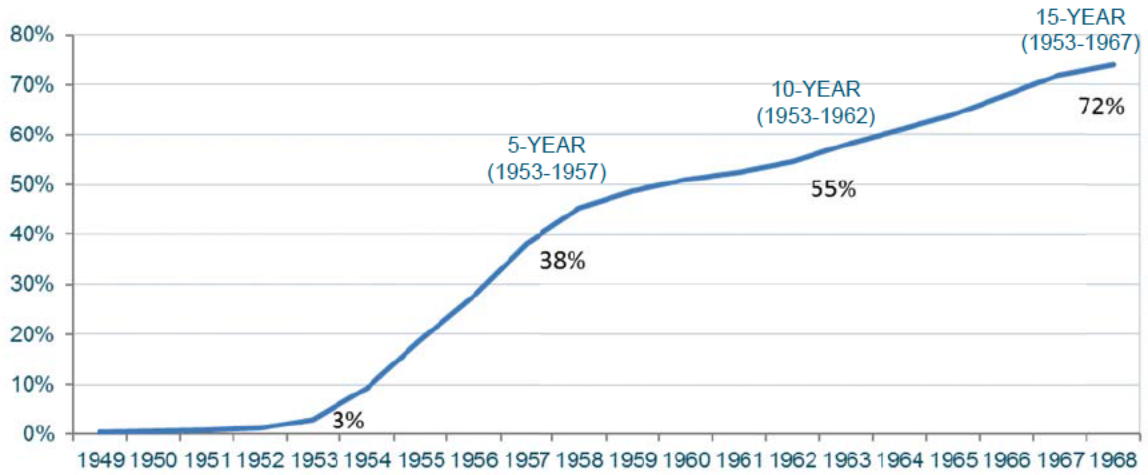
PRODUCT FORM USAGE AND ADOPTION

ADOPTION: DIFFUSION OF INNOVATION

*Everett Rogers, i*n the book *DIFFUSION OF INNOVATION,* suggests five main steps in the innovation-decision process:
1) knowledge, (2) persuasion, (3) decision, (4) implementation, and (5) confirmation.^

- Knowledge: learns of the innovation and gains some understanding of how it functions
- Persuasion: when one forms a favorable or unfavorable opinion of how it functions
- Decision: activities that lead to a choice to adopt or reject
- Implementation: takes place when an individual puts an innovation into use
- Confirmation: seeks reinforcement of an innovation-decision that has already been made, but he or she may reverse this previous decision if exposed to conflicting messages

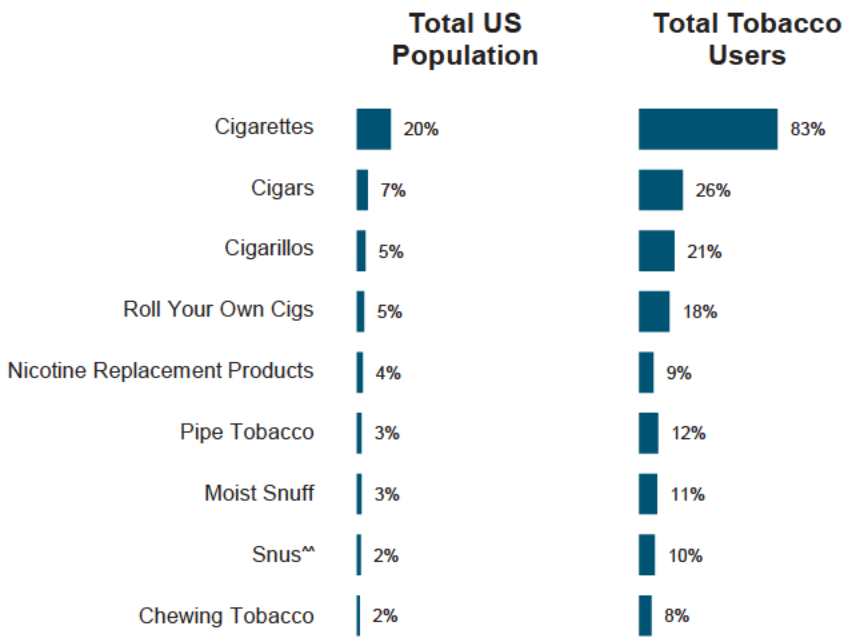
MARKET SHARE DEVELOPMENT OF FILTERED CIGARETTES^^



^ SOURCE: Everett Rogers, *Diffusion of Innovation*, (New York: Simon and Schuster 1995), p.20
^^ Federal Trade Commission Cigarette Report for 2014 (issued 2106)

PRODUCT FORM USAGE AND ADOPTION

Percentage of (a) the US population, and (b) US tobacco users that have used ___ within the past two weeks^:



PATH Study* (n=32,320) found a total of 387 people (1.2%) who claimed to use snus –respondents cited brand(s) that aren't snus products

Brand	# Users
Camel	198
Skoal	99
Marlboro	19
Copenhagen	14
General	1
Other "incorrect" brands	1

331 "believed" snus users (1.0%)

88 people who have used snus in past 30 days

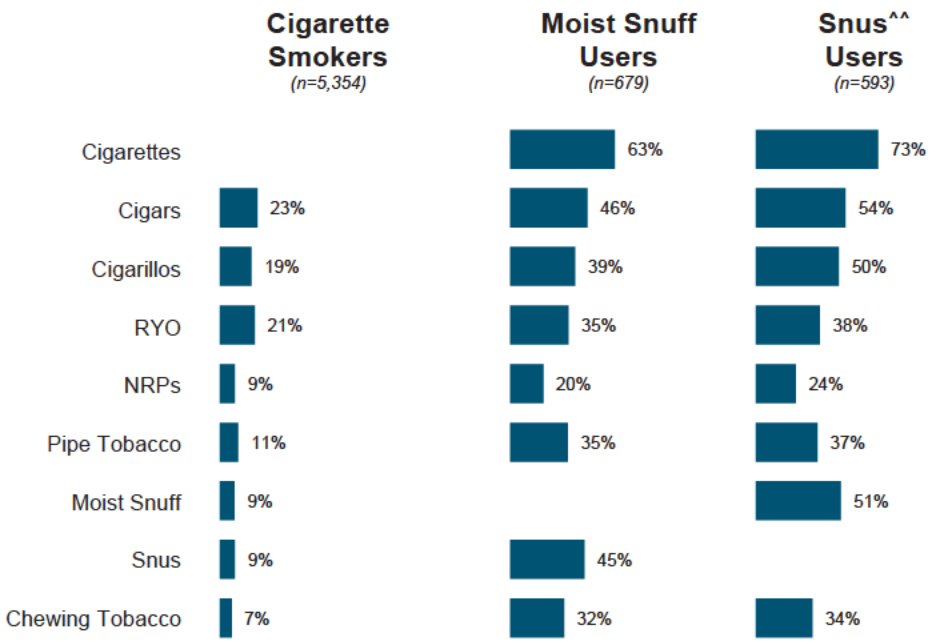
Swedish Match.

^ Source: Swedish Match 2016 tracking study. Total sample = 20,511.
^^ Swedish Match believes all snus-related responses are overstated due to confusion between snus and moist snuff pouches.
* Source: Population Assessment of Tobacco and Health (PATH) Study, Wave 1, adult data.

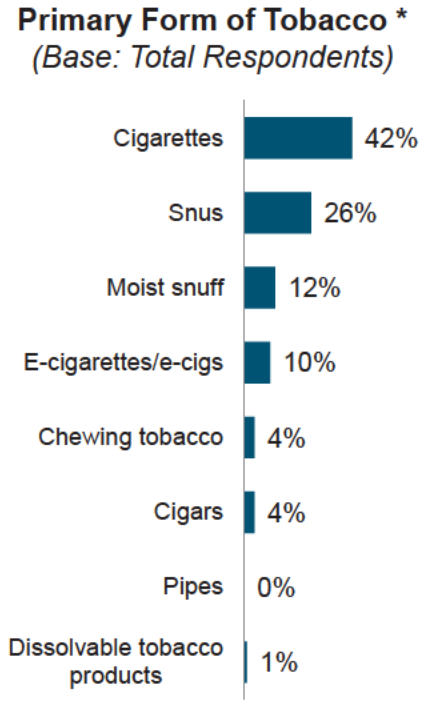
PRODUCT FORM USAGE AND ADOPTION

POLY USE^ AND SNUS SPECIFIC INFORMATION*

Broad-based poly use within the tobacco category…



… and in snus category, where among snus users, snus isn't even the #1 used tobacco form.



Swedish Match.

^ Source: Swedish Match 2016 tracking study. Total sample = 20,511.
^^ Swedish Match believes all snus-related responses are overstated due to confusion between snus and moist snuff pouches.
* Source: Swedish Match 2016 brand tracking study. Total sample = 503.

PRODUCT FORM USAGE AND ADOPTION

PATH STUDY: LITTLE CURRENT CONSIDERATION FOR SNUS, MINIMAL SWITCHING OVERALL

- **Q: Have you considered switching from [PRODUCT] to any of the following products? Choose all that apply.**

- Considered switching from cigarettes to snus pouches:
  Yes: 35 (0.34%)
  No: 10,227 (99.66%)
  Total: 10,262
- Considered switching from cigarettes to e-cigarettes:
  Yes: 619 (6.03%)
  No: 9,643 (93.97%)
  Total: 10,262
- Have **not** considered switching from snus pouches to another product:
  Yes: 194 (97.00%)
  No: 6 (3.00%)
  Total: 200
- Have **not** considered using any products in addition to snus pouches:
  Yes: 189 (95.00%)
  No: 10 (5.00%)
  Total: 199

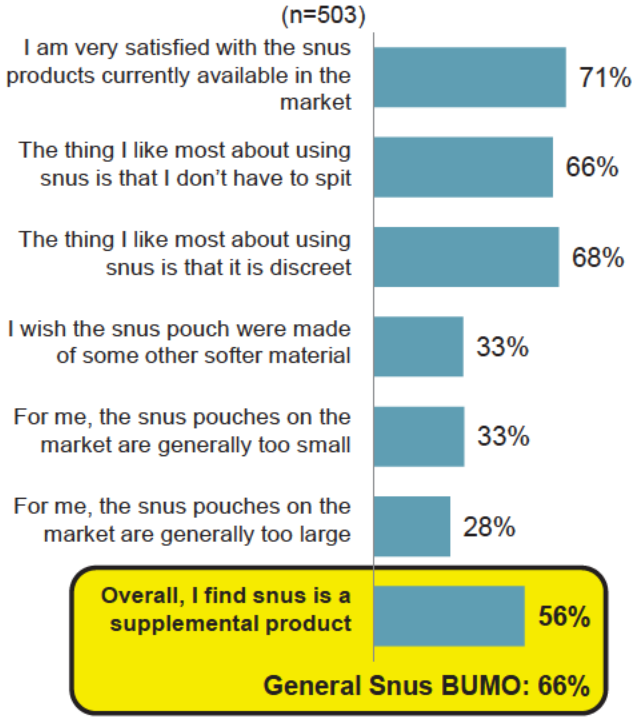
Source: NIH and FDA: Population Assessment of Tobacco Health (PATH)

PRODUCT FORM USAGE AND ADOPTION

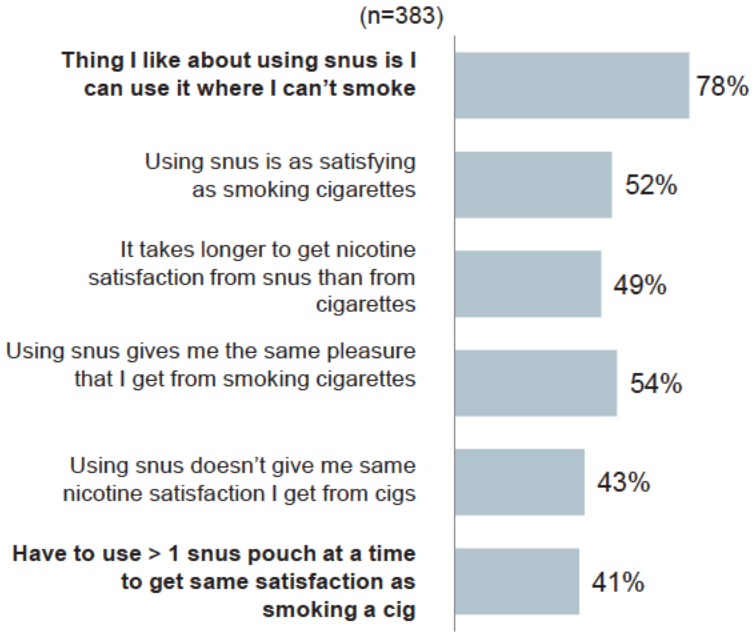
PEOPLE VIEW SNUS AS SUPPLEMENTAL, AN OPTION FOR WHEN SMOKING IS NOT. USAGE OF >1 POUCH UP VS. PRIOR YEARS.

- **Metrics all relatively unchanged v. prior years; "supplemental product" question is new as of 2016.**

Snus Attitudes/Perceptions
% Agree (Rated 1,2)†
(Base: Total Respondents)



Snus Attitudes/Perceptions
% Agree (Rated 1,2)†
(Base: Smokes Cigarettes)



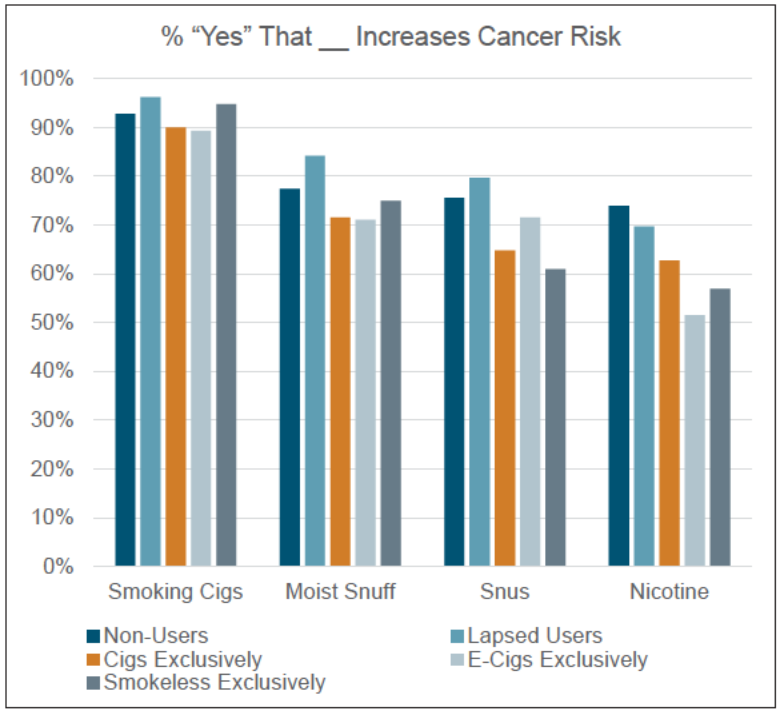
Source: Swedish Match 2016 brand tracking study. Total sample = 503.

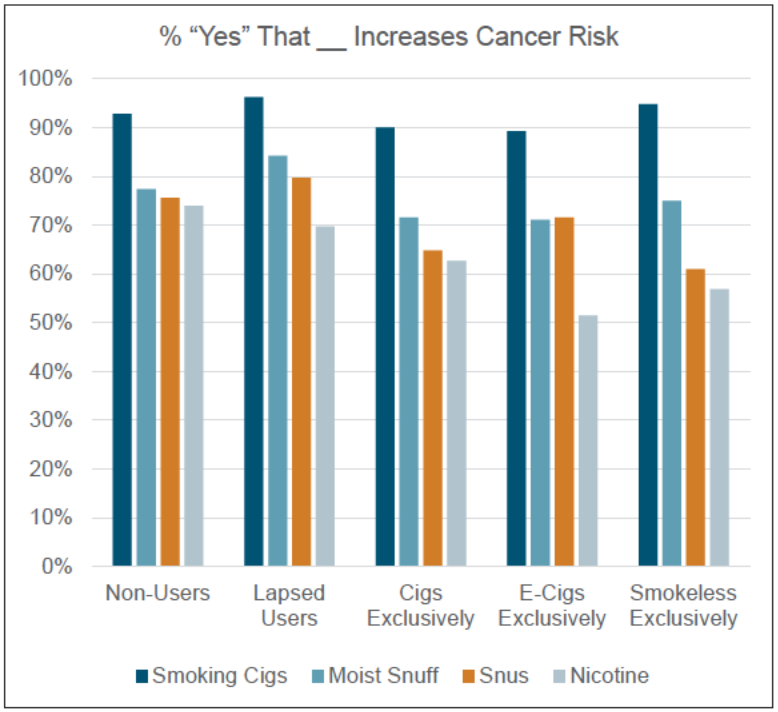
Swedish Match.

PERCEIVED RISK BY PRODUCT FORM

PERCEIVED INCREASE IN CANCER RISK BY USERS AND PRODUCTS

Cigarettes clearly deemed more risky; remaining products arguably clustered, or similar in reputation.





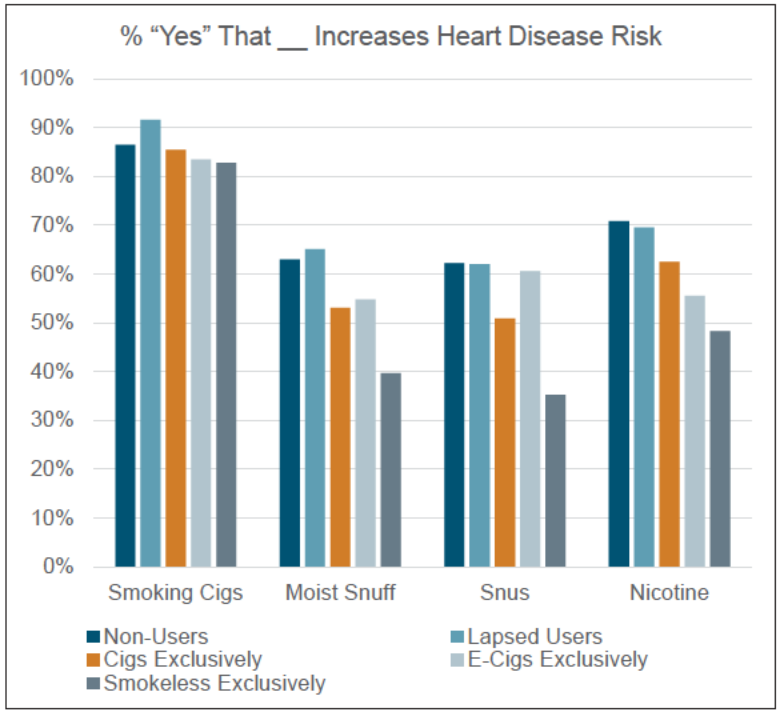
Swedish Match.

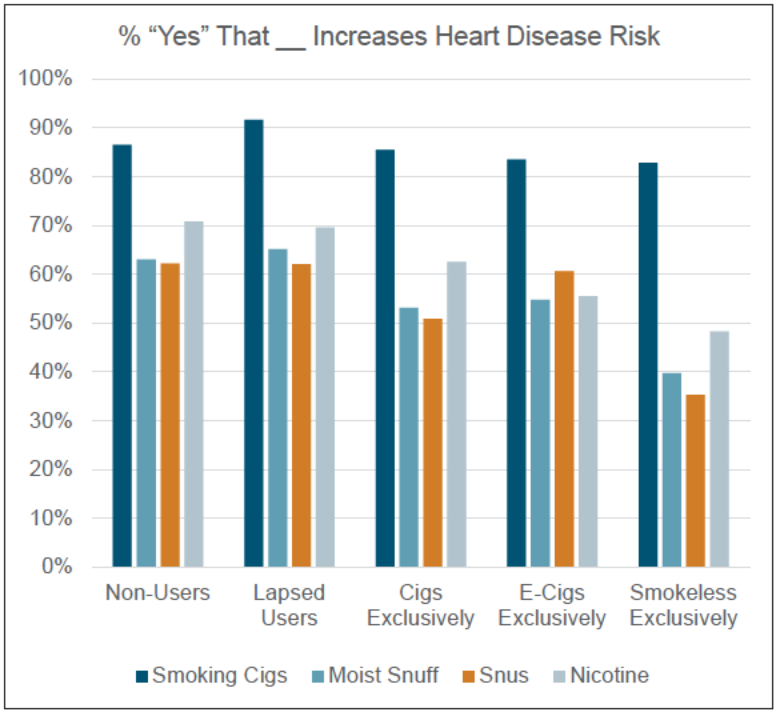
^ Source: Swedish Match 2016 tracking study. Total sample = 20,511.

PERCEIVED RISK BY PRODUCT FORM

PERCEIVED INCREASE IN HEART DISEASE RISK BY USERS AND PRODUCTS

Cigarettes clearly deemed more risky; remaining products arguably clustered, or similar in reputation.





^ Source: Swedish Match 2016 tracking study. Total sample = 20,511.

DISCUSSION ON FUTURE CONSUMER RESEARCH PERTAINING TO GENERAL SNUS MRTP APPLICATION

MARCH 22, 2017

Steve Seiferheld
Director, Market Research
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WHERE THINGS STAND TODAY

- **With the benefit of hindsight, Swedish Match acknowledges flaws in previously submitted consumer research, flaws that raise questions regarding interpretation of results within the General Snus MRTP application.**
  - Failure to present stimuli within the context in which a consumer would reasonably consume any information about the products;
  - Lack of feedback establishing what consumers understand about the risks of using General Snus, in light of the modified risk information;
  - Use of a non-probability sample in the study;
  - Use of semantics requiring respondents to speculate on future behavior, as opposed to gathering a more definitive statement regarding behavioral intentions;
  - Poorly chosen response scales, with text anchors likely to have confused respondents.

SWEDISH MATCH POINT OF VIEW ON MOVING FORWARD

1. **Swedish Match can, and will, deliver a consumer research study with the following key components:**
   - Objective: the evaluation of hypothesized marketing materials, comprised of claims, messaging, and creative.
   - Methodology: consumer survey research, guided by best practices within questionnaire design, statistical sampling, cognitive testing, and data analysis.
     - Process to also include ample qualitative pre-testing of creative prior to final, broader survey research.
     - Intention to employ 3rd party vendor and independent, Ph.D. level consultant to ensure final product meets any reasonable scientific standard.

2. **Swedish Match cannot deliver the "best" or "correct" research absent the collaboration of CTP staff responsible for evaluating consumer research.**
   - We strongly believe that we have a product, General Snus, that can favorably impact public health through substitution for other tobacco products, especially cigarettes.
   - We are not positioned to guess at the right criteria required by CTP; we need to get it right this one time.
     - "Right" → in line with the expectations of CTP when it comes to demonstrating effect on consumer attitudes and intentions.

SWEDISH MATCH POINT OF VIEW ON MOVING FORWARD

3. In the pre-market setting, Swedish Match cannot deliver an actual use test that will accurately quantify the impact of reduced-risk marketing.

- Current actual use of General Snus, even snus overall, does not provide enough information to measure how MRTP can affect the tobacco category.
  - Data from the PATH study clearly demonstrate the **current absence of interest among smokers in switching to snus**.
    - Considered switching from cigarettes to snus pouches:

Yes:	35	0.34%
No:	10,227	99.66%
Total:	10,262	

  - PATH data combined with sales figures guarantees that an actual use test conducted via observational study would not yield results with any actionability.
- A controlled, designed study would "artificially" create a market aware of marketing claims regarding risk reduction. In the context of General Snus, we would see results not guaranteed to be repeatable given current sales and distribution of the product.

Swedish Match is committed to conducting actual use research through observational cohort tracking in the post-MRTP environment, where results would be credible and informative.

RESEARCH PROTOCOL OUTLINE

Below we outline Swedish Match's current plan for consumer research addressing General Snus and MRTP-related marketing. We actively request input from CTP.

- **Research hypotheses.**
- **Methodology for testing hypotheses.**
  - Questionnaire development and contents.
  - Cognitive testing.
  - Data collection methodology.
  - Sampling algorithm.
  - Data analysis.
- **Potential timeline.**
  - Timeline will include qualitative research conducted in advance of the final consumer research study, utilized to refine stimuli and ensure putting our best material in front of respondents.

RESEARCH PROTOCOL - HYPOTHESES

- **Swedish Match will conduct consumer research with the goal of validating the hypotheses detailed on the following slides. All examples assume:**
  - Stimuli will have been screened and approved by CTP as usable in a post-market setting.
    - Takes into account commentary from Dr. Lutqvist regarding potential confusion of including warning labels and claims on same pieces of information.
  - Respondents will have been randomized to being or not being exposed to stimuli;
  - Stimuli will focus on one General Snus SKU, specifically our best-selling SKU.
    - Assumed that all results would be consistent across remaining SKUs, which differ predominantly by flavor.
    - One General Snus SKU contains "mini" pouches, though Swedish Match sees no reason why responses would vary between mini and "normal" sizes snus pouches.
  - Respondents assigned to the test cell (i.e. exposed to stimuli) will be exposed to stimuli in a randomized order, answering key performance indicating questions after each stimuli.
    - Respondents will not see greater than three (3) stimuli.
    - If Swedish Match and CTP determine that greater than three (3) stimuli should be tested, study design will be updated to reflect an appropriate stimuli rotation.

RESEARCH PROTOCOL – SURVEY QUESTIONS ADDRESSING HYPOTHESES

- **The intent study will probe consumers on the topics addressed under Hypotheses.**
- **While not necessarily intended to be final, the next slides outline a likely set of questions that will be utilized to measure the information referred to in the Hypotheses.**
  - As stated earlier, Swedish Match requests CTP feedback on all elements of the research protocol.
  - All questions will go through cognitive testing; the examples presented here have not necessarily gone through testing in these exact forms.
    - Though worth noting, all questions come from either the PATH study or well-studied scale questions.

PRIMARY SURVEY QUESTIONS FOR ADDRESSING RESEARCH HYPOTHESES

Hypothesis	Primary Response Variable Question	Comparison Of Interest
1. Exposure to stimuli will result in respondents deeming General Snus to be less harmful than cigarettes, compared to respondents unexposed to stimuli.	**Is using General Snus less harmful, about the same, or more harmful than smoking cigarettes?[1]** **Less harmful** **About the same** **More harmful** **I don't know** **I prefer not to answer**	Respondents exposed to marketing stimuli v. respondents not exposed to marketing stimuli. Stimuli exposure randomly determined.
2. Exposure to stimuli will result in respondents deeming General Snus to be less likely to cause major adverse health conditions, such as heart disease, lung cancer, and stroke, compared to respondents unexposed to stimuli.	**Based on what you know or believe, does using General Snus cause [INSERT ADVERSE HEALTH CONDITION] in users?[2]** **Yes** **No** **I don't know** **I prefer not to answer**	Respondents exposed to marketing stimuli v. respondents not exposed to marketing stimuli. Stimuli exposure randomly determined.

1. Based on PATH study, updated July 21, 2016. Sourced from variable R01_AS1105. Alternative of 5-point scale (much less harmful, mildly less harmful, about the same, mildly more harmful, much more harmful) to be considered.
2. Based on PATH study, updated July 21, 2016. Sourced from variable R01_AC9060.

PRIMARY SURVEY QUESTIONS FOR ADDRESSING RESEARCH HYPOTHESES

Hypothesis	Primary Response Variable Question	Comparison Of Interest
3. Exposure to stimuli will result in current tobacco-using respondents more likely to express interest in learning more about General Snus through their own research, compared to respondents unexposed to stimuli.	**Over the next 30 days, how likely are you to try and learn more about General Snus?**[3]	Respondents exposed to marketing stimuli v. respondents not exposed to marketing stimuli. Stimuli exposure randomly determined.
4. Exposure to stimuli will result in current tobacco-using respondents more likely to consider purchasing General Snus, if the product is available in a local retailer and is not deemed cost-prohibitive, compared to respondents unexposed to stimuli.	**Over the next 30 days, how likely are you purchase General Snus, assuming it is available at one of your local retailers and affordable for you?**[3] **[Juster scale, as above]**	Respondents exposed to marketing stimuli v. respondents not exposed to marketing stimuli. Stimuli exposure randomly determined.

JUSTER'S 11-POINT PROBABILITY SCALE

Score	Verbal Equivalent
0	No chance, almost no chance [1 in 100]
1	Very slight possibility [1 chance in 10]
2	Slight possibility [2 chances in 10]
3	Some possibility [3 chances in 10]
4	Fair possibility [4 chances in 10]
5	Fairly good possibility [5 chances in 10]
6	Good possibility [6 chances in 10]
7	Probable [7 chances in 10]
8	Very probably [8 chances in 10]
9	Almost sure [9 chances in 10]
10	Certain, practically certain [99 chances in 100]

3. Juster 11-Point Probability Scale. Developed by F.T. Juster in 1964.

PRIMARY SURVEY QUESTIONS FOR ADDRESSING RESEARCH HYPOTHESES

Hypothesis	Primary Response Variable Question	Comparison Of Interest
5. Exposure to stimuli will fail to conclude that non-users or past-users of tobacco express any interest in learning more about General Snus through their own research, compared to current tobacco-using respondents.	**Over the next 30 days, how likely are you to try and learn more about General Snus?**[3]	Will compare current tobacco users to non-users and past-users. Sub-segment of interest: only respondents exposed to stimuli.
6. Exposure to stimuli will fail to conclude that non-users or past-users of tobacco consider purchasing General Snus, if the product is available in a local retailer and is not deemed cost-prohibitive, compared to current tobacco-using respondents.	**Over the next 30 days, how likely are you purchase General Snus, assuming it is available at one of your local retailers and affordable for you?**[3] **[Juster scale, as above]**	Will compare current tobacco users to non-users and past-users. Sub-segment of interest: only respondents exposed to stimuli.

JUSTER'S 11-POINT PROBABILITY SCALE

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5	Fairly good possibility [5 chances in 10]
6	Good possibility [6 chances in 10]
7	Probable [7 chances in 10]
8	Very probably [8 chances in 10]
9	Almost sure [9 chances in 10]
10	Certain, practically certain [99 chances in 100]

3. Juster 11-Point Probability Scale. Developed by F.T. Juster in 1964.

PRIMARY SURVEY QUESTIONS FOR ADDRESSING RESEARCH HYPOTHESES

Hypothesis	Primary Response Variable Question	Comparison Of Interest
7. Exposure to stimuli will conclude that smokers who have attempted to quit 2+ times during prior two years will be more likely to express interest in learning more about General Snus through their own research, compared to smokers who have not attempted to quit 2+ times during prior two years.	**Over the next 30 days, how likely are you to try and learn more about General Snus?**[3]	Will compare current smokers trying to quit v. current smokers not trying to quit. Sub-segment of interest: cigarette smokers.
8. Exposure to stimuli will conclude that smokers who have attempted to quit 2+ times during prior two years will be more likely to consider purchasing General Snus, if the product is available in a local retailer and is not deemed cost-prohibitive, compared to smokers who have not attempted to quit 2+ times during prior two years.	**Over the next 30 days, how likely are you purchase General Snus, assuming it is available at one of your local retailers and affordable for you?**[3] **[Juster scale, as above]**	Will compare current smokers trying to quit v. current smokers not trying to quit. Sub-segment of interest: cigarette smokers.

JUSTER'S 11-POINT PROBABILITY SCALE

Score	Verbal Equivalent
0	No chance, almost no chance [1 in 100]
1	Very slight possibility [1 chance in 10]
2	Slight possibility [2 chances in 10]
3	Some possibility [3 chances in 10]
4	Fair possibility [4 chances in 10]
5	Fairly good possibility [5 chances in 10]
6	Good possibility [6 chances in 10]
7	Probable [7 chances in 10]
8	Very probably [8 chances in 10]
9	Almost sure [9 chances in 10]
10	Certain, practically certain [99 chances in 100]

3. Juster 11-Point Probability Scale. Developed by F.T. Juster in 1964.

PRIMARY SURVEY QUESTIONS FOR ADDRESSING RESEARCH HYPOTHESES

Hypothesis	Primary Response Variable Question	Comparison Of Interest
9. Exposure to stimuli will fail to conclude that adults ages 18-24 express less interest in learning more about General Snus through their own research, compared to adults ages 25 or over.	**Over the next 30 days, how likely are you to try and learn more about General Snus?**[3]	Respondents ages 18-24 v. ages 25+. Stimuli exposure randomly determined.
10. Exposure to stimuli will fail to conclude that adults ages 18-24 express less consider to purchase General Snus, if the product is available in a local retailer and is not deemed cost-prohibitive, compared to adults ages 25 or over.	**Over the next 30 days, how likely are you purchase General Snus, assuming it is available at one of your local retailers and affordable for you?**[3] **[Juster scale, as above]**	Respondents ages 18-24 v. ages 25+. Stimuli exposure randomly determined.

JUSTER'S 11-POINT PROBABILITY SCALE

Score	Verbal Equivalent
0	No chance, almost no chance [1 in 100]
1	Very slight possibility [1 chance in 10]
2	Slight possibility [2 chances in 10]
3	Some possibility [3 chances in 10]
4	Fair possibility [4 chances in 10]
5	Fairly good possibility [5 chances in 10]
6	Good possibility [6 chances in 10]
7	Probable [7 chances in 10]
8	Very probably [8 chances in 10]
9	Almost sure [9 chances in 10]
10	Certain, practically certain [99 chances in 100]

3. Juster 11-Point Probability Scale. Developed by F.T. Juster in 1964.

RESEARCH PROTOCOL – DATA COLLECTION AND SAMPLING ALGORITHM

- **Proposed data collection methodology:**
  - Online surveying: to account for 60%-70% of responses.
  - Computer-assisted telephone interviews (CATI): remaining 30-40% of responses.
    - CATI interviews will administer the same survey as online, with minimal adaptation only as necessary to ensure a natural conversational process.
    - Inclusion of CATI intended to offset the tendency for online survey respondents to skew more affluent than general population.
- **Sampling algorithm:**
  - Probability based sampling, paired with oversampling of certain user groups.
    - Will provide a pure "total US" view of the data, while allowing for deep-diver analysis of sub-segments of interest.
  - For primary sub-segments of interest, recommending minimum sample size of n=1,600.
    - Assumes 95% confidence rate, statistical power of 80% in detecting a 5% difference in proportion estimates.
    - Oversampling will not reach n=1,600.
    - Proposed sample sizes detailed in table on the right. All numbers assumed to be feasible at this time.

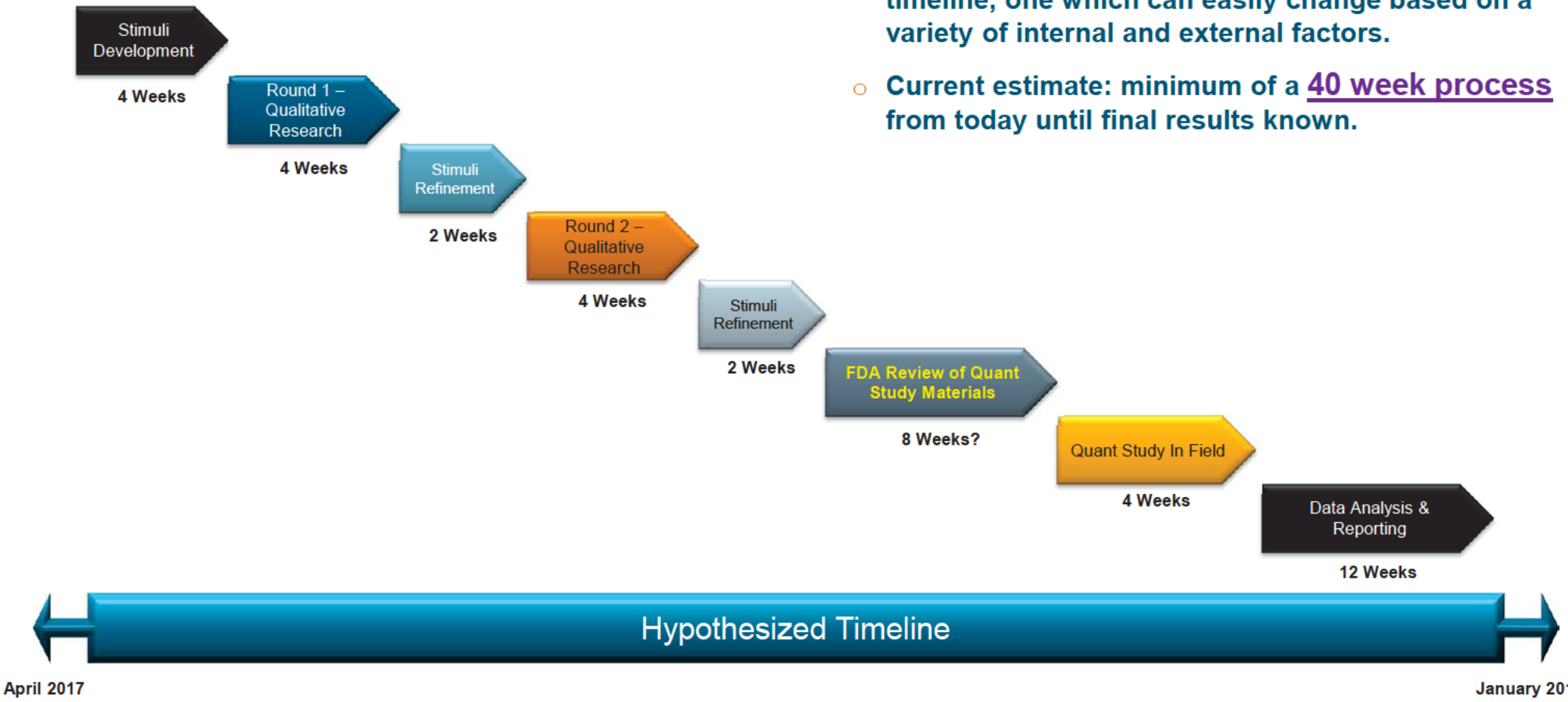
	Exposed To Stimuli (test)	**Not Exposed To Stimuli** (control)
Non-users (never regularly used tobacco or nicotine products)	n=3,800	n=3,800
Lapsed users (used tobacco or nicotine products regularly, but not currently)	n=950	n=950
Current users (actively use tobacco or nicotine products)	n=1,900	n=1,900
OVER-SAMPLE*: Augment respondents ages 18-24	n=950	n=950
OVER-SAMPLE*: People who have tried to quit smoking 2+ times over past two years	n=950	n=950
Sub-Totals:	n=8,550	n=8,550
TOTAL:	n=17,100	

* Over-sample is incremental to probability-based recruitment. Total sample for category to be greater than over-sample amount.

RESEARCH PROTOCOL – DATA ANALYSIS

- **Final data analysis plan to be identified based on input from research partner, Ph.D. level analytical consultant, and CTP.**
  - Research partner and Ph.D. consultant yet to be identified.
- **Anticipated analytical techniques consistent with standard statistical practice regarding survey research.**
  - Multi-variate regression, including logistic regression where appropriate.
  - ANOVA
    - Pairwise-comparisons where appropriate.
  - Contingency table; Chi-Square tests for independence.
- **In particular, questions involving Juster Scale more apt to be addressed by ANOVA and pairwise-means comparisons.**
- **All analyses will assume a 95% confidence level threshold in order to conclude statistical significance.**

RESEARCH PROTOCOL - TIMELINE



- **Swedish Match has developed a very high-level timeline, one which can easily change based on a variety of internal and external factors.**
- **Current estimate: minimum of a 40 week process from today until final results known.**

OUTSTANDING QUESTIONS FOR DISCUSSION

- **Swedish Match hopes to have input from CTP on a variety of topics, including the ones listed below. Desired timing for CTP input is ASAP, to allow for the workstream to begin in the near term.**
  - Who at CTP will be the primary point-of-contact for guidance on consumer research?
  - Does CTP believe the hypotheses to be sufficient for establishing MRTP?
  - Will CTP accept research in which the stimuli utilize one General Snus SKU?
    - Current eight SKUs in total.
  - Will CTP allow for stimuli to include only a subset of the warning labels currently in rotation for General Snus?
    - E.g. a claim involving cancer does not marry well with a warning statement "WARNING: THIS PRODUCT CAN CAUSE MOUTH CANCER".
  - Are there any aspects of the outlined research protocol that do not meet expectations?
  - What level of specificity would CTP like in terms of a formal document laying out the research protocol?
    - E.g., PATH study level? These slides?
  - Does CTP wish to provide input into the qualitative research taking place in advance of the final, quantitative consumer study?

THANK YOU!

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