

October 19, 2023

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
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Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**SUBJECT: PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers –
PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-
MR0000029**

Dear Sir or Madam:

Per the FDA Center for Tobacco Products PMTA and MRTP Annual Report requirements relating to Swedish Match USA, Inc.'s. ("Swedish Match", "our" or "we") General Snus products, please accept the following combined documents to encompass one PMTA MRTP Postmarket Annual Report submission as follows:

FDA's PMTA Marketing Orders, included as **Attachment A** - Periodic Report requirements under section 910(f) of the FD&C Act, Postmarket Annual Report.

FDA's MRTP Modified Risk Granted Orders, included as **Attachment B** – Risk Modification ("Granted Orders"), dated October 22, 2019.

FDA's MRTP Modified Risk Renewal Acceptance, included as **Attachment C** - dated August 31, 2023

Swedish Match acknowledges the obligation of the PMTA Marketing Orders, that beginning October 2016, FDA may determine whether continued marketing of the tobacco product is appropriate for the protection of public health, or whether there are or may be grounds for withdrawing or temporarily suspending the Marketing Order.

Swedish Match acknowledges the obligation per Appendix C, Section IV, of the Granted Modified Risk Orders, and the Renewal Acceptance, the requirement that on an annual basis the PMSS Protocols, a Description of the Implementation of all Advertising and Marketing Plans, Annual Age Verification/Youth Access Policies & Procedures Review, and Manufacturing Information must be submitted to FDA, as required under section 911(i)(2) of the FD&C Act.

Please note that due to inability to convert certain data/tables/information to Adobe format, and to allow data information to be viewed in a more legible manner, certain attachments/appendices are included as Excel documents (noted in bold print below) and can be located attached to this document (**please see 'Attachments' (the “paperclip” icon on the right hand column if using Adobe DC) of this filing to view the files).**

As we have done for previous reports, Swedish Match will simultaneously submit media (.mp4) files as a separate independent transmission. This is due to the size of the media/video files and previous difficulty with the inability of Adobe format to link the media files to the final submission.

For recordkeeping purposes, Swedish Match provides the following information relative to the following STNs for the period November 2022 through October 2023:

1. **PM0000010 – PM0000017** (**PM0000010, PM0000011, PM0000013 & PM0000015 are no longer in Market in the U.S.)*
2. **MR0000020 - MR0000022, MR0000024 - MR0000025, and MR0000027- MR0000029** (**MR0000020 -MR0000021, MR0000024 & MR0000027 are no longer in Market in the U.S.)*

LIST OF GENERAL TOBACCO PRODUCT SUBMISSIONS – Current Marketing Status

Product Manufacturer	Swedish Match USA, Inc.
Product Category	Smokeless Tobacco Products
STN: Product Name	<i>PM0000010 & MR0000020: General Loose</i>
Product Sub-Category	Loose Snus
Package Type	Cardboard Can with Plastic Lid
Package Quantity	45.0 g
Characterizing Flavor	None
Marketing Status	<i>Out of Market - Effective 6/12/2017 was taken off the market.</i>
STN: Product Name	<i>PM0000011 & MR0000021: General Dry Mint Portion Original Mini</i>
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	6.0 g
Characterizing Flavor	Mint
Marketing Status	<i>Out of Market - Effective 12/31/2020 was taken off the market.</i>
STN: Product Name	<i>PM0000012 & MR0000022: General Portion Original Large</i>
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	None
Marketing Status	<i>In Market.</i>
STN: Product Name	<i>PM0000013 & MR0000024: General Classic Blend Portion White Large – 12 ct</i>
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	10.8 g
Characterizing Flavor	None
Marketing Status	<i>Out of Market - effective 1/15/2016 was taken off the market.</i>
STN: Product Name	<i>PM0000014 & MR0000025: General Mint Portion White Large</i>
Product Sub-Category	Portioned Snus
Package Type	Plastic Can

Package Quantity	24.0 g
Characterizing Flavor	Mint
Marketing Status	In Market.
STN: Product Name	<i>PM0000015 & MR0000027: General Nordic Mint Portion White Large – 12 ct</i>
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	10.8 g
Characterizing Flavor	Mint
Marketing Status	<i>Out of Market - effective 1/15/2016 was taken off the market.</i>
STN: Product Name	PM0000016 & MR0000028: General Portion White Large
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	None
Marketing Status	In Market.
STN: Product Name	PM0000017 & MR0000029: General Wintergreen Portion White Large
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	24.0 g
Characterizing Flavor	Wintergreen
Marketing Status	In Market.

Swedish Match submits that this submission and the information we are supplying in connection with this Report, are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact us.

Sincerely yours

(b) (6)

Gerard J. Roerty, Jr.

Vice President, General Counsel & Secretary

Annual Report Attachments (Links located in Bookmarks)

Attachment A – PMTA Marketing Orders

Attachment B - Modified Risk Granted Orders dated 10/22/19

Attachment C – Modified Risk Renewal Acceptance dated 08/31/23

Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting

Attachment 1A.1 – General PMSS Sales

Attachment 1A.2 – General PMSS Distribution Report **(Excel Attachment)**

Attachment 1B - Annual PMSS Adverse Experiences Report (PM11, PM12, PM14, PM16 & PM17)

Attachment 1C – PMSS Surveillance Consumer Perception Behavior & Health

Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20

Attachment 2A - General Snus Analysis of Implementation of Marketing Plans

Attachment 3A- FDA AFPPH Recommendations Letter for PM10, PM11, PM12, PM14, PM16 and PM17 dated 6/1/18

Attachment 3B (1-5) – Annual Full Text Articles

Attachment 3B.1 - Chen et al 2023 Perceptions and Discussion of Snus on Twitter

Attachment 3B.2 - Dai_Leventhal 2023 Use Trad Smokeless Snus Dissolvable Tobacco among US Youth

Attachment 3B.3 - Lee et al (2022) Meta Analysis of Snus and Smokeless

Attachment 3B.4 - Liber et al (2023) MRTP Claim Authorisation and General Snus

Attachment 3B.5 - Yuan et al (2022) Swedish Snuff etc and Peripheral Artery Disease

Attachment 4A – 2023: PM11, PM12, PM14, PM16 & PM17 Manufacturing Deviations Summary

Document Appendices – Post-Market Surveillance & Studies Report

Appendix 1C (1.1) - Descriptive Tables 14, 14.1, 16-18, & 20-24: General Snus Patterns of Use Study – Wave 4 Study Report **(Excel Attachment)**

Appendix 1C (1.2) - Study Questionnaire: General Snus Patterns of Use Study – Wave 4 Study Report

Appendix 1C (1.2a) Consumer Facing General Snus Patterns of Use Study Baseline to Wave 4

Appendix 1C (1.3) - Study Protocol - General Snus Patterns of Use Study - Version 4

Appendix 1C (1.4) - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 4 Study Report

Appendix 1C (1.5) – Technical Report: General Snus Patterns of Use Study – Wave 4 Study Report FINAL

Document Appendices – Analysis of Implementation of Marketing Plans

Appendix 2A (1) - General Snus Website – FULL Webpages: Marketing Plan

Appendix 2A (2) - General Snus Website – MRTP Only Webpages: Marketing Plan

Appendix 2A (3) - General Snus Advertising: Marketing Plan (Age/Youth)

Appendix 2A (4) - General Snus DM, EM, FB, POS, Pkg: Marketing Plan

Appendix 2A (5) - General Snus Digital Ad Domain List: Marketing Plan **(Excel Attachment)**

Appendix 2A (6) - General Snus Store List: Marketing Plan **(Excel Attachment)**

Appendix 2A (7) - General Snus Trade Advertising Plan: Marketing Plan

Appendix 2A (7.1) - General Snus 2023 Trade Media Calendar Advertising Plan **(Excel Attachment)**

Document Appendices – Summary of AFPPH Research Reports

Appendix 3A (1) – Consumer Insights Use Behavior

Tables

Table 1.a. – Annual summary of publications not previously reported (on cover letter - listed below)

Section 1 – Annual Post-Market Surveillance and Studies Report Summary

General Snus Use Behavior and Consumer Understanding and Perception – [Common to both MRTTP & PMTA Reports]

See Appendix 3A (1) – Consumer Insights Use Behavior

Sales and Distribution Reporting – [Common to both MRTTP & PMTA Reports]

See Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting

See Attachment 1A.1 – PMSS Sales

See Attachment 1A.2 – PMSS Distribution Report (Excel Attachment)

Adverse Experiences Reporting - [Common to both MRTTP & PMTA Report]

See Attachment 1B - Annual PMSS Adverse Experiences Report

Surveillance Consumer Perception Behavior & Health – [MRTTP Report Specific]

See Attachment 1C – PMSS Surveillance Consumer Perception Behavior & Health

See Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20

- **Appendix 1C (1.1) - Descriptive Tables 14, 14.1, 16-18, & 20-24: General Snus Patterns of Use Study – Wave 4 Study Report (Excel Attachment)**
- **Appendix 1C (1.2) - Study Questionnaire: General Snus Patterns of Use Study – Wave 4 Study Report**
 - **Appendix 1C (1.2a) - Consumer Facing General Snus Patterns of Use Study Baseline to Wave 4**
- **Appendix 1C (1.3) - Study Protocol - General Snus Patterns of Use Study - Version 4**
- **Appendix 1C (1.4) - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 4 Study Report**
- **Appendix 1C (1.5) – Technical Report: General Snus Patterns of Use Study – Wave 4 Study Report**

Section 2 - Advertising and Marketing Plans Annual Report

General Snus MRTTP Marketing Support Plan – [Common to both MRTTP & PMTA Reports]

See Attachment 2A - General Snus Analysis of Implementation of Marketing Plans

- **Appendix 2A (1) - General Snus Website – FULL Webpages: Marketing Plan**
- **Appendix 2A (2) - General Snus Website – MRTTP Only Webpages: Marketing Plan**
- **Appendix 2A (3) - General Snus Advertising: Marketing Plan**
- **Appendix 2A (4) - General Snus DM, EM, FB, POS, Pkg: Marketing Plan**
- **Appendix 2A (5) - General Snus Digital Ad Domain List: Marketing Plan (Excel Attachment)**
- **Appendix 2A (6) - General Snus Store List: Marketing Plan (Excel Attachment)**
- **Appendix 2A (7) - General Snus Trade Advertising Plan: Marketing Plan**
- **Appendix 2A (7.1) - General Snus 2022 Trade Media Calendar Advertising Plan (Excel Attachment)**

Labeling Changes and Revised Full Color Printed Labeling Submission – [PMTA Report Specific]

In conjunction with this Report for the period November 1, 2022 – October 31, 2023, we are supplying copies of the revised top, side and bottom label final print proofs which include dimensions, Pantone color numbers, and legible text (**See Appendix 2A (4) - General Snus Packaging**). As this is the eighth annual report for this product, we are not required to submit actual physical labels for this product.

Section 3 – Annual Age Verification/Youth Access Procedures Review

Summary of Implementation & Effectiveness of Age-related Policies/Procedures - [MRTP Report Specific]

Swedish Match does not make any sales direct to consumers. Swedish Match focuses its efforts on responsible marketing practices. Information on Swedish Match's responsible marketing practices can be found in Section 2-Advertising and Marketing Plans Annual Report (**See Appendix 2A (3)**).

Section 4 - Manufacturing Information Annual Report

Manufacturing Facility Changes - [Common to both MRTP & PMTA Reports]

There has been no change to the manufacturing, facilities or controls, due to production of the General Snus products, during the reporting period November 1, 2022 – October 31, 2023.

Manufacturing Deviations Relating to Characteristics of the Final Product – [Common to both MRTP & PMTA Reports]

Swedish Match is supplying a summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicated any deviation(s) that may affect the characteristics of the final product for the reporting period November 1, 2022 – October 31, 2023 (**See Attachment 4A - Annual Reporting Manufacturing Deviations_Summary**). There were no manufacturing deviations for the reporting period for any of the General Snus products in market.

Section 5 – Summary – How the Tobacco Product Continues to be Appropriate for the Protection of the Public Health (AFPPH)

Ongoing Studies/Publications/Science Data – [PMTA Report Specific]

Swedish Match asserts this report for the period November 1, 2022 – October 31, 2023, contains appropriate scientific evidence and, to the extent possible, addresses the recommendations made by FDA in its June 1, 2018, correspondence (**See Attachment 3A- FDA Recommendations Letter for PM0000010, PM0000011, PM0000012, PM0000014, PM0000016 and PM0000017**). The attached research reports, containing information as requested by FDA, allow for a complete and substantive review of all General Snus products in market, and demonstrate that the tobacco product continues to be appropriate for the protection of public health.

The Post Market Surveillance & Studies Report mentioned above includes actual use behavior. This information can be found in **Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health**.

For the reporting period November 1, 2022 – October 31, 2023, we provide the following research:

1. Consumer Insights Use Behavior Report - Appendix 3A (1)

The subsequent bullets summarize the attached research, specifically addressing the inclusions recommended by FDA in its June 1, 2018, correspondence:

- **Appendix 3A (1): Consumer Insights Use Behavior**
The 2021 & 2022 submissions included the following: Category and Brand Awareness, Category & Brand Usage, Purchase Dynamics, Demographics

2022: Focused on freshness, history, and originality

- o Messaging options, markers/descriptors, and impact on purchase
 - o Snus storage: importance, how it is stored
 - o Usage (not included in 2021 submission): Combustible cigarette usage P30D, Brands used 30D, Snus used P30D, Where General is used, Where General is purchased
- 2021:** Focused on MRTP (messaging options, awareness, perception, understanding and impact on purchase)
- Swedish Match is supplying a summary of publications not previously reported (**See Table 1.a.** below). Full text articles are available in **Attachment 3B (1-5)** - Full Text Articles. Swedish Match conducted a literature search of PubMed and Google Scholar using “snus” and “snus 2021” and “snus 2022” to access a general outline of peer reviewed Swedish snus-focused articles published in 2021 and 2022. Criteria for labeling articles as “not relevant” included articles not in English, articles using only U.S. snus (e.g., Camel Snus), and articles only mentioning snus in passing while not using snus in its research design. These “not relevant” articles are not attached.

Table 1.a. Summary of Publications not Previously Reported

Item#	Publication Citation and Summary
1.	<p>Chen, J., Xue, S., Xie, Z., Li, D. (2022): Perceptions and Discussions of Snus on Twitter: Observational Study JMIR Med Inform 2022;10(8):e38174. doi: 10.2196/38174.</p> <ul style="list-style-type: none"> • This authors of the study examined public perceptions and discussions of snus on Twitter (now rebranded as “X”). Tweets about snus were collected from March 11, 2021 - February 26, 2022. A temporal analysis (examine change in number of snus-related tweets over time) and a sentiment analysis (examine the sentiments of snus-related tweets) were conducted. Topic modeling was applied to tweets to determine popular topics. Finally, a keyword search and hand-coding were used to understand the health symptoms mentioned in snus-related tweets. • The sentiment analysis showed that the proportion of snus-related tweets with a positive sentiment was significantly higher than the proportion of negative sentiment tweets (4341/11,631, 37.32% vs 3094/11,631, 26.60%; $P < .001$). The topic modeling analysis revealed that positive tweets focused on snus’s harm reduction and snus use being an alternative to smoking, while negative tweets focused on health concerns related to snus. Mouth and respiratory symptoms were the most mentioned health symptoms in snus-related tweets.

2.	<p>Hongying, D. and Leventhal, A.M. (2023): "Use of Traditional Smokeless, Snus, and Dissolvable Tobacco Among U.S. Youth," <i>American Journal of Preventive Medicine</i>, 64 (2), 2023, P. 204-212. doi: 10.1016/j.amepre.2022.09.011.</p> <ul style="list-style-type: none"> Smokeless tobacco product categories (e.g., snus, dissolvable, and traditional smokeless) is often amalgamated in youth epidemiologic research despite differences across these products. Prevalence, trends, and correlates of U.S. youth use across different classes of oral tobacco products are unknown. Using 2011–2020 National Youth Tobacco Survey (N=193,933) data, authors tested for cross-year linear and quadratic trends in the weighted prevalence of ever and current use of traditional smokeless tobacco, snus, and dissolvable tobacco. Assessment showed declines in the prevalence of ever use of traditional smokeless tobacco (11.0% to 5.6%; linear trend, $p<0.0001$) and snus (5.2% to 2.4%; $p<0.0001$) but no change in ever dissolvable tobacco use (0.8%–1.2%). In 2020, an estimated 1,546,000 U.S. youth ever used traditional smokeless tobacco (7.7% high school, 3.0% middle school), 662,000 ever used snus (high school: 3.5%, middle school: 1.0%), and 326,000 ever used dissolvables (high school: 1.5%, middle school: 0.8%). Differences in the epidemiology of oral tobacco use across product types among U.S. youth suggest that oral tobacco products should be disaggregated in future research and policy strategies.
3.	<p>Lee, P.N., Coombs, K.J., Hamling, J.S. (2022): "Review with meta-analysis relating North American, European and Japanese snus or smokeless tobacco use to major smoking-related diseases" in <i>World J Meta-Anal</i> 2022; 10(3): 130-142. doi: 10.13105/wjma.v10.i3.130</p> <ul style="list-style-type: none"> Authors summarized data on risks of four diseases associated with current smokeless tobacco ("ST") or snus use. Publications in English in 1990-2020 were considered that, based on epidemiological studies in North America, Europe or Japan, estimated risks of lung cancer, COPD, IHD/AMI, or stroke according to use of ST or snus. For each disease, relative risk estimates adjusted at least for age were extracted relating ST or snus use to risk, and combined using random-effects meta-analysis. For snus, 16 publications described results from 12 studies, one in Norway and the rest in Sweden. There were no results for COPD, and only three for lung cancer, with these reporting a relative risk of 0.80 (0.40-1.30) for current vs never use. More extensive data were available for IHD/AMI and stroke. Using the latest results from each study, combined estimates for current vs. never use were 1.00 (0.91-1.11, $n = 5$) for IHD/AMI and 1.05 (0.95-1.17, $n = 2$) for stroke, while for current vs. non-current use they were 1.10 (0.92-1.33, $n = 9$) for IHD/AMI and 1.12 (0.86-1.45, $n = 9$) for stroke. Meta-analyses including earlier results from some studies also showed no significant association between snus use and IHD/AMI or stroke. Authors concluded that risks of smoking-related diseases from snus use in Scandinavia are not demonstrated, while those from ST use in the United States are less than from smoking.
4.	<p>Liber, A.C., Seidenberg, A.B., and Pesko, M.F. (2023): "MRTP claim authorisation and General Snus sales in the USA: evidence from a difference-in-differences model." <i>Tobacco Control</i> Published Online First: 21 June 2023. doi: 10.1136/tc-2022-057890.</p> <ul style="list-style-type: none"> Using 2017–2021 Nielsen sales data from 19 US states, the authors assessed whether logged unit sales of General Snus were affected by the October 2019 MRTP authorization, compared with (1) sales of other snus brands and (2) sales of non-snus smokeless products; we also examined (3) if sales of non-General Snus brands were affected by General Snus's MRTP authorization, compared with sales of non-snus smokeless tobacco products.

	<ul style="list-style-type: none"> Although sales declined in absolute terms, sales of General Snus relative to other snus brands were unchanged after MRTP authorization (–9.0%, 95% CI –19.6% to 1.60%, p=0.098). However, compared with non-snus smokeless brand sales, sales of General Snus (+14.7%, 95% CI 5.23% to 24.2%, p=0.002) rose after MRTP authorization. Compared with non-snus smokeless products, sales of non-General Snus brands also rose after MRTP authorization (+23.7%, 95% CI 9.5% to 38.0%, p=0.001). Although only General Snus received MRTP authorization, this designation appears to have slowed declines for the entire snus category. This suggests consumers may make determinations regarding product risk to a product class rather than individual products.
5.	<p>Yuan, S., Titova, O. E., Damrauer, S., Akesson, A., and Larsson, S.C. (2022): “Swedish snuff (snus) dipping, cigarette smoking, and risk of peripheral artery disease: a prospective cohort study,” Scientific Reports 12: 12139 (2022). doi:10.1038/s41598-022-16467-x</p> <ul style="list-style-type: none"> Study using Cohort of Swedish Men assessed whether Swedish snuff (snus) is associated with peripheral artery disease (“PAD”) Cox proportional hazards regression was used to analyze the data with a mean follow-up period of 9.1 years (from July 1, 2009 to December 31, 2019), identifying cigarette smoking but not Swedish snus dipping as associated with an increased risk of PAD. Compared with never snus dippers, the hazard ratio of PAD was 0.95 (95% confidence interval [CI] 0.73–1.24) for past snus dippers and 0.88 (95% CI 0.66–1.17) for current snus dippers. Compared to never smokers, the hazard ratio of PAD was 1.38 (95% CI 1.14–1.68) for past smoker who stopped smoking for ≥ 10 years, 2.61 (95% CI 1.89–3.61) for past smoker who stopped smoking for < 10 years, and 4.01 (95% CI 3.17, 5.08) for current smoker. Authors concluded that cigarette smoking, but not Swedish snus dipping, increases the risk of PAD.

Sales and Distribution Reporting – [Common to both MRTP & PMTA Reports]

Swedish Match is supplying a summary of sales and distribution data for the reporting period November 1, 2022 – October 31, 2023. This information includes total U.S. sales reported in dollars and units (i.e., number of cans), and volume (i.e., net weight multiplied by units) with breakdowns by US census region and retail markets and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops).

See Attachment 1A - Annual PMSS Sales & Distribution Reporting

Attachment 1A.1 – PMSS Sales

Attachment 1A.2 – PMSS Distribution Report (**Excel Attachment**)

Adverse Experiences Reporting - [Common to both MRTP & PMTA Report]

Swedish Match did not receive any reports of serious or unexpected adverse experiences, relative to General snus tobacco products in market for the reporting period November 1, 2022 – October 31, 2023. There have been no changes to the reference risk information.

We are supplying a summary of consumer contacts (all other reported adverse experiences) relative to General tobacco products in market for the reporting period November 1, 2022 – October 31, 2023. (**See Attachment 1B - Annual PMSS Adverse Experiences Report**)

Data on Current Product Users - [PMTA Report Specific]

Data and information on current product users are included in the **Consumer Insights Use**

259 **Behavior Report - Appendix 3A (1).** Including research (provided above at **Attachment 3B (1-4)**)
260 and sales and distribution data (provided above at **Attachments 1A.1 & 1A.2.**), there is no further
261 product user data for the reporting period November 1, 2022 – October 31, 2023. Likewise, there
262 has been no change in the intended target market for these products for the reporting period
263 November 1, 2022 – October 31, 2023.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000010

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Loose
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000010.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000010**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 05:58:03 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Loose Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000011

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Dry Mint Portion Original Mini
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
Portion Count:	20 pouches
Portion Mass:	300 mg
Portion Length:	28 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000011.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000011**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 05:59:58 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Dry Mint Portion Original Mini Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000012

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Portion Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	33 mm
Portion Width:	18 mm
Portion Thickness:	6 mm
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000012.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000012**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

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Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 06:00:57 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Portion Original Large Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000013

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Classic Blend Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:²	(b) (4)

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
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 - Progress reports;
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 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000013.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000013**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
 - b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:01:52 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Classic Blend Portion White Large - 12ct





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000014

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Mint Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000014.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000014**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
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6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

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Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 06:03:46 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Mint Portion White Large Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000015

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Nordic Mint Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:²	(b) (4)

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000015.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000015**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
 - b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

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Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 06:04:40 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Nordic Mint Portion White Large - 12ct Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000016

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000016.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000016**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 06:05:34 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Portion White Large Labeling





DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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

FDA Submission Tracking Number (STN): PM0000017

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:¹	General Wintergreen Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:²	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000017.**

For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000017**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 06:06:25 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Wintergreen Portion White Large Labeling





U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

October 22, 2019

**MODIFIED RISK GRANTED ORDERS --
RISK MODIFICATION**

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

FDA Submission Tracking Numbers (STNs): MULTIPLE STNs, See Appendix A

Dear Mr. Roerty:

We completed review of your MRTPAs¹ and are issuing modified risk granted orders for the tobacco products identified in Appendix A.

Based on our review of your MRTPAs, we find that the modified risk tobacco products, as described in your applications and specified in Appendix A, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Therefore, we authorize the marketing of the modified risk tobacco products with the following modified risk information:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

Under the provisions of section 911, you may introduce or deliver for introduction into interstate commerce the modified risk tobacco products, in accordance with these risk modification orders. These risk modification orders include requirements related to conditions of marketing under section 911(h) and postmarket surveillance and studies under section 911(i) as well as requests related to other record retention and reporting, as outlined in the attached appendices.

These orders expire 5 years from the issue date of this letter. If you wish to renew your orders, we recommend a request for renewal is received by FDA 360 days prior to the expiration date. Your renewal may cross-reference your MRTPAs that are subject to these orders.

The requirements in these risk modification orders are intended to help ensure that your modified risk tobacco products, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not

¹ Modified Risk Tobacco Product Applications (MRTPAs) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

currently use tobacco products. However, compliance with these requirements alone is not a guarantee that the modified risk tobacco products, as actually used by consumers, will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, particularly if, despite these measures, there is a significant increase in youth initiation or initiation by non-users. FDA will continue to monitor the marketing of your modified risk tobacco products and their impact on the population.

These orders authorizing the marketing of these modified risk tobacco products do not mean FDA “approved” the modified risk tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads, or would mislead consumers into believing, among other things, that the modified risk tobacco products specified in Appendix A are “approved” by FDA.² The modified risk tobacco products subject to these risk modification orders are subject to withdrawal as described in section 911(j).

We remind you that all regulated tobacco products, including the modified risk tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the modified risk tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{3,4} using eSubmitter.⁵ Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA’s Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁶; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

² See Section 301(tt) of the FD&C Act.

³ <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>

⁴ FDA’s Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁵ <https://www.fda.gov/industry/fda-esubmitter>

⁶ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

If you have any questions regarding these orders, please contact Shireen Fotelargias, Regulatory Health Project Manager, at (240) 402-0435 or Shireen.Fotelargias@fda.hhs.gov.

If you have any questions regarding postmarket activities for the modified risk tobacco products subject of these orders, please contact Eugene Y Chuang, at (240) 402-9302 or Eugene.Chuang@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.10.22 08:58:56 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A- List of Tobacco Products That Are Subject of This Letter

Appendix B- Required Postmarket Surveillance and Studies

Appendix C- Advertising and Promotion Requirements

Appendix D- Recordkeeping and Retention

Appendix E- Manufacturing Information

Appendix A
List of Tobacco Products That Are Subject of This Letter

Common Attributes of MRTPAs	
Submission Date:	June 10, 2014
Receipt Date:	June 10, 2014
Product Manufacturer:	Swedish Match USA, Inc.
Product Category:	Smokeless Tobacco Products
Modified Risk Information:	Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
MR0000020: General Loose⁷	
Product Subcategory:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
MR0000021: General Dry Mint Portion Original Mini⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
MR0000022: General Portion Original Large⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000024: General Classic Blend Portion White Large – 12 ct⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
MR0000025: General Mint Portion White Large⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
MR0000027: General Nordic Mint Portion White Large – 12 ct⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint

⁷ STN: Product Name (Brand/sub-brand or other commercial name used in commercial distribution)

MR0000028: General Portion White Large⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000029: General Wintergreen Portion White Large⁷	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen

Appendix B

Required Postmarket Surveillance and Studies (PMSS)

Under Section 911(i)(1) of the FD&C Act, FDA must require postmarket surveillance and studies for any product for which an applicant received an order under 911(g)(1) in order to: "...determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product."

I. PMSS Content

MRTP Use Behavior and Consumer Understanding and Perception

After receiving authorization, the determination of whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole is likely to be driven by use behavior. Therefore, monitoring use of the eight General Snus products that are the subject of these applications in terms of uptake, dual use, and complete switching is required. In particular, your PMSS must assess the extent to which new MRTP users were non-users, smokers, or other tobacco product users before initiating the MRTPs and the extent to which new users of the MRTPs become exclusive users or dual users with cigarettes or other tobacco products over time. Relatedly, such surveillance must include an assessment of consumers' understanding of the claim and perceptions of the products. In particular, PMSS must assess the extent to which users of these products understand that, to reduce their risk of disease relative to smoking as described in the modified risk information, they must use General Snus exclusively. **To adequately assess these impacts, you must conduct PMSS that include assessing users' behavior and consumer understanding at multiple time points.**

In addition, FDA has determined that assessing the impact of your MRTP orders on uptake of the products requires surveillance of MRTP sales and distribution, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting MRTP sales and distribution in the U.S. by product, major metropolitan areas, and channels where the products are sold (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops). Your annual PMSS report must include:

- U.S. sales and distribution of the tobacco products by quarter since the granting of your modified risk granted orders (for the initial reporting period) or the previous reporting period (for all reports that follow), including, for each MRTPA STN, total U.S. sales and distribution reported in dollars and units, and broken down by major metropolitan areas, and channels where the products were distributed and sold during the reporting period (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops).
- A brief synthesis and summary of the sales and distribution data for the initial reporting period or the previous reporting period (for all reports that follow), including annual and quarterly growth rate (percent change) in total U.S. sales and distribution of the tobacco products for each MRTPA STN, post-MRTP authorization.

M RTP Use and Adverse Experiences

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole, your PMSS must include ongoing surveillance of all adverse experiences associated with the use of the MRTPs. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported adverse experiences for the tobacco products, which includes a listing of all adverse experiences during the reporting period and a cumulative list, including all serious and unexpected adverse experiences previously reported. The summary must be accompanied by an analysis of the reports and a statement of any changes to risk information related to the products including nature, frequency, and potential aggravating factors.

In addition, the PMTA orders for your General snus products, issued on November 10, 2015, require you to report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product within 15 calendar days after the report is received by you. These experiences may become known to you through any source, including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. We request that when submitting such reports, you reference both your PMTAs and you MRTPAs for these products. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT FOR STN(s) PM0000010-PM0000017 and MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029.**

For purposes of this reporting, *serious adverse experience* means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of this reporting, *unexpected adverse experience* means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA (including the results of human subject investigations) and other relevant sources of information, such as postmarket reports and studies;

- The expected natural progression of any underlying disease, disorder, or condition of the person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

Surveillance of New Research Study Findings the MRTPs and Consumer Perception, Behavior, or Health

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole, your PMSS must include surveillance of new research study information about the MRTPs and consumer perception, behavior, or health. In particular, your PMSS protocol must include procedures for monitoring and assessing findings both in your own studies (i.e., studies conducted by you or on your behalf) and in publications including any new scientific data (published or otherwise) regarding the MRTPs and consumer perception, behavior, or health. Your annual PMSS report must include:

- A summary of significant findings about the tobacco products from research studies conducted by you or on your behalf, whether or not such studies were specifically required under this order. A summary of significant findings in publications not previously reported and full copies of the articles. This must include any new scientific data (published or otherwise) on the MRTPs and consumer perception, behavior, or health.

II. Submitting PMSS Protocols and Reports

Within 30 days of receiving this notice, you must submit complete protocols for your PMSS as required under section 911(i)(2) of the FD&C Act. Label your submission clearly as a "PMSS Protocol," and reference your MRTPA Submission Tracking Numbers (STNs). If you have more than one protocol, submit each protocol as a separate submission. If applicable, each protocol should include the name(s) of the principal investigator(s) and materials that demonstrate the relevant professional credentials and training that qualify them to lead the study. Within 60 days of receipt of the protocol(s), FDA will determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol(s) will result in collection of the data or other information that FDA designates as necessary to protect public health, pursuant to section 911(i)(2) of the FD&C Act. FDA will notify you of and provide opportunities to address, any deficiency in the submission. If the PMSS protocol is amended subsequent to FDA approval, FDA must receive the amended protocol promptly. For protocol amendments that are administrative in nature (e.g., corrections in punctuation or titles), the amended protocol must be received by FDA within 30 days of the update. For protocol amendments that seek to modify the study design (including endpoints, sites, questionnaires, methodology, etc.) or other scientific parameters, you may not initiate the change until you receive FDA approval.

As part of the requirement to conduct PMSS, you must initiate and conduct your PMSS per timeframes established in your protocols and approved by FDA. Note that for PMSS that involve human subjects, the anticipated start date for each study must account for the time required for securing IRB approval, as needed. In addition to specifying the start date, your protocols must contain timelines for completion of major study milestones including, as applicable, the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. If you deviate from these timelines, we request that you report the deviation within 30 days to FDA.

Section 911(i) requires that the results of PMSS be submitted on an annual basis. These reports must be identified as “PMSS Report”, and the MRTPA STNs should be referenced for each report. The PMSS Report must indicate the beginning and ending date of the period covered by the report and must include accomplishments since the last reporting period. For quantitative updates on studies in progress (e.g., participant accrual), reports should describe both interim (since the last reporting period) as well as cumulative (since study initiation) accomplishments. The PMSS Report describing studies in progress must describe the status of PMSS, including, as applicable the status of recruitment, data collection, and analysis; a summary of the study milestones achieved and any deviations from the agreed upon timelines in the protocol; a summary of protocol amendments; and a summary of any preliminary analyses conducted. Once a study is completed, the PMSS Report should include the complete final study report.

Appendix C

Advertising and Promotion Requirements

I. Recordkeeping and Retention

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to establish and maintain the following records:

- Records pertaining to the products' labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
 - Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information;
 - Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
 - Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
 - Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
 - Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/or promotional materials;
 - Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
 - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
 - Targeting of specific adult audiences by age-range(s), including young adult audiences, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
 - Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
 - Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
 - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
 - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
 - Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products
 - Copies of all records pertaining to media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and

- Policies and procedures for real-time digital media monitoring to identify, correct, and prevent any delivery of advertising impressions to youth, ages 17 years and under, including documentation of such monitoring activities and implementation of corrective and preventive measures

II. Notifications

Under section 911(h)(5) of the FD&C Act these risk modification orders require that for the first six months after the date of your modified risk order you provide FDA a 30-day notification for all labeling, advertising, marketing, and/or promotional materials for which you plan on disseminating to the public. These notifications are not for pre-approval, but are required so that FDA can have timely access to your marketing plans and materials, and if needed, provide you advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of your products will benefit the health of the population as a whole. You may begin disseminating the materials 30 days after providing notification to FDA. This notification must be received by FDA **at least 30 days prior** to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. The notification must include:

- Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the products. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the text may be provided separately and referenced. Digital media, such as videos, must be submitted in a format that FDA is able to open and review.
- All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
 - Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
 - Target specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and psychographic characteristics that reflect your intended target audience(s), including how the target audience(s) are defined and the insights used to develop the target audience profile(s) and the source of such insights;
 - Restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
 - Use owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
 - Use partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
 - Conduct any consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated; and/or
 - Use public-relations outreach to create labeling for, advertise, market, and/or promote the products.

III. Periodic Reporting

Under sections 911(h)(5) of the FD&C Act, these orders require that you submit periodic reports every 6 months to FDA once during the month of June of each year and once during the month of December of each year, beginning June 2020. For the six-month reporting period, the report must include:

- A cover letter that includes the following text in your subject line: **PERIODIC REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and reporting period.
- All final printed labeling (including all variations, such as those reflecting different required warnings) not previously submitted (e.g., if previously submitted under section 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), including the date the labeling was first disseminated and the date when the labeling was discontinued, and a description of all changes to the labeling. The labeling must include all the panels and be presented in the actual size and color with legible text. The labeling must include labels, inserts/onserts, instructions, and any other accompanying information or materials for the products.
- All final full-color advertising, marketing, and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers not previously submitted (e.g., if previously submitted under 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), along with the original date such materials were first disseminated and the date they were discontinued, and a description of all changes to the materials. The materials must be legible, include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text may be provided separately and clearly referenced. Digital media, such as videos must be submitted in a format that FDA is able to open and review.

IV. Annual Reporting

Under section 911(h)(5) of the FD&C Act, these risk modification orders require that you submit the following reports to FDA **on an annual basis**, beginning twelve months from the date of this order. For each twelve-month reporting period, these annual reports must include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans – whether conducted by you, on your behalf, or at your direction – by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:
 - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

- Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect the intended target audience(s), how the target audience(s) were defined and the insights used to develop the target audience profiles(s) and the source of such insights;
- Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
- Use of owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
- Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
- Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
- Use of public-relations outreach to create labeling for, advertise, market, and/or promote the products; including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel and by product.
- An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under), not previously submitted. This analysis should be verified against post-launch delivery-verification reports submitted to you from an accredited source.
- A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to youth, ages 17 and under, and including a summary of implementation of any corrective and preventive measures, not previously submitted.

V. Additional Conditions for Marketing

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to:

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in your **owned digital properties** (e.g., your company-owned, consumer-directed, product-branded website(s) and/or mobile applications) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare consumer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your products on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content- (e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such

- labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product(s) running on another company's website; paid advertising for the product(s) running in social media; paid distribution of influencer content) – whether conducted by you, on your behalf, or at your direction:
 - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:
 - “First-party” age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and
 - “Second-party” age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.
 - “First-party” and “second-party” data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.
 - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – **to track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to youth, ages 17 and under. Such monitoring also requires post-launch delivery verification reports be submitted to you from an accredited source.
 - For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the products – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as “sponsored by [firm name]” in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the products, on your behalf, or at your direction.

The requirements above are intended to help ensure that your modified risk tobacco products, as actually used by consumers, will continue to benefit the health of the population as a whole. Limiting youth initiation of the products and, relatedly, youth exposure to advertising and marketing materials for the products are important factors in the population health benefit analysis. Accordingly, FDA also recommends limiting youth-exposure to any of the tobacco products' labeling, advertising, marketing, and/or promotion appearing in print media publications.

After receiving authorization, the determination of whether the eight modified risk General Snus products, as actually used by consumers, continue to benefit the health of the population as a whole

is likely to be driven by use behavior. An uptake in youth initiation and use of the products would have a significant negative impact on the population health benefit analysis. To help ensure that your products, as actually used by consumers, continue to benefit the health of the population as a whole, we strongly recommend that you take measures to limit youth initiation and use of the products, beyond limiting advertising and promotion as required in this order. For example, we strongly recommend you adopt the following measures related to all digital sales of your products:

- For any **digital sales** – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale of the products to individuals who are under the federal minimum legal age to purchase tobacco products.

Relatedly, we request that you submit the following information to CTP on an annual basis:

- A summary of the implementation and effectiveness of any policies and procedures regarding verification of the age and identity of purchasers of the products.
- A summary of the implementation and effectiveness of any policies and procedures regarding restrictions on youth access to the products.

We remind you that if FDA can no longer make the determination that your products, as actually used by consumers, will benefit the health of the population as a whole, FDA must withdraw the modified risk orders, after an opportunity for an informal hearing. See under section 911(j)(1) of the FD&C Act. Although adopting the measures above is not in itself a guarantee that the products will continue to benefit the health of the population as a whole, it is an important step in helping to ensure that there are no grounds for withdrawal of your orders.

Appendix D

Recordkeeping and Retention

The risk modification orders for your modified risk tobacco products are effective for 5 years from the issue date of the orders. If you wish to renew your orders, we recommend you submit a request for renewal 360 days prior to the end of your effective timeframe. In order to help ensure that your risk modification orders meet the standard for renewal and to help expedite the review of any renewal applications, we request that you establish and maintain the records listed below. The records should be retained for a period of not less than four years from the date of distribution of the last batch of the tobacco products listed in your orders under section 911(g)(1). The records should be legible, written in English, and upon request, available for inspection and copying by officers or employees duly designated by the Secretary. Please note that Appendices B and C require you to periodically submit some of these records to FDA (e.g., in PMSS reports and/or advertising and promotion-related reports). Additionally, we remind you that the PMTA orders for your General snus products issued on November 10, 2015, also require you to establish and maintain records, some of which overlap with the records listed below:

- The MRTPAs submitted prior to the orders
- Postmarket reports, as described in the Required PMSS Appendix, including adverse experience reports and all relevant documentation associated with the experience
- Records of all nonclinical or clinical studies, including:
 - Source data;
 - Study protocols (including statistical analysis plan);
 - Amendments showing the dates and reasons for any protocol revisions;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observation records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications
- Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the products
- Records pertaining to the sale, distribution, or other disposition of the products, specifically:
 - A list of distributors and retailers of the products, including brick-and-mortar and digital⁸;
 - Any available information (not to include personally identifiable information) about product purchases, such as purchasers' demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use);
 - Policies and procedures regarding verification of the age and identity of purchasers of the products; and

⁸ For the purposes of this order, here and throughout the document, "digital" includes internet/online and mobile.

- Policies and procedures regarding restrictions on youth access to the products
 - Health hazard analyses, if performed voluntarily or directed by FDA
 - Records pertaining to any and all complaints associated with any of the products that you receive or of which you are aware
-

Appendix E

Manufacturing Information

The PMTA orders for your General Snus products, issued on November 10, 2015, require you to report to the FDA manufacturing information. We request that when submitting such reports, you reference both your PMTAs and your MRTPAs for these products. When cross-referencing, please provide the date of submission and location in the submission where the information is covered. When cross-referencing, please provide the date of submission and location in the submission where the information is covered.

For each twelve-month reporting period, the annual reports should include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A description of each change made to the manufacturing process, facilities, or controls during the reporting period including:
 - A comparison of each change to what was described in the MRTPAs;
 - The rationale for making each change; and
 - A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke or aerosol constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of the tobacco products and the basis for concluding that each manufacturing change did not result in any modification to the products.⁹
- A summary of all manufacturing deviations, investigations, and corrective and preventive actions, including, but not limited to, those deviations associated with processing, testing, packing, labeling, storage, holding, and distribution and indicate any deviation(s) that may affect the characteristics of the products. For additional information on manufacturing deviations, see below.

Manufacturing Deviations

You should promptly investigate all manufacturing deviations including, but not limited to, those associated with processing, testing, packing, labeling, storage, holding, and distribution. The PMTA orders for your General snus products, issued on November 10, 2015, require that, for products that have been distributed, if the deviation may negatively impact public health, you promptly identify and report that deviation to CTP. We request that when submitting such reports, you reference both your PMTAs and your MRTPAs for these products.

Discontinuation and Reintroduction

If you discontinue the manufacture, preparation, compounding, or processing for commercial distribution of these modified risk tobacco products and later decide to reintroduce the modified risk tobacco products into the market, please contact the Office of Compliance and Enforcement prior to reintroduction.

⁹ We note that any modifications made to a tobacco product would render it a new tobacco product that would be subject to the premarket review requirements under section 910 of the FD&C Act.

< 9/11/23 - Rec'd US Mail >

**FDA U.S. FOOD & DRUG
ADMINISTRATION**U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

August 31, 2023

ACCEPTANCESwedish Match U.S.A. Inc.
Attention: Gerard J. Roerty, Jr., General Counsel
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219**FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A**

Dear Gerard Roerty, Jr.:

We accept your MRTPAs¹ for the tobacco products identified in Appendix A. Note that attributes in Appendix A may display converted values.

Your MRTPAs will move forward in the review process. FDA may request to conduct inspections, which may include manufacturing inspections and clinical and nonclinical research inspections, to verify the information submitted in your MRTPAs. The results of these inspections may also be used to verify the information submitted in any additional applications that reference the same manufacturing and research information. To ensure that the appropriate records and personnel will be available during the inspections, FDA will notify the point(s) of contact identified prior to the inspection start date.

We will notify you if samples are required for independent testing and verification. If samples are required, you will be notified by letter of the number of samples required and the laboratory address where samples must be received. All requested samples should be received by the laboratory identified in the letter within 14 calendar days of the request.

The Freedom of Information Act (FOIA) staff assists the Office of Science with certain aspects of your applications. A representative of that staff may contact you to address redaction of your MRTPAs in connection with the public availability requirement under section 911(e) of the FD&C Act. These communications are not part of the scientific review and information submitted in response to FOIA requests are to be submitted to the FOIA office.

¹ Modified Risk Tobacco Product Applications (MRTPAs) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Tamirra Glover M.S., Regulatory Health Project Manager, at (301) 796-6727 or tamirra.glover@fda.hhs.gov.

Sincerely,

Digitally signed by Nicholas R. Hasbrouck -S
Date: 2023.08.31 13:12:09 -04'00'

Nicholas Hasbrouck, M.S.
Supervisory Regulatory Health Project Manager
Division of Regulatory Project Management
Office of Science
Center for Tobacco Products

Enclosure (if provided electronically, the Appendix is not included in physical mail):
Appendix A – Tobacco Products Subject of This Letter

Appendix A^{2,3,4,5,6}
Tobacco Products Subject of This Letter

Common Attributes	
Submission date	July 17, 2023
Receipt date	July 17, 2023
Applicant	Swedish Match U.S.A. Inc.
Product manufacturer	Swedish Match U.S.A. Inc.
Product category	Smokeless Tobacco Products
Product order under 911(g)	911(g)(1) Risk Modification Order
Modified Risk Claim	Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
Attributes	Tobacco Product
STN	MR0000256.PD1
Product subcategory	Loose Snus
Product Name	General Loose
Package Type	Cardboard Can with Plastic Lid
Product Quantity	45.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Additional Properties	Tobacco Cut Size: (b) (4)

² Properties to uniquely identify the tobacco products were provided by the applicant as of the date of this review, and not confirmed by FDA. Upon scientific review, the unique identification may be revised.

³ Brand/sub-brand or other commercial name used in commercial distribution.

⁴ Providing portion mass plus two of the three portion dimensions (along with other specified properties) will allow for full identification of portioned moist snuff and snus products

⁵ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

⁶ The characterizing flavor previously identified as "None" has been updated to "Tobacco" to accurately reflect that the product provides a tobacco characterizing flavor from the filler. As such, this product does not have any change in characterizing flavor.

Attributes	Tobacco Product
STN	MR0000256.PD2
Product subcategory	Portioned Snus
Product Name	General Dry Mint Portion Original Mini
Package Type	Plastic Can with Lid
Product Quantity	6.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	20 pouches
Portion Mass	300 mg
Portion Length	28 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD3
Product subcategory	Portioned Snus
Product Name	General Portion Original Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	33 mm
Portion Width	18 mm
Portion Thickness	6 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD4
Product subcategory	Portioned Snus
Product Name	General Classic Blend Portion White Large - 12ct
Package Type	Plastic Can with Lid
Product Quantity	10.8 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	12 pouches
Portion Mass	900 mg
Portion Length	34 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size: (b) (4)

Attributes	Tobacco Product
STN	MR0000256.PD5
Product subcategory	Portioned Snus
Product Name	General Mint Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size (b) (4)
STN	MR0000256.PD7
Product subcategory	Portioned Snus
Product Name	General Nordic Mint Portion White Large - 12ct
Package Type	Plastic Can with Lid
Product Quantity	10.8 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	12 pouches
Portion Mass	900 mg
Portion Length	34 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size (b) (4)
STN	MR0000256.PD8
Product subcategory	Portioned Snus
Product Name	General Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size (b) (4)

Attributes	Tobacco Product
STN	MR0000256.PD9
Product subcategory	Portioned Snus
Product Name	General Wintergreen Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Wintergreen
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size: (b) (4)

FDA STN	UPC	Product Name
		Total General
MR0000020	6-09249-62053-8, 6-90249-62024-8, 6-09249-62000-2	General Loose
MR0000021	6-09249-66053-4, 6-09249-66024-4, 6-09249-66000-8	General Dry Mint Portion Original Mini
MR0000022	6-09249-60053-0, 6-09249-60024-0, 6-09249-60000-4	General Portion Original Large
MR0000024	6-09249-69052-4, 6-09249-69022-7, 6-09249-69002-9	General Classic Blend Portion White Large (12 c
MR0000025	6-09249-67053-3, 6-09249-67024-3, 6-09249-67000-7	General Mint Portion White Large
MR0000027	6-09249-68052-5, 6-09249-68022-8, 6-09249-68002-0	General Nordic Mint Portion White Large (12 ct
MR0000028	6-09249-61054-6, 6-09249-61024-9, 6-09249-61000-3	General Portion White Large
MR0000029	6-09249-64053-6, 6-09249-64024-6, 6-09249-64000-0	General Wintergreen Portion White Large

(b) (4)

Summary of Consumer Contacts (Adverse Experiences)

Product	General Dry Mint Portion Original Mini
SKU Number	4800
FDA Tracking Number	PM0000011
Reporting Period	October 1, 2022 to September 23, 2018

Item #	Complaint Description	Count	Importance
---	No reported complaints	---	---

Product	General Mint Portion White Large
SKU Number	
FDA Tracking Number	PM0000014
Reporting Period	October 1, 2017 to September 30, 2018

Item #	Consumer No.	Complaint Received	Complaint Description	Additional Information
--------	--------------	--------------------	-----------------------	------------------------

(b) (4)				
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(b) (4)

Summary of Consumer Contacts (Adverse Experiences)

Product	General Portion Original Large
SKU Number	4880
FDA Tracking Number	PM0000012
Reporting Period	October 1, 2022 to September 23, 2023

Item #	Complaint Description	Count	Importance
(b) (4)			

Summary of Consumer Contacts (Adverse Experiences)

Product	General Mint Portion White Large
SKU Number	4352
FDA Tracking Number	PM0000014
Reporting Period	October 1, 2022 to September 30, 2023

Item #	Complaint Description	Count	Importance
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(b) (4)

Summary of Consumer Contacts (Adverse Experiences)

Product	General Portion White Large
SKU Number	4881
FDA Tracking Number	PM0000016
Reporting Period	October 1, 2022 to September 30, 2023

Item #	Complaint Description	Count	Importance
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(b) (4)

Summary of Consumer Contacts (Adverse Experiences)

Product	General Wintergreen Portion White Large
SKU Number	4882
FDA Tracking Number	PM0000017
Reporting Period	October 1, 2022 to September 30, 2023

Item #	Complaint Description	Count	Importance
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(b) (4)



FDA **U.S. FOOD & DRUG**
ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

April 16, 2020

Swedish Match USA, Inc.
Attention: Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
FDA Submission Tracking Number (STN): TC0005410

Dear Mr. Roerty:

We completed review of your protocols for the proposed postmarket surveillance and studies (PMSS) submission for the tobacco products identified in Appendix A and do not have concerns. **You may proceed with initiation of the studies.**

Additionally, we have determined that the principal investigator proposed in your PMSS submission appears to have sufficient qualifications and experience to conduct such postmarket surveillance and studies, which are designed to collect data or other information as set forth in your October 22, 2019 Modified Risk Granted Order.

All regulated tobacco products, including the modified risk tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure that the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{1,2} using eSubmitter.³ Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁴; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

¹ For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

² FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

³ For more information about eSubmitter, see <https://www.fda.gov/industry/fda-esubmitter>

⁴ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

If you have any questions regarding postmarket activities for the tobacco products identified in Appendix A, please contact Eugene Chuang, at (240) 402-9302 or eugene.chuang@fda.hhs.gov.

Sincerely,



Lillian Ortega
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement
Center for Tobacco Products

Enclosures:

- Appendix A – List of Tobacco Products That Are Subject of This Letter
- Appendix B – List of Amendments Received for Postmarket Surveillance and Studies

Appendix A
List of Tobacco Products That Are Subject of This Letter

Product STN	Tobacco Product Name	Date of Modified Risk Granted Order
MR0000020	General Loose	October 22, 2019
MR0000021	General Dry Mint Portion Original Mini	October 22, 2019
MR0000022	General Portion Original Large	October 22, 2019
MR0000024	General Classic Blend Portion White Large – 12 ct	October 22, 2019
MR0000025	General Mint Portion White Large	October 22, 2019
MR0000027	General Nordic Mint Portion White Large – 12 ct	October 22, 2019
MR0000028	General Portion White Large	October 22, 2019
MR0000029	General Wintergreen Portion White Large	October 22, 2019

Appendix B
List of Amendments Received for Postmarket Surveillance and Studies

Amendments Received	
Date of Submission:	February 18, 2020
Date of Receipt:	February 18, 2020
Reviewed:	Yes
Status:	Active
Brief Description:	Response to January 17, 2020 FDA Information Request Letter
Date of Submission:	April 1, 2020
Date of Receipt:	April 1, 2020
Reviewed:	Yes
Status:	Active
Brief Description:	Response to March 19, 2020 FDA Teleconference

(b) (4)

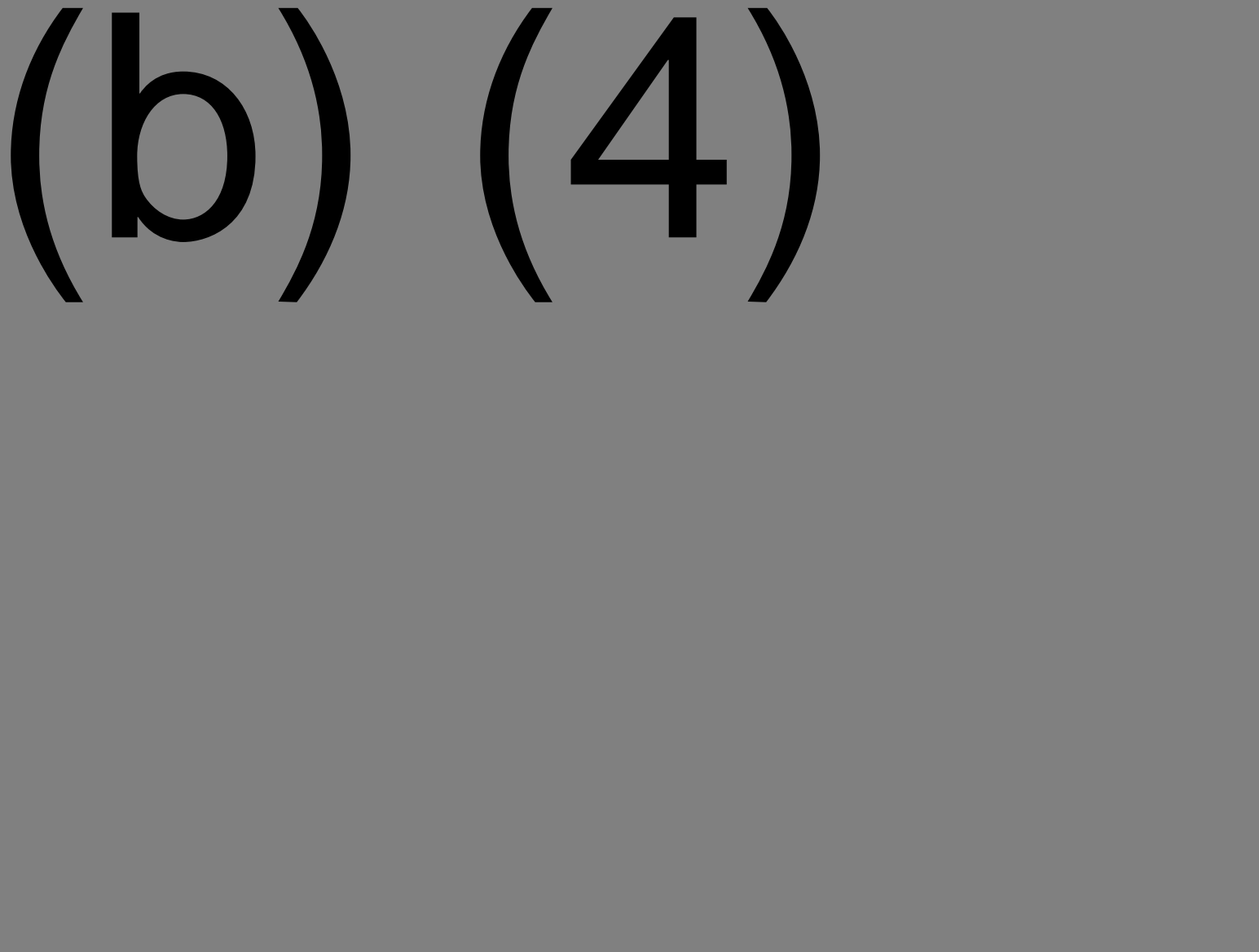
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(b) (4)

(b) (4) -
General Snus MRTP
Post-Market Surveillance

Consumer Facing Materials

(b) (4)

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(b) (4)

(b) (4)



General Snus® Patterns of Use Study – Version 4.0
Protocol **SMU 19-01GENS**

Swedish Match USA, Inc.

Protocol for General Snus® Patterns of Use Study

Protocol SMU 19-01GENS

Status: Approved

Date: 15 June 2020

Prepared by: 

Confidentiality Statement

Notice: The Contents of this document and any attachments to it may contain confidential and/or legally privileged information. This information is only for use by the intended recipient. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or taking action based upon the information contained herein is strictly prohibited. If this document was received in error, please notify the sender and delete it thereafter from your system. Swedish Match USA, Inc., its parent and affiliate companies.

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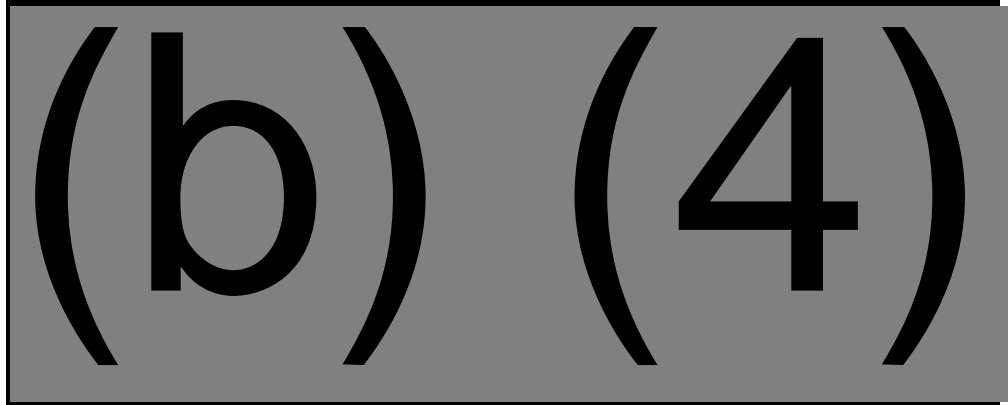
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1. ABBREVIATIONS

CASRO	Council of American Survey Research Organizations
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
FTP	File Transfer Protocol
HINTS	Health Information National Trends Survey
IRB	Institutional Review Board
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
PATH	Population Assessment of Tobacco and Health
PII	Personally Identifiable Information
RESPONDENTS	Users of General Snus at Baseline survey
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SMU	Swedish Match USA, Inc.
TNP	Tobacco/Nicotine Product(s)
U.S.	United States

2. RESPONSIBLE PARTIES

2.1. Investigator(s) and Contributors



2.2. Sponsor:

Swedish Match USA, Inc.

Tryggve Ljung, Vice President Scientific Affairs

3. SYNOPSIS

Title	General Snus® Patterns of Use Study
Protocol version identifier	Version 4.0 FINAL
Date of last version of protocol	June 15, 2020
Protocol number	SMU 19-01GENS
Author	Tryggve Ljung, MD., Ph.D.

Rationale and background	<p>In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for <i>General Snus®</i>, a moist tobacco product placed under the upper lip that does not involve spitting or chewing¹. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing <i>General Snus®</i> a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22, 2019. This proposed study is planned to be part of the post marketing surveillance following the risk modification order.</p> <p>The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.</p>
Research question and objective	<p>The overarching research questions within this study are as follows: (i) <i>How do General Snus® users use tobacco and nicotine products (TNP)</i>, and (ii) <i>how do they perceive health risks associated with cigarettes and General Snus®?</i> These questions will be studied using a self-reported survey examining patterns of use for the previous 30 days (Baseline-Wave 1) and assessment of TNP use among the same <i>General Snus®</i> users again at 6 months (Wave 2), 1-year (Wave 3) and 2-year (Wave 4) intervals post baseline.</p> <p><u>Primary Objectives</u></p> <p>Use behavior will be assessed, utilizing data from all 4 waves of the study:</p> <ol style="list-style-type: none"> 1. Compare TNP patterns of use, between all 4 waves. The study will examine self-reported usage patterns for participants, in aggregate, over time. The study will report on frequency of use of <i>General Snus®</i> use, as well as other TNP, if multiple TNP use is reported. Of specific interest will be usage patterns of cigarettes. Intent to quit and actual quitting of cigarettes will be assessed at each wave of the study.

	<ol style="list-style-type: none"> 2. Among <i>General Snus</i>® users, compare consumption patterns of cigarettes and <i>General Snus</i>® over the last 30 days (Baseline) with consumption patterns in Waves 2 through 4. Of particular interest is whether usage of <i>General Snus</i>® offsets usage of cigarettes. 3. Characterize <i>General Snus</i>® users in terms of prior TNP use and demographics and compare this to new users of smokeless TNP as reported in the Population Assessment of Tobacco and Health (PATH) 4. Compare the tendencies of <i>General Snus</i>® users to quit cigarettes or use <i>General Snus</i>® in an incremental fashion, in a supplemental fashion, or in complete substitution of cigarettes. <p><u>Secondary Objectives</u></p> <p>Risk Perception and understanding of the MRTP claim will be assessed utilizing data from all 4 Waves of the study:</p> <ol style="list-style-type: none"> 1. Assess perceptions of risk of certain health conditions (mouth cancer, heart disease, and lung cancer, separately) among <i>General Snus</i>® users. <ol style="list-style-type: none"> a. Assess the absolute risk attributed to using only <i>General Snus</i>® daily, smoking only cigarettes daily, dual use of <i>General Snus</i>® and cigarettes daily, and never having used any TNPs. 2. Assess the extent to which <i>General Snus</i>® users understand the risk reduction as stated in the modified risk claim
Study design	<p>The <i>General Snus</i>® Patterns of Use Study is a longitudinal, prospective study that consists of multiple waves to gain an understanding of how <i>General Snus</i>® is and has been used among consumers. Respondents will complete surveys at Baseline, and again at 6 months, 1 year and 2 years post Baseline period. All participants for the Baseline wave must have reported use of <i>General Snus</i>® at least once in the previous 30 days and report use on some days or every day. Using an online survey designed by Kantar, participants will self-report patterns of all TNP use over the past 30 days at baseline, and again at 6 months, 1 year, and 2 years post baseline.</p> <p>In addition to reporting TNP use, participants will report their perceptions of health risk and their understanding of the modified risk claim.</p>
Population	<p>The study will be conducted among legal age <i>General Snus</i>® users in the U.S. The Baseline survey will be administered to 1,500 U.S. consumers who meet all the following criteria:</p> <ul style="list-style-type: none"> • Have used <i>General Snus</i>® at least once or more within past 30 days prior and report using it every day or some days prior to study initiation • Minimum age of 21 years • Agree to participate in four surveys over the two-year period • Able to read and speak English • Currently a resident of the United States

	<ul style="list-style-type: none"> • Provide electronic informed consent and personal contact information <p>Individuals who meet any of the following criteria will be excluded:</p> <ul style="list-style-type: none"> • Respond as “don’t know” or “decline to answer” to specific demographics (gender, geographical region). • Unwilling or unable to provide electronic informed consent and personal contact information • Employed in any of the following fields or professions: market research, marketing, advertising, manufacturers of TNP, or physicians • Taken part in a consumer research study on tobacco in the past 2 weeks
Data sources	<p>Due to the low incidence of <i>General Snus</i>® users among the general population, sample for this cohort will be recruited directly from purchasers of <i>General Snus</i>®. Invitation stickers will be placed on product packaging (i.e. each individual canister) for all flavors of <i>General Snus</i>®. Invitations to known General Snus consumers will also be sent to consumers who have opted-in/registered to receive communications from General Snus.</p> <p>After completion of the Baseline wave, participants will be sent periodic reminders of the future waves of the study and be given a bonus compensation after the Wave 4 survey as an attempt to reduce the expected attrition of participants over time.</p>
Study size	<p>1,500 consumers will be recruited for the Baseline wave, distributed from each of 4 geographic regions in the US². Due to the low incidence of General Snus users, demographic quotas will not be established. However, completes by region will be monitored in comparison to General Snus sales by region.</p> <p>Reminders of Waves 2 through 4 will be sent to those who participated in the Baseline wave, however, it is anticipated that up to 40% of participants will drop out each year, resulting in 900 participants at the 1-year post Baseline and 540 at the 2-year post Baseline (final wave).</p>
Data analysis	<p>All analyses performed for the <i>General Snus</i>® Patterns of Use Study will be descriptive in nature.</p> <p>Descriptive statistics used to understand the distribution of socio-demographic and outcomes variables will be based on the raw data (i.e., prior to any recoding or any aggregation required for the final presentation of results). Respondents with values for variables that are illogical or deemed unreliable, as determined by the underlying distribution, will be considered for removal prior to performing the main analyses. The SAP will provide greater detail on this topic.</p> <p>Numeric variables will be described using total sample size, number of missing observations (if applicable), means, standard deviations, medians, minimums, and maximums. Categorical variables will be described using frequencies, percentages, and the number of missing observations (if applicable).</p>

	Unless otherwise specified in the SAP, descriptive statistics reported for the main analyses will include the number of non-missing observations, means, standard deviations, and 95% confidence intervals (CIs), for numeric variables. For categorical variables it will include the number of non-missing observations, frequencies, percentages, and 95% CIs for the percentage of participants endorsing each category.
Milestones	Start of Baseline data collection Q2 2020 End of Baseline data collection Q3 2020

4. AMENDMENTS AND UPDATES

Number	Date	Section of study protocol	Description of Change	Reason
1				
2				
...				

5. BACKGROUND AND RATIONALE

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General Snus®*, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General Snus®* a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22, 2019. This proposed study is planned to be part of the post marketing surveillance following risk modification order.

The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.

6. OBJECTIVES

The overarching research questions within this study are as follows: (i) *How do General Snus® users use TNP, and (ii) how do they perceive health risks associated with cigarettes and General Snus®?* These questions will be studied using a self-reported survey examining patterns of use for the previous 30 days (Baseline-Wave 1) and assessment of TNP use among the same General Snus® users again at 6 months (Wave 2), 1-year (Wave 3) and 2-year (Wave 4) intervals post Baseline.

6.1. Primary Objectives:

Use behavior will be assessed, utilizing data from all 4 waves of the study:

1. Compare TNP patterns of use, between all 4 waves. The study will examine self-reported usage patterns for participants, in aggregate, over time. The study will report on frequency of use of General Snus® use, as well as other TNP, if multiple TNP use is reported. Of specific interest will be usage patterns of cigarettes. Intent to quit and actual quitting of cigarettes will be assessed at each wave of the study.
2. Among General Snus® users, compare consumption patterns of cigarettes and General Snus® over the last 30 days (Baseline) with consumption patterns in Waves 2 through 4.
Of particular interest is whether usage of General Snus® offsets usage of cigarettes.
3. Characterize General Snus® users, especially new users, in terms of prior TNP use and demographics and compare this to new users of smokeless TNP as reported in the Population Assessment of Tobacco and Health (PATH)
4. Compare the tendencies of General Snus® users to quit cigarettes or use General Snus® in an incremental fashion, in a supplemental fashion, or in complete substitution of cigarettes.

6.2. Secondary Objectives:

Risk Perception and understanding of the MRTP claim will be assessed utilizing data from all 4 Waves of the study:

1. Assess perceptions of risk of certain health conditions (mouth cancer, heart disease and lung cancer, separately) among General Snus® users.
 - a. Asses the absolute risk attributed to using only General Snus® daily, smoking only cigarettes daily, dual use of General Snus® and cigarettes daily, and never having used any TNPs.
2. Assess the extent to which General Snus® users, especially new users, understand the risk reduction as described in the modified risk claim

7. RESEARCH METHODS

7.1. Data Source

Due to the low incidence of *General Snus*® users among the general population, sample for this cohort will be recruited directly from purchasers of *General Snus*®. Study invitation stickers will be placed on product packaging (i.e. each individual canister) for all the flavors of *General Snus*®. The sticker initiative will target approximately 11,000 geographically distributed retail outlets where *General Snus*® is sold. Efforts will be made to ensure that stickers are distributed across all locations at the same time and that all *General Snus*® users will have the same chance to participate in this study (See Attachment 3 for an example of the sticker).

The study invitation sticker will be approved by the Sterling Institutional Review Board and includes a statement of getting paid for providing opinions, as well as eligibility requirements, such as being 21 years of age and older, limiting one participant per household, and that eligibility is limited to a set number of participants. Additionally, the sticker will identify a website to learn more information about the survey and provide a unique registration code.

Invitations to known General Snus consumers will also be sent to consumers who have opted-in/registered to receive communications from General Snus. These consumers will be sent an email invitation to participate in the survey. Within the invitation, a unique participation code will be provided, along with a link to the survey landing page.

From the website, participants will be taken to a study welcome screen; that screen and all following survey pages will be hosted on Kantar or Kantar third-party partner servers.

Users who are interested in participating will visit the website address shown on the *General Snus*® canister invitation sticker or click on survey link embedded in the email invitation. Upon entry, the participant will be shown the study welcome screen, enter qualifying registration/participation code and redirected to a secure and unique survey link. The first set of questions will be the survey screener which will be designed to qualify the participant using the study inclusion and exclusion criteria (further described in Section 7.4.1 and 7.4.2 “Inclusion/Exclusion Criteria”). If potential participants agree to participate in the study after reading the statement of informed consent, they will select “I agree to participate” and will then be taken to the survey instrument. Those who select “I do not agree to participate” will be thanked before exiting.

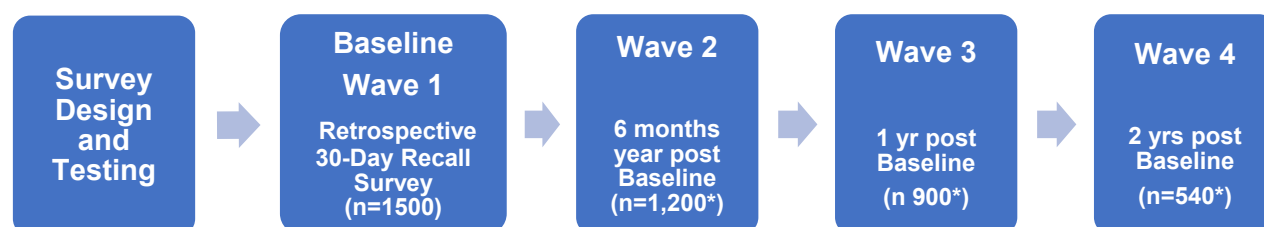
By giving nearly every *General Snus*® user an equal chance to participate in the study, a geographically representative sample of *General Snus*® users will be obtained. Respondents will complete a customized web-based survey of invited consumers who meet inclusion and exclusion criteria (explained in Sections 7.4.1 and 7.4.2) and who agree to participate.

After completion of the Baseline wave, participants will be sent periodic reminders of the future waves of the study as an attempt to reduce the expected attrition of participants over time.

7.2. Study Design

As noted previously, the General Snus® Patterns of Use Study seeks to evaluate TNP patterns of use among General Snus® users through a Baseline Study focused on 30-day recall of TNP use, accompanied by follow up studies comprised of another 30-day recall period at 6-months, 1- and 2-year intervals after the Baseline study.

Figure 1: Summary of Research Phases



**Study population is estimated for Waves 2, 3 and 4, based on Kantar experience in implementing multiple wave longitudinal studies, coupled with enhanced retention strategies.*

For the Baseline Study and Waves 2 through 4, all participants who qualify and have signed the electronic Informed Consent form will access a web survey online via a computer, smartphone, or tablet. To enhance retention, participants who completed the Baseline survey will be allowed to participate in any of the subsequent waves, even if they fail to participate in one of the of the follow-up waves. Each study is a 15-20-minute survey where participants are asked to self-report TNP use history within the past 30 days. A 30-day recall period was selected based both upon review of the available tobacco and nicotine peer reviewed literature utilizing 30-day recall for understanding current and recent usage of TNP⁴ as well as applying the PATH methodology of asking consumers to recall specific TNP use in a 30-day period.⁴

Prior to launching the study in full, Kantar will quality check the survey. The primary objective of this quality check is to confirm that all facets of the data collection process function according to protocol; items of specific interest include the length of interview, and the accuracy of the web-based instrument (i.e., survey), all of which work to ensure the primary objectives of the research are met.

Participants who complete the survey will receive their honoraria in the form of reward points aligned to the fair market value assigned to the survey length, enhanced to improve retention over the 2-year study period. Respondents will receive compensation for each wave of the study they complete and an additional bonus compensation after completing the third wave of the study. A literature review shows retention in longitudinal studies is enhanced by offering generous honoraria for participation.^{5,6}

At the completion of each wave of the study, General Snus® users will be reminded about the next wave of the study. Interim reminders between each wave will also be sent to each participant at 3-month intervals to reduce the attrition rate between surveys. Respondents' email and contact information will be validated to improve the recontact rate.

7.3. Study Population

The study will be conducted among legal age General Snus® users in the U.S. The Baseline survey will be administered to 1,500 U.S. consumers who meet all the study Inclusion Criteria.

7.4. Sample Size

The Baseline study will have a total sample of n=1,500 participants. Each participant who participates in the Baseline study will agree to participate in the subsequent waves. Additionally, periodic reminders will be sent at 3-month intervals to all participants in the Baseline study in an attempt to retain participants for each subsequent wave. Respondents who complete the Baseline study may participate in any of the subsequent waves. Based on (b) (4) prior experience with longitudinal consumer studies of these types, it is anticipated that there would be up to 50% drop out rate each year. Strategies added to this study to improve retention will be increased honoraria, periodic reminders, and allowing a respondent to continue in any subsequent wave, so long as they complete the Baseline wave. Using these retention strategies, (b) (4) anticipates a 40% drop out rate each year, resulting an estimated sample of n=1200 participants in Wave 2, n=900 participants in Wave 3 and n=540 participants in Wave 4. With an estimated population of at least 40,000 General Snus® users in the U.S., a sample size of 540 would provide 0.05% margin of error with 95% confidence interval. Actual sample sizes for each Wave will be stated in the final report.

7.4.1. Sample Selection: Inclusion Criteria

In addition to the cohorts to be included in this study, participants must meet the following criteria to be included:

- Have used General Snus® at least once or more within past 30 days prior AND use it every day or some days prior to study initiation
- Minimum age of 21 years
- Agree to participate in four surveys over the two-year period
- Able to read and speak English
- Currently a resident of the United States
- Individuals who provide electronic informed consent and personal contact information

7.4.2. Sample Selection: Exclusion Criteria

Respondents who meet any of the following criteria will be excluded:

- Respond as “don’t know” or “decline to answer” to specific demographics (gender, geographical region)
- Unwilling or unable to provide electronic informed consent and personal contact information
- Employed in any of the following fields or professions: market research, marketing, advertising, manufacturers of TNP, or physicians
- Have taken part in a consumer research study on tobacco in the past 2 weeks

7.5 Variables

7.5.1. Exposure

The length of interview for this survey instrument is estimated to be 15 minutes. Respondents will be able to complete the online survey via computer, tablet, or smartphone. However, participants will be told in their invite to the survey that their experience will be optimized if completed on a computer or tablet.

7.5.2 Outcomes

Outcomes that will be used to evaluate the primary objectives are as follows:

Reported use in the last 30 days will be assessed by using one item observing **frequency** of use for cigarettes, General Snus® and other TNP used over the last 30 days. The item is based on the approach employed in PATH for observing current TNP use.⁴ Response options for frequency of use include “Every day,” “Some Days,” “Not at All,” and “Don’t know”. See Figure 2 for an example. Data will be captured at baseline and in each subsequent wave.

Figure 2: Examples of Variables Supporting the Primary Objectives

Q. In the **past 30 days**, how often did you use each of the following tobacco or nicotine products?

	Every day	Some Days	Not at All	Don't Know
LIST PRODUCTS SELECTED USED PAST 30 DAYS IN A3				

Self-reported consumption for both cigarettes and General Snus® will be assessed with questions regarding daily use in each wave of the survey. Examples are shown below using the General Snus® survey questions. Similar consumption questions will be asked of those who also reported using cigarettes in the previous 30 days. See Attachments 1 Baseline Questionnaire and Attachment 2: Waves, 2, 3, and 4 Questionnaires

Average number of General Snus® pouches used per day for everyday users will be assessed using one item asked of participants who report using General Snus® every day. The item will report the number of General Snus® pouches used each day. This item is based on the approach employed in PATH for observing TNP use⁴.

Q. For everyday users: On average, about how many General Snus® pouches do you now use each day? Open ended answer....

	_____ # of General Snus® pouches use each day [RANGE = 0-80]
--	--

Average number of General Snus® pouches used per day for somedays users will be assessed using two items asked of participants who report using General Snus® some days. One item will report the number of days General Snus® pouches was used. The second item will report the number of General Snus® pouches used on each of those days. These items are based on the approach employed in PATH for observing TNP use⁴.

Q. On how many of the past 30 days did you use General Snus® pouches?

	_____ # of days used General Snus® pouches [RANGE = 1-30]
--	---

Q. On average, on those days you used General Snus® pouches, how many pouches did you usually use each day?

	_____ # of General Snus® pouches use each day [RANGE = 0-80]
--	--

Average Percent of days General Snus® is used in aggregate will be derived based on the item in the survey assessing General Snus® usage in everyday users and the items assessing General Snus® in the somedays user.

Quitting behaviors for cigarettes will be assessed at each wave of the research with items assessing past and current quitting. See Figure 3 for examples

Figure 3: Cigarette Quitting Behavior Examples

Quit cigarettes in the past 30 days will be assessed of all cigarette users using two items

Q. Have you completely quit smoking cigarettes in the past 29 days? [SELECT ONE ONLY]

1	Yes
2	No

Respondents who have not quit using cigarettes in the past 30 days, will be asked if they are currently trying to quit.

Currently trying to quit will be assessed using one item

Q. Are you currently trying to quit smoking cigarettes?

1	Yes
2	No

7.5.3. Secondary Objectives

Outcomes that will be used to evaluate the secondary objectives are as follows:

Perceptions of absolute risk will be assessed in each wave of the survey using a single-choice scale (5-point Likert scale, fully anchored; from 1= Very low chance to 5= Very high chance, also including “Don’t know” and “Decline to answer”) for each of three health conditions (mouth cancer, heart disease, and lung cancer). This scale was modified from the risk perception scale in HINTS.⁷ See Figure 4 for an example for cigarettes. The same question will be asked for use of *General Snus*® alone and dual use of both cigarettes and *General Snus*®.

Figure 4: Perceptions of Absolute Risk Example

Q: In your opinion, what is the chance that a person who **only smokes cigarettes every day** would suffer from the following health conditions during his/her lifetime?

[SELECT ONE FOR EACH ROW; RANDOMIZE ROWS AS IN B1]

		Very Low Chance	Low Chance	Moderate Chance	High Chance	Very High Chance	Don't Know
1	Heart disease	1	2	3	4	5	99
2	Lung cancer	1	2	3	4	5	99
3	Mouth cancer	1	2	3	4	5	99

Understanding of the MRTP claim will be assessed using two items to determine risk perception relative to cigarettes and the elements stated in the claim. See Figures 5 and 6 below.

Figure 5. Understanding of MRTP claim

Q. Using *General Snus*® instead of cigarettes....

SELECT ONLY ONE RESPONSE

1	Puts you at lower risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis.
2	Does not affect your risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis.
3	Puts you at higher risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis.
4	None of the above
5	Don't Know
6	Decline to answer

Those who answer correctly, will asked a follow up question. See Figure 6 for the example

Figure 6. Understanding of MRTP claim

Q. You said that using *General Snus*® instead of cigarettes puts you at lower risk of diseases. If you are going to use *General Snus*® instead of cigarettes to lower your risk of diseases, how many cigarettes, if any, can you smoke per day?

SELECT ONLY ONE RESPONSE

1	Zero (0) cigarettes
2	Up to 5 cigarettes
3	Up to 20 cigarettes
4	As many as you want to smoke
5	Don't Know
6	Decline to answer

7.5.4. Other Variables

Some additional variables will be collected that will not be used to support the primary and secondary objectives. For example, baseline characteristics of age, gender, ethnicity, education, and geographical region will be collected to characterize the sample users in terms of prior TNP use and demographics and then compare this to new users of smokeless TNP as reported in the Population Assessment of Tobacco and Health (PATH). Details of this analysis will be specified in the SAP

7.6. Data Management

Kantar will be responsible for all study data management. The protocol specifies data sources, data collection modes, software products and servers used for data collection, data management and data transfer procedures, as well as the measures that will be taken to protect the security and integrity of the data as they are collected and stored during the study.

Kantar subscribes to Safe Harbor and pledges to follow the Council of American Survey Research Organizations (CASRO) Code of Conduct, both providing principles and guidelines to ensure participant confidentiality and privacy.

Examples of best practices include but are not limited to:

- The implementation of controls and procedures to maintain the confidentiality, integrity, and availability of personal information in accordance to company policy and applicable local legislation;
- Data handling procedures ensuring secure transfer and storage of personal identifiable information;
- Restricting access to personal information to only those that require access to perform their job;
- Properly informing participants about the survey's aim and how their personal information will be used and protected.

7.6.1. Data Quality Control

The data collected for this study will be monitored for adherence with the study protocol. All data will be collected using a programmed web survey. Prior to initiating the study, appropriate edit programming will be conducted to assure the final dataset requires minimal cleaning of invalid responses. The questionnaire will be designed so that instructions are as easy to understand and clear as possible to help avoid missing data. These programming procedures for the web-based survey data entry tool will include response ranges, consistency checks, skip patterns, and other special edit procedures where applicable. At every step of data processing, results or data will be cross checked Kantar team members who independently replicate the results and/or verify that the data have been handled appropriately and accurately. Any inconsistencies identified during this process are corrected before any further analysis is completed.

Participants will access the survey via information on the General Snus package which includes a website address and unique registration code. Upon entering the survey site, participants will provide their registration code which will be verified as a qualifying registration code against a master list. Registration codes will be randomly generated and can be activated for use only once. In subsequent waves, enrolled participants will each receive a unique survey link which will direct them to the follow up survey. Upon completion, the survey link will no longer be active and cannot be used again. To prevent respondents from registering more than once, Kantar will track each respondent's IP address when registering for the study and prevent more than one registrant from the same IP address. Digital fingerprints will be used to prevent duplication by participants. This approach combines detected attributes of a device (operating system, IP address, software versions) to create a unique device signature. Built in survey logic will be used to detect digital fingerprints and determine if a specific digital fingerprint has previously entered the survey. If the

digital fingerprint has previously accessed the survey and resulted in a terminate or complete, the participant will not be allowed to continue to the survey and will be routed to a termination screen.

Other quality control procedures include the identification of participants with little variability in their responses, for example due to disinterest in the project (“straight liners”), participants that complete the survey much faster than expected (“speeders”), and/or that provide disproportionate or nonsensical numeric responses compared to the average (outliers). Removed participants will be held in a separate data file with that will be utilized for the analysis.

7.6.2. Data Base Lock

After data collection is complete, data quality and completeness will be evaluated. Once the data quality check is complete, the database will be locked, and the data will no longer be subject to change.

7.6.3. Data Transfer

Kantar will transfer final data files to SMU in a zipped file via a secure FTP site at the conclusion of the study. SMU will confirm receipt of these files. File name will include the study name and date of transfer.

7.6.4. Data Storage and Archiving

All electronic data files will be kept on secure servers, with backup processes in place. Paper data files will be scanned and filed accordingly.

Only de-identified data will be transferred for analysis purposes.

Personally Identifiable Information (PII) will be stored separately from the study data. Electronic records of data files and study documents will be transferred in a secure manner to SMU and retained and stored on a secured server maintained by SMU as required by law.

7.7. Data Analysis

A formal and more detailed statistical analysis plan (SAP) will be prepared by Kantar as the survey is being developed. This SAP will be submitted after finalization of the study protocol and survey.

7.7.1. Quantitative data analysis

The main analyses for the study will consist of descriptive analysis. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a Statistical Analysis Plan (SAP), which will be dated, filed, and maintained by the sponsor. The final SAP may require modification of plans outlined in the protocol; any major modifications of primary outcome definitions or their analyses would be reflected in a protocol amendment.

Quality control of the data will also be performed. This will focus on identifying potential outliers that exist in the dataset. Identification of potential outliers will be based on investigation of the underlying distribution of the variable. Respondents with values on particular variables that are extreme, as determined by the underlying distribution, will be considered for removal prior to performing the main analyses. This said, the *a priori* assumption for all data collected is that it is true and accurate.

The study team will format and properly label the data sets (including all responses from participants and the date that the survey was completed) in a statistical package (SAS 9.4 or IBM SPSS version

23), transform the data (if appropriate) so they are suitable for analysis, and produce a data codebook that describes the variables in the data sets. The data sets will contain a subject ID number and will not contain any information that could be used to identify individual participants. Additional detail on data quality measures can be found in section 7.7.4 “Quality Control”.

7.7.2. Statistical considerations

Descriptive analysis will provide summary statistics for all variables. Summary statistics will include counts and proportions for categorical variables and means, standard deviations, medians, minimums and maximums for ordinal and continuous variables. Descriptive statistics will be used to describe the sample as well as verify the quality of the data. Inferential statistical testing will be conducted to evaluate change in primary and secondary outcome measures (i.e., patterns of use, risk perception, understanding of claim) from baseline and each follow-up wave of the study. Baseline vs. each follow-up (waves 2, 3, and 4) will be conducted using paired sample t-tests for continuous variables and McNemar test for categorical variables in order to account for correlated measures.

7.7.3. Results and Reporting

Due to the longitudinal nature of the study design with data collected at four time points (Baseline and 6 months [Wave 2], 1 year [Wave 3], and 2 years [Wave 4] post Baseline), the sample size will inevitably drop from each time point. The primary objective of the study is to compare TNP patterns of use, between Baseline and Waves 2 through 4. To reduce bias and maintain sample size, data from participants who complete the Baseline survey and any of the subsequent waves, participant will be retained for analysis. This will allow us to observe changes in patterns of TNP use across time for the same individuals. This study includes a Baseline report (all participants will be analyzed and reported), an interim report of all Primary and Secondary Objectives at Wave 3 participant and a final report of all Secondary Objectives at Wave 4 participant). Study reports will be provided in MS Word with results tables incorporated.

7.7.4. Quality Control

There are several aspects to quality control as described below:

Survey Instrument Programming

- The web-based survey will be created by one programmer using the Decipher software for web-based survey programming (v117, Fresno, CA).
- Then, the survey will be checked by another programmer independent of the day-to-day project to ensure all programming is correct.
- After the survey has been programmed, the survey link and content will be reviewed by a separate team within the operations group from the perspective of the participant (i.e. the link is reviewed online and not within the Decipher software).
- All logic, ranges, termination points, “other specify” and open ends are checked to ensure they match the intentions of the questionnaire.

7.7.5. Data Management and Analyses

- Respondents who lack variability in their responses to a battery of questions (“straight liners”) will be identified using a standard deviation customized for each battery found in the survey. Those people whose responses have a standard deviation of zero, a very low standard deviation, or a discernable pattern in their answers inconsistent with any coherent understanding of the question

will be flagged and examined individually. Respondents who are straight lining or giving patterned responses consistently throughout the survey will be removed from the analysis.

- Preliminary outliers will be identified using 3x standard deviations from the mean or those beyond the 5th and 95th percentiles. Each data point will be examined individually to determine whether the response represents realistic data. More specific details on handling of outliers will be provided in the SAP. Outliers will be identified and handled consistently and transparently and documented in the final report. This said, the a priori assumption is that all data reported is true and accurate and preliminary outliers will be identified based on the underlying distribution of the data, and through descriptive analysis.
- All statistical analyses and results output will be checked by another researcher for quality control.

7.8. Limitations of the Research Methods

The data collected will be based on responses to a web-based survey. The perceived health risk assessments are intended to simulate real world perceptions after exposure to real world information on General Snus® but obviously do not have the same contextual, social, and emotional consequences of actual decisions.

In addition, since data from this study will depend on participant self-reporting, subsequently reported variables may also be subjected to recall bias. Self-reported data collection is a standard approach and any potential problems with recall bias are anticipated to be constant across time points.

Respondents will be recruited based on their exposure to an invitation sticker on General Snus® package available in retail outlets. As a result, recruitment could be considered a convenience sample. Consumers who do not frequent these retail outlets will not have the opportunity to participate. Further, due to sample selection during recruitment, participants who are more interested in research or, perhaps healthy enough to participate, may be over-represented, hence the possibility of selection bias. Although these issues raise concerns about the external validity of the findings (e.g., our sample may not be fully generalizable to all consumers), the recruitment plan is designed to mirror the underlying populations (see Section 7.3 “Study Population” for more detail). In fact, regardless of how participants are recruited, there will always exist the possibility that the people who decline the opportunity to participate in the research differ in a systematic way from the people who accept the opportunity.

Participation in all 4 waves over 2 years will result in participant attrition as stated earlier in Section 7.4 “Sample Size”. It is possible that the remaining sample after all 4 waves may be biased towards those who are more loyal users of General Snus®. To minimize this risk, reminders will be sent to all participants and a bonus compensation will be given for those who participate in the first 4 waves. Additionally, participants who complete the Baseline survey and complete in any subsequent wave will be included in the data set for analysis.

8. PROTECTION OF HUMAN SUBJECTS

This study is an observational study; there is no assignment of a participant to any TNP, or vice versa. No additional diagnostic or monitoring process is required for participation or during the study. This study will assess self-reported patterns of use and risk perceptions. Additionally, the study will end with a debriefing statement to inform all participants that all information within stimuli is for market research purposes only and not approved or endorsed by the FDA.

8.1. Regulatory authority approvals/authorizations

The study will be carried out in accordance with CTP guidance on data for human studies designed to evaluate the risks and benefits to the population as a whole¹. Additionally, Kantar conducts all of our research in accordance with the requirements of our Quality System, which confirms to ISO 20252:2012 the International Standard for Market Research, Certification Number: 1019.

8.1.1. Institutional review board (IRB)

Documented approval from an appropriate IRB in the U.S. will be obtained prior to study start. When necessary, an extension, amendment or renewal of the IRB approval will be obtained and forwarded to SMU. The IRB will supply to SMU, upon request, a list of the IRB members involved in the vote and a statement to confirm that the IRB is organized and operates according to applicable laws and regulations.

8.1.2. Respondent information and consent

Prior to beginning the survey, potential participants will be provided with an electronic statement of informed consent. The consent informs potential participants that participation in the study is voluntary and that responses will remain confidential. It also includes information about the goals of the study, the approximate length of the survey, incentives for participation. Lastly, the statement of informed consent provides potential participants with the resource references to address any concerns they may have. A link to the host site is given if the participant has any specific questions about the survey instrument or incentives for participation. Contact information for the IRB is also provided if the participant has any questions or concerns about their rights as a research participant. Contact information to the sponsor's product complaint office, will be provided or to report any product questions, complaints or product concerns.

After potential participants read the statement of informed consent, they will be asked, "Do you voluntarily agree to participate in this study?". Respondents who select "I agree to participate" will be able to complete the survey. At any time during survey completion, the participant may choose to exit the survey should they decide not to participate any further. Data provided by a participant who exits the survey prematurely will not be utilized in any analyses. Respondents who select "I do not agree to participate" will be thanked for their time before exiting. IRB written approval / favorable opinion of the electronic informed consent form and any other written information provided to participants will be obtained prior to the initiation of the study.

8.1.3. Confidentiality

SMU as well as all investigators ensure adherence to applicable data privacy protection regulation. Data are transferred in encoded form only. The entire documentation made available to SMU does not contain any data which, on its own account or in conjunction with other freely available data, can be used to re-identify natural persons. The investigators are obligated to ensure that no documents contain such data.

All records identifying the subject will be kept confidential and will not be made publicly available. Respondent names will not be supplied to SMU. If the participant name appears on any document, it must be obliterated before a copy of the document is supplied to SMU. Study findings stored on a computer will be stored in accordance with local data protection laws.

9. REFERENCES

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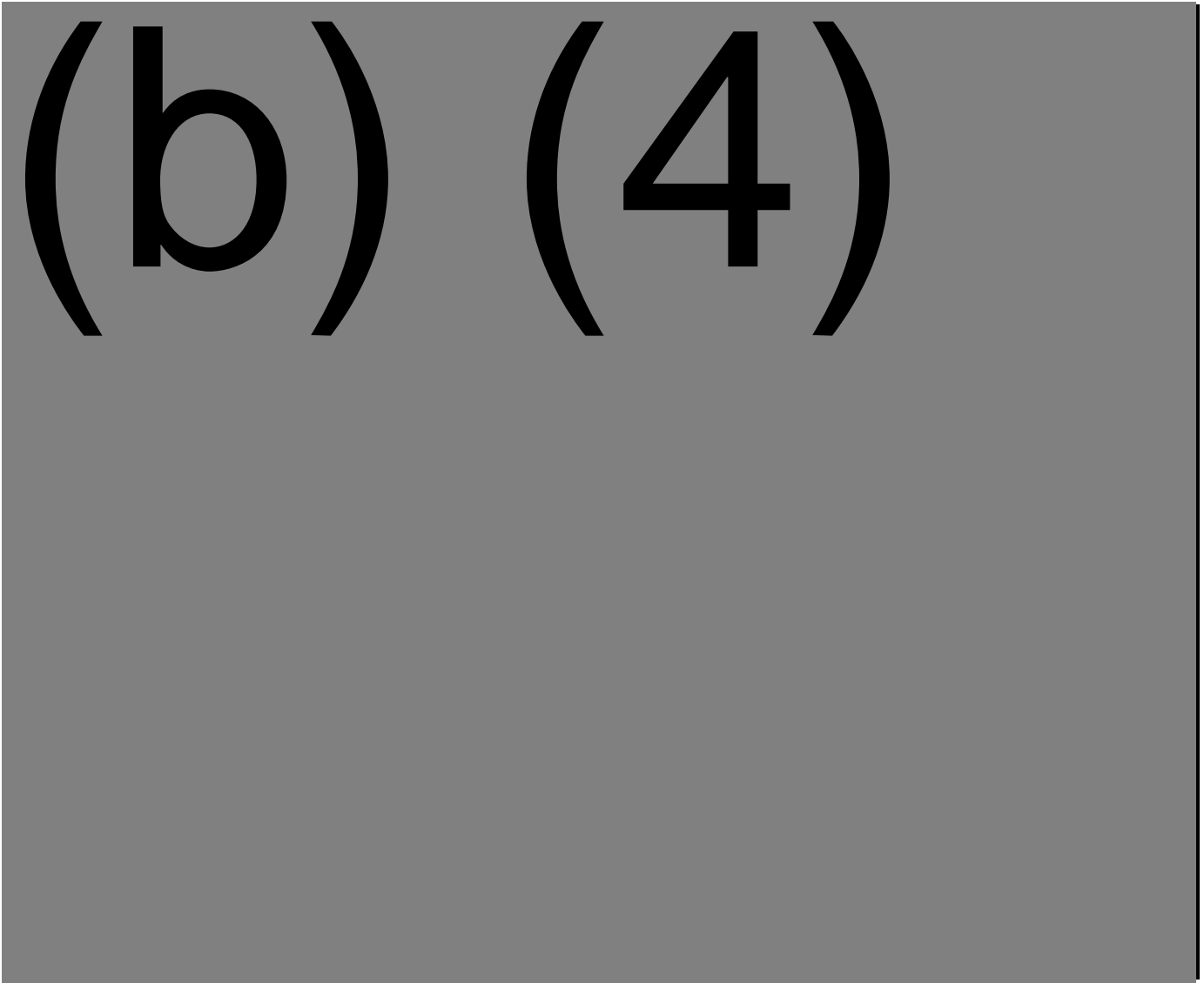
10. ATTACHMENTS

10.1. Attachment 1: Baseline Questionnaire

10.2. Attachment 2: Waves 2, 3, and 4 Questionnaires

10.3. Attachment 3: General Snus® Sticker

Below is an example of the invitation sticker that will be placed on the General Snus® package.



INVESTIGATOR SIGNATURE

I have read this protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.

I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure that they are fully informed regarding the conduct of the study and the obligations of confidentiality.

Investigator (Main Author):

Name (typed or printed):

Company:

Signature: _____

(b) (4), (b) (6)

Note: If the address or telephone number of the investigator changes during the course of the study, written notification will be provided by the investigator to SMU; a protocol amendment will not be required.

SPONSOR SIGNATURE

Sponsor:

Name (typed or printed):

Tryggve Ljung

Company:


Swedish Match

Signature: _____

Date: _____

(Day Month Year)

(b) (4), (b) (6)



(b) (4)

STATISTICAL ANALYSIS PLAN
General Snus® Patterns of Use
Protocol No. SMU 19-01GENS



Swedish Match USA, Inc.

Statistical Analysis Plan

General Snus® Patterns of Use Study

SMU 19-01GENS

Status: Approved
Date: 24 March 2020
Prepared by: **(b) (4)**

Confidentiality Statement

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Swedish Match USA, its parent and affiliate companies

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1. LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviations	Definition
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
FTP	File Transfer Protocol
HINTS	Health Information National Trends Survey
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
MTSS	Motivation To Stop Scale
PATH	Population Assessment of Tobacco and Health
PMTA	Premarket Tobacco Product Application
Respondents	Total sample which includes ZYN® users and ZYN® non-users
SAP	Statistical Analysis Plan
SAS®	Statistical Analysis System
SMNA	Swedish Match North America
SMU	Swedish Match USA, Inc.
TNP	Tobacco/Nicotine Product
U.S.	United States

2. RESPONSIBLE PARTIES

2.1 Investigator and Contributors

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(b) (4)

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3. STATISTICAL ANALYSIS PLAN (SAP) AMENDMENTS AND UPDATES

Number	Date	Section of SAP	Amendment or Update	Reason
...				

4. BACKGROUND AND RATIONALE

In 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law, giving the FDA the power to regulate the tobacco industry and establishing the Center for Tobacco Products (CTP) within the FDA. This law gives the CTP authority to regulate the marketing/advertising content and sale of tobacco/nicotine products^a (TNP). The FDA requires that the marketing of a new tobacco product be appropriate for the protection of the public health as determined “on the basis of well-controlled investigations” (Section 910).¹

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General Snus*®, a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General Snus*® a MRTP designation providing some guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on September 17, 2018 and the FDA granted the risk modification order on October 22, 2019. This proposed study is planned to be part of the post marketing surveillance following risk modification order.

The output of this research will be submitted to the FDA as part of the surveillance requirement of the MRTP order.

5. OBJECTIVES

The overarching research questions within this study are as follows: (i) *How do General Snus*® users use TNP, and (ii) *how do they perceive health risks associated with cigarettes and General Snus*®? These questions will be studied using a self-reported survey examining patterns of use for the previous 30 days (Baseline-Wave 1) and assessment of TNP use among the same *General Snus*® users again at 6 months (Wave 2), 1-year (Wave 3) and 2-year (Wave 4) intervals post Baseline.

5.1 Primary Objectives

Use behavior will be assessed, utilizing data from all 4 waves of the study:

1. Compare TNP patterns of use, between all 4 waves. The study will examine self-reported usage patterns for participants, in aggregate, over time. The study will report on frequency of use of *General Snus*® use, as well as other TNP, if multiple TNP use is reported. Of specific interest will be usage patterns of cigarettes. Intent to quit and actual quitting of cigarettes will be assessed at each wave of the study.
2. Among *General Snus*® users, compare consumption patterns of cigarettes and *General Snus*® over the last 30 days (Baseline) with consumption patterns in Waves 2 through 4.

Of particular interest is whether usage of *General Snus*® offsets usage of cigarettes.

^a “Tobacco/nicotine products” (TNP) refers to any combination of the following products: cigarettes, e-cigarettes, moist snuff, chewing tobacco, snus, nicotine pouches, cigars, cigarillos, and filtered cigars filled with tobacco, pipe tobacco, hookah and water pipe tobacco, and aids to help stop smoking. This list of tobacco/nicotine products defining TNP is based on the Population Assessment of Tobacco and Health.

3. Characterize *General Snus*® users, especially new users, in terms of prior TNP use and demographics.
4. Compare the tendencies of *General Snus*® users to quit cigarettes or use *General Snus*® in an incremental fashion, in a supplemental fashion, or in complete substitution of cigarettes.

5.2 Secondary Objectives

Risk Perception and understanding of the MRTP claim will be assessed utilizing data from all 4 Waves of the study:

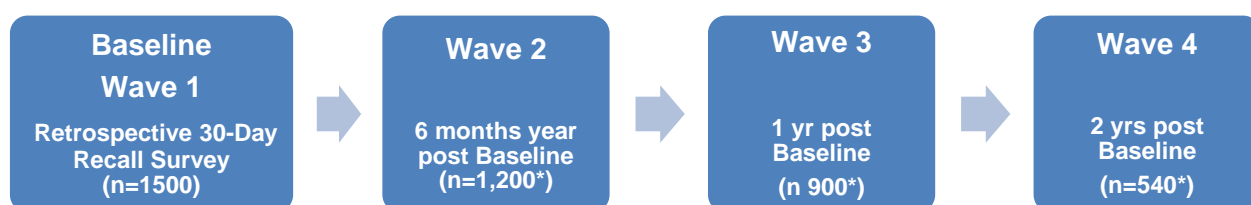
1. Assess perceptions of risk of certain health conditions (mouth cancer, heart disease and lung cancer, separately) among *General Snus*® users.
 - a. Assess the absolute risk attributed to using only *General Snus*® daily, smoking only cigarettes daily, dual use of *General Snus*® and cigarettes daily, and never having used any TNPs.
2. Assess the extent to which *General Snus*® users, especially new users, understand the risk reduction as described in the modified risk claim

6. OVERALL STUDY DESIGN

6.1 Study Design

The *General Snus*® Patterns of Use Study seeks to evaluate TNP patterns of use among *General Snus*® users through a Baseline Study focused on 30-day recall of TNP use, accompanied by follow up timepoints comprised of another 30-day recall period at 6-months, 1- and 2-year intervals after the Baseline timepoint.

Figure 1: Summary of Research Phases



**Study population is estimated for Waves 2, 3 and 4, based on [REDACTED] experience in implementing multiple wave longitudinal studies, coupled with enhanced retention strategies.*

For the Baseline Study and Waves 2 through 4, all participants who qualify and have signed the electronic Informed Consent form will access a web survey online via a computer, smartphone, or tablet. Each timepoint is a 15-20-minute survey where participants are asked to self-report TNP use history within the past 30 days. A 30-day recall period was selected based both upon review of the available tobacco and nicotine peer reviewed literature utilizing 30-day recall for understanding current and recent usage of TNP³ as well as applying the PATH methodology of asking consumers to recall specific TNP use in a 30-day period.³

Prior to launching the study in full, (b) (4) will quality check the survey. The primary objective of this quality check is to confirm that all facets of the data collection process function according to protocol; items of specific interest include the length of interview, and the accuracy of the web-based instrument (i.e., survey), all of which work to ensure the primary objectives of the research are met.

Participants who complete the survey will receive their honoraria in the form of reward points aligned to the fair market value assigned to the survey length. Respondents will receive compensation for each wave of the study they complete and an additional bonus compensation after completing the third wave of the study. At the completion of each wave of the study, *General Snus*® users will be reminded about the next wave of the study. Interim reminders between each wave will also be sent to each participant at 3-month intervals to reduce the attrition rate between surveys. Respondents' email and contact information will be validated to improve the recontact rate.

Due to the low incidence of *General Snus*® users among the general population, sample for this cohort will be recruited directly from purchasers of *General Snus*®. Study invitation stickers will be placed on product packaging (i.e. each individual canister) for all the flavors of *General Snus*®. The sticker initiative will target approximately 2,000 geographically distributed retail outlets where *General Snus*® is sold. Efforts will be made to ensure that stickers are distributed across all locations at the same time and that all *General Snus*® users will have the same chance to participate in this study. More information on recruitment of *General Snus*® users through the *General Snus*® invitation sticker initiative is available in the *General Snus*® Patterns of Use Study protocol.⁴

Participants in the *General Snus*® Patterns of Use Study will only be those who meet inclusion and exclusion criteria (explained in **Sections 6.2.1** and **6.2.2**). To enhance retention, participants who completed the Baseline survey will be allowed to participate in any of the subsequent waves, even if they fail to participate in one of the of the follow-up waves. All respondents who have completed a Baseline survey will be included in the final analyses regardless of whether they completed any follow-up waves.

6.2 Study Cohorts

The study sample consists of the adult population of U.S. states where *General Snus*® is available in retail outlets and who are at least 21 years old. To meet the objectives of the *General Snus*® Patterns of Use Study, the study will be conducted among legal age *General Snus*® users in the U.S. The Baseline survey will be administered to 1,500 U.S. consumers who meet all the study Inclusion Criteria. The definition of TNP use, and the product types constituting TNP for this study, were adapted from the Population Assessment of Tobacco and Health (PATH) study³. In the PATH study, a threshold of lifetime use is established for cigarette use, which is having smoked 100+ cigarettes in a lifetime and for all other TNP is based on recollection of ever using the TNP fairly regularly.³ Current use is based on now using the product every day or some days.³

6.2.1 Subject Selection: Inclusion Criteria

In addition to the already mentioned cohort definitions, respondents must meet all of the following criteria to be included in the study:

- Have used *General Snus*® at least once or more within past 30 days prior AND use it every day or some days prior to study initiation
- Minimum age of 21 years
- Agree to participate in four surveys over the two-year period
- Able to read and speak English
- Currently a resident of the United States
- Individuals who provide electronic informed consent and personal contact information

6.2.2 Subject Selection: Exclusion Criteria

Respondents who meet any of the following criteria will be excluded from the study:

- Respond as “don’t know” or “decline to answer” to specific demographics (gender, geographical region)
- Unwilling or unable to provide electronic informed consent and personal contact information
- Employed in any of the following fields or professions: market research, marketing, advertising, manufacturers of TNP, or physicians
- Have taken part in a consumer research study on tobacco in the past 2 weeks

6.3 Study Sample Size

The Baseline study will have a total sample of $n=1,500$ participants. Each participant who participates in the Baseline study will agree to participate in the subsequent waves. Respondents who complete the Baseline study may participate in any of the subsequent waves. Based on Kantar’s prior experience with longitudinal consumer studies of these types, it is anticipated that there would be a 40% drop out rate each year, resulting an estimated sample of $n=1200$ participants in Wave 2, $n=900$ participants in Wave 3 and $n=540$ participants in Wave 4. A precision analysis was performed based on the following assumptions: a confidence interval of 95% ($\alpha=.05$) and a small interval half width for one sample proportion. The precision analysis suggested that a sample size of 540 per group would have a probability of at least 0.80 for proportions ranging from 0.10 through 0.90 and a half-width of 0.05.

6.4 Variables of Relevance to the Study

6.4.1 Outcomes

Primary Objectives

Outcomes that will be used to evaluate the primary objectives are as follows:

Reported use in the last 30 days will be assessed by using one item observing **frequency** of use for cigarettes, General Snus® and other TNP used over the last 30 days. The item is based on the approach

employed in PATH for observing current TNP use.⁴ Response options for frequency of use include “Every day,” “Some Days,” “Not at All,” and “Don’t know”.

Self-reported consumption for both cigarettes and *General Snus*® will be assessed with questions regarding daily use in each wave of the survey. Examples of reported *General Snus*® consumption survey questions can be found in the *General Snus*® Pattern of Use Study protocol.³ Similar consumption questions will be asked of those who also reported using cigarettes in the previous 30 days.

Average number of *General Snus*® pouches used per day for everyday users will be assessed using one item asked of participants who report using *General Snus*® every day. The item will report the number of *General Snus*® pouches used each day. This item is based on the approach employed in PATH for observing TNP use³.

Average number of *General Snus*® pouches used per day for somedays users will be assessed using two items asked of participants who report using *General Snus*® some days. One item will report the number of days *General Snus*® pouches was used. The second item will report the number of *General Snus*® pouches used on each of those days. These items are based on the approach employed in PATH for observing TNP use³.

Average Percent of days *General Snus*® is used in aggregate will be derived based on the item in the survey assessing *General Snus*® usage in everyday users and the items assessing *General Snus*® in the some day users.

Intention to quit cigarettes will be assessed at each wave using the Motivation to Stop Scale (MTSS).⁵ The MTSS consists of one item with seven response options ranging from 1 (lowest) to 7 (highest level of motivation to stop smoking), also including “Don’t know.” Scale developers found that odds of quit attempts increased linearly with increasing levels of motivation. In the current study, we use the MTSS both for assessing intention to quit cigarettes and for other TNPs. Consistent with published research using the MTSS, we will report the mean MTSS score.⁶ The MTSS was selected for use in the *General Snus*® Patterns of Use Study due to its brevity and validation as a strong and accurate predictor of quit attempts.

Quitting behaviors for cigarettes will be assessed at each wave of the research with items assessing past and current quitting and for those who have not or are not currently trying to quit, by assessing intention to quit. Respondents who have not quit using cigarettes in the past 30 days, will be asked if they are currently trying to quit. **Currently trying to quit** will be assessed using one item asking “Are you currently trying to quit smoking cigarettes with “yes” or “no” response options

Secondary Objectives

Outcomes that will be used to evaluate the secondary objectives are as follows:

Perceptions of absolute risk will be assessed using a single-choice scale (5-point Likert scale, fully anchored; from 1= Very low chance to 5= Very high chance, also including “Don’t know” and “Decline to answer”) for each of three health conditions (mouth cancer, heart disease, and lung cancer). This scale was modified from the risk perception scale in HINTS.⁷

Understanding of the MRTP claim will be assessed using two items to determine risk perception relative to cigarettes and the elements stated in the claim. The first item is whether there is correct understanding of the claim for using *General Snus*® instead of cigarettes. Response options include *General Snus*® “puts you at lower risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis”, “Does not affect your risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis”, “Puts you at higher risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis”, “None of the above,” “Don’t know” and “Decline to answer.”

The second item is whether there is correct understanding on the number of cigarettes smoked per day to lower the risk of diseases. Response options are zero, up to 5, or up to 20 cigarettes, “As many as you want to smoke”, “Don’t know” and “Decline to answer.”

Summaries of the outcomes for primary and secondary objectives, including measurement domain, subcategories, measurement details, and metrics, are presented in **Tables 1-4, 5-6**, respectively.

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Table 3. Outcomes Table for Primary Objective 3 – *TBD*

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6.4.2 Respondent Characteristics

Socio-demographic Variables

State of residence, which will be assessed using a single item asking the respondent what state they spend most days of the year in.

Age of the respondent will be assessed using a single item asking the respondent how many years old they are. Age of respondent will be categorized for reporting using the following age groups: 21-24, 25-34, 35-44, 45-54, and 55+ years old.

Gender will be assessed using a single item asking the respondent if they are male or female. Decline to answer is also an option.

Racial or ethnic background will be assessed using a single item asking the respondent which best describes their racial/ethnic background. Response options include: Caucasian/White, Black/African American, Hispanic (e.g., Latin American, Mexican, Puerto Rican, Cuban), Asian or Pacific Islander, Native American or Alaskan native, mixed racial background, other, don't know, and decline to answer.

Highest grade or level of school completed will be assessed using a single item asking the respondent which response corresponds to the highest level of education they have attained. Response options include: Less than high school, some high school – no diploma, General Educational Development (GED), high school graduate – diploma, some college but no degree, Associate degree, Bachelor's degree (e.g., BA, AB, BS), Post-graduate degree (e.g., MBA, PhD, JD, etc.), don't know, and decline to answer.

Marital Status will be assessed using a single item asking the respondent their marital status. Response options include: Now married, widowed, divorced, separated, never married, and decline to answer.

Household income in the last 12 months will be assessed using a single item asking respondents which category best describes their total household income in the last 12 months. Response options include: Less than \$10,000, \$10,000 to \$14,999, \$15,000 to \$24,999, \$25,000 to \$34,999, \$35,000 to \$49,999, \$50,000 to \$74,999, \$75,000 to \$99,999, \$100,000 to \$199,999, \$200,000 or more, don't know, and decline to answer.

6.5 Time Points of Importance

Time time points of importance in the Prospective Study include the 30 day period for Baseline (Wave 1), Month 6 (Wave 2), Year 1 (Wave 3) and Year 2 (Wave 4).

7. STATISTICAL ANALYSIS

7.1 Presentation of Analysis Results

Numerical data will be presented by the total N-size, missing values (where applicable), mean, standard deviation (SD), median, minimums, and maximums. Numeric data, if reported as such, will be displayed to 2 decimal places. Otherwise, numeric data will be grouped into ranges and summarized by frequencies and percentages. Categorical data will be presented using frequencies (counts) and percentages; the number of missing values will also be presented (if applicable). Percentages will be displayed to 1 decimal place and counts with zero decimal places.

7.2 Study Analysis

All analyses performed for the *General Snus®* Patterns of Use Study will include descriptive analysis and inferential statistical testing of changes in over time, across waves of the study.

Descriptive Analysis

Descriptive statistics used to understand the distribution of socio-demographic and outcomes variables (see **Sections 6.4.1** and **6.4.2**) will be based on the raw data (i.e., prior to any recoding or any aggregation required for the final presentation of results). Respondents with values for variables that are illogical or deemed unreliable, as determined by the underlying distribution, will be considered for removal prior to performing the main analyses. (See **Section 8.2** and **8.3** for details regarding this process). Numeric variables will be described using total sample size, number of missing observations (if applicable), means, standard deviations, medians, minimums, and maximums. Categorical variables will be described using frequencies, percentages, and the number of missing observations (if applicable).

Unless otherwise specified in the table shells (**Section 10**), descriptive statistics reported for the main analyses will include the number of non-missing observations, means, standard deviations, and 95% confidence intervals (CIs), for numeric variables. For categorical variables it will include the number of non-missing observations, frequencies, percentages, and 95% CIs for the percentage of respondents endorsing each category.

Inferential Statistical Testing

Inferential statistical testing will be conducted to evaluate change in primary and secondary outcome measures (i.e., patterns of use, risk perception, understanding of claim) from baseline and each follow-up wave of the study. Baseline vs. each follow-up (waves 2, 3, and 4) will be conducted using paired sample t-tests for continuous variables and McNemar test for categorical variables in order to account for correlated measures. These inferential statistical comparisons will reveal whether changes are occurring across the waves of the study within individuals. For paired sample t-tests, means (baseline and follow-up), standard deviations (baseline and follow-up), t-test statistic, degrees of freedom, and p-value will be reported. For McNemar tests, proportions in percentages (baseline and follow-up) and p-values will be reported. Any two-sided p-values of less than 0.05 will be considered to be statistically significant.

The study team will format and properly label the data sets (including all responses from respondents and the date that the survey was completed) using SAS® software (Statistical Analysis System, version 9.3)⁸ so they are suitable for analysis. The data sets will contain a subject ID number and will not contain any information that could be used to identify individual respondents.

7.3 Socio-demographic Characteristics

Descriptive statistics will be reported for all socio-demographic variables outlined in **Section 6.5.2**. Specifically, state of residence, age of respondent, gender, racial or ethnic background, highest grade or level of school completed, marital status, and household income in the last 12 months, will be reported for the *General Snus*® users. **Table 13** presents a table shell showing how descriptive statistics for socio-demographic variables will be reported.

7.4 Primary Objectives

Descriptive statistics for accomplishing primary objectives will be reported for patterns of TNP use (for *General Snus*® users) at Baseline, Month 6, Year 1, and Year 2. Descriptive statistics will include the number of non-missing observations, frequencies, percentages, and 95% CIs for the percentage of respondents endorsing each category for categorical variables. Inferential statistical testing will also be conducted. **Tables 7 to 10** below provide summaries of the analyses that will be used to accomplish the primary objectives, including the objective, outcomes, cohorts, and the statistical analysis. **Tables 14 to 21** present table shells for reporting the descriptive results.

7.5 Secondary Objectives

Descriptive statistics for accomplishing secondary objectives utilizing data from Baseline, Month 6, Year 1, and Year 2 will be reported for perceptions of absolute risk and understanding of the MRTP claim. Descriptive statistics will include the number of non-missing observations, frequencies, percentages, and 95% CIs for the percentage of respondents endorsing each category, for categorical variables. Inferential statistical testing will also be conducted. **Tables 11 to 12** below provide summaries of the analyses that will be used to accomplish the secondary objectives, including the objective, outcomes, cohorts, and the statistical analysis. **Tables 22 to 24** present tables shells for reporting the descriptive results.

Table 7. Analysis Table for Primary Objective 1 – TNP patterns of use among *General Snus®* users

Objective	Outcomes	Cohorts	Statistical Analysis
Specifically, assess the use of:	Patterns of use: Reported use at Baseline, Month 6, Year 1, Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each TNP use. Within-individual change from baseline to each follow-up wave will be examined using McNemar's test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Cigarettes			
E-cigarettes			
Moist snuff			
Chewing tobacco			
<i>General Snus®</i>			
Nicotine pouches			
Cigars, cigarillos or filtered cigars filled with tobacco			
Pipe tobacco			
Hookah or water pipe tobacco			
Aids to help stop smoking			
Specifically, assess intention to quit:	Patterns of use: Intention to quit (Motivation to Stop Scale ⁵ mean scores) at Baseline	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, means, standard deviations, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Cigarettes	Patterns of use: Quitting behavior over the past 30 days and currently at Baseline, Month 6, Year 1, Year 2		

Table 8. Analysis Table for Primary Objective 2 – General Snus® and cigarettes pattern of use

Objective	Outcomes	Cohorts	Statistical Analysis
Specifically, assess pattern usage for:			
General Snus®	Average number of <i>General Snus®</i> pouches used <u>everyday</u> over the past 30 days at Baseline and Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, means, standard deviations, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
	Average number of <i>General Snus®</i> pouches used on <u>some days</u> over the past 30 days at Baseline and Month 6, Year 1, and Year 2		
	Percent of days that <i>General Snus®</i> is used <u>everyday</u>		
Cigarettes	Average number of cigarettes smoked <u>everyday</u> over the past 30 days at Baseline and Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, means, standard deviations, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
	Average number of cigarettes smoked on <u>some days</u> over the past 30 days at Baseline and Month 6, Year 1, and Year 2		
	Percent of days that cigarettes are smoked <u>everyday</u>		

Table 9. Analysis Table for Primary Objective 4 – Supplemental, incremental, complete substitution of *General Snus®* in place of cigarettes, and quitting cigarettes.

Objective	Outcomes	Cohorts	Statistical Analysis
Specifically, assess incremental TNP usage for:	Average daily reported cigarettes smoked at Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, means, standard deviations, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Cigarettes			
Specifically, assess supplemental TNP usage for:	Average daily reported cigarettes smoked at Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, means, standard deviations, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Cigarettes			
Specifically, assess complete substitution of cigarettes for <i>General Snus®</i>	Complete substitution of cigarettes for <i>General Snus®</i> at Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less

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			than 0.05 will be considered statistically significant.
Specifically, assess quitting cigarettes usage.	Quitting cigarettes based on reports of quitting cigarettes completely at Month 6, Year 1, and Year 2	General Snus® users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.

Table 10. Analysis Table for Secondary Objective 1 – Perceptions of absolute risk.

Objective	Outcomes	Cohorts	Statistical Analysis
Specifically, assess perceived absolute risk attributed using <i>General Snus</i>® daily but using no other TNPs for:	Absolute risk attributed to using <i>General Snus</i> ® daily at Baseline, Month 6, Year 1, and Year 2	<i>General Snus</i> ® users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each health condition. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Mouth cancer			
Heart disease			
Lung cancer			
Specifically, assess perceived absolute risk attributed to smoking only cigarettes daily but using no other TNPs for:	Absolute risk attributed to smoking only cigarettes daily at Baseline, Month 6, Year 1, and Year 2	<i>General Snus</i> ® users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each health condition. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Mouth cancer			
Heart disease			
Lung cancer			
Specifically, assess perceived absolute risk attributed to dual use of <i>General Snus</i>® and to smoking cigarettes daily but using no other TNPs	Absolute risk attributed to dual use of <i>General Snus</i> ® and to smoking cigarettes daily at Baseline, Month 6, Year 1, and Year 2	<i>General Snus</i> ® users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each health condition. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Mouth cancer			
Heart disease			
Lung cancer			

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Specifically, assess perceived absolute risk attributed to never having used any TNPs for:	Absolute risk attributed to never having used any TNPs at Baseline, Month 6, Year 1, and Year 2	<i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each health condition. Within-individual change from baseline to each follow-up wave will be examined using paired-sample t-test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Mouth cancer			
Heart disease			
Lung cancer			

Table 11. Analysis Table for Secondary Objective 2 – Understanding of the MRTP claim for *General Snus®*

Objective	Outcomes	Cohorts	Statistical Analysis
Specifically, assess whether respondents understand the MRTP claim for risk of disease from using <i>General Snus®</i> instead of cigarettes:	Understanding of the MRTP claim at Baseline, Month 6, Year 1, and Year 2	1) <i>General Snus®</i> users 2) New <i>General Snus®</i> users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each TNP used at the time of retrospective survey administration. Within-individual change from baseline to each follow-up wave will be examined using McNemar's test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Puts them at lower risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis			
Does not affect their risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis			
Puts them at higher risk for mouth cancer, heart disease, lung cancer, stoke, emphysema, and chronic bronchitis			
None of the above			
Don't Know			

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STATISTICAL ANALYSIS PLAN

General Snus® Patterns of Use

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Decline to answer			
Specifically, assess whether respondents understand the MRTP claim for number of cigarettes smoked to lower risk of disease:	Understanding of the MRTP claim at Baseline, Month 6, Year 1, and Year 2	1) <i>General</i> Snus® users 2) New <i>General</i> Snus® users	Descriptive statistics will be reported: number of non-missing observations, percentages, frequencies, and 95% confidence intervals for each TNP used at the time of retrospective survey administration. Within-individual change from baseline to each follow-up wave will be examined using McNemar's test. Two-sided p-value of less than 0.05 will be considered statistically significant.
Zero cigarettes			
Up to 5 cigarettes			
Up to 20 cigarettes			
As many as you want to smoke			
Don't Know			

8. STATISTICAL AND ANALYTICAL ISSUES

8.1 Data Capture and Management

8.1.1 Data Capture

The web-based survey will be created by the (b) (4) programming team using (b) (4) for web-based survey programming (v117, Fresno, CA). After the survey has been programmed and tested, the survey link and content will be reviewed by a separate team within (b) (4) fielding operations group from the perspective of the respondent (i.e. the link is reviewed online and not within the (b) (4)).

The data collected for this study will be monitored for adherence with the Study Protocol³. All data will be collected using a programmed web survey.⁹ Prior to initiating the study, appropriate edit programming will be conducted to assure the final dataset requires minimal cleaning of invalid responses. These programming procedures for the web-based survey data entry tool will include response ranges, consistency checks, skip patterns, and other special edit procedures where applicable. At every step of data processing, results or creating grouping variables will be cross-checked by (b) (4) Health operations team members who independently replicate the results and/or verify that the data have been handled appropriately and accurately. Any inconsistencies identified during this process are corrected before data are provided to (b) (4) analytical team to begin study analysis.

8.1.2 Data Management and Analysis QC Process

- Until the approval of the *General Snus®* Patterns of Use SAP by SMNA, the data will remain blinded and locked.
- Once data are unlocked, the analytical team will perform the following checks prior to conducting data analyses specified in the SAP:
 - The classification of participants into the study cohorts based on self-reported use or non-use of TNP will be confirmed.
 - Completion of the survey will be verified, and any respondent who did not complete the full survey will be removed from analysis.
 - It will be verified that respondents satisfied the inclusion and exclusion criteria.
 - The actual quota frequencies for each study cohort in the data set will be compared against the quota frequencies specified in the Study Protocol. Any discrepancies will be documented in the final report.
- All variable coding will follow as specified in the SAP (e.g., grouping age by age brackets, and total household income in the last 12 months).
- All statistical analyses and results output will be validated by another researcher on the analytical team for quality control. Validation will cover:
 - Correct coding of variables;
 - Correct use of statistical methods as specified in the analysis section;

- Correct export of results from SAS® output to Excel tables.

8.2 Handling of Missing Data

The structure of the Study questionnaire does not have “true” missing data. The online survey does not allow respondents to proceed without receiving an answer to the present question. No partially completed surveys will be included in the final Study analyses. For the Study, data points are either missing because the respondent selected “Don’t know” or “Decline to answer,” or they did not qualify to answer the question due to survey skip logic. Thus, these types of missing data will be kept as is and will be reported descriptively (percentages and counts). The questionnaire was designed (and tested through cognitive interviewing) so that instructions are as easy to understand and as clear as possible, to help avoid missing data.

The Baseline period questionnaire do not allow respondents to proceed without answering the present question. Hence, missing observations for completed surveys arise because the respondent selected “Don’t know” or “Decline to answer,” or s/he did not qualify to answer the question due to prior answers. No modifications will take place in these instances.

However, missing data in the Month 6, Year 1 and Year 2 periods can also arise from incomplete surveys. Study participants can remain in the study while failing to complete follow-up surveys per Month 6, Year 1, and Year 2 periods. Data will be absent in those situations, i.e. the investigator will not impute values. Daily TNP patterns of use outcomes, such as average daily use for cigarettes or *General Snus*® use for a respondent over a 30 day period, will be calculated based on the number of non-missing entries. Specifically, if 15 entries are available for a respondent in a given 30 day period, then the respondent’s average daily use for each TNP will be based on the average of the 15 available entries. Likewise, if 20 entries are available for a respondent in a given 30 day period, then the respondent’s average daily use for each TNP will be based on the average of the 20 available entries.

The rationale and utilization of “Don’t know” and “Decline to answer” response options are as follows:

- In this study, a “Decline to answer” response option without a “Don’t Know” option will be provided for any question where there is personally sensitive information, but the answer would be known to the respondent (e.g., age, gender, etc.).
- “Don’t know” and “Decline to answer” options will be provided for all other questions.

8.3 Identification of Outliers

- When conducting online research, invariably some respondents will find a way to complete the survey without attempting to provide accurate, relevant responses. To ensure that those respondents do not compromise the integrity of the data, measures are taken to eliminate their data from consideration prior to actual analyses. This process requires objectivity and removes respondent data regardless of directionality. The process will seek to identify the following respondent types:
 - Respondents who are “speeders”, defined as those who complete the survey in under 2 minutes.

- Respondents who were found to be inattentive. Specifically, we included an item at the end of the survey (Section C [demographics]) to serve as an *attention check*, “*For this question, please select number two to demonstrate your attention.*”
- Data from these respondents will be flagged in the data file. Additionally, the number of respondents flagged and the rationale for their identification as outliers will be reported in the final report.
- Sensitivity analyses will be conducted for every outcome with the outliers removed. The results of the sensitivity analyses will be reported as to whether the exclusion of the outliers changed the descriptive results in a substantive way.

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11. ATTACHMENTS

General Snus[®] Patterns of Use Study Protocol – January 28, 2020.

General Snus[®] Patterns of Use Study Baseline Survey (Wave 1) – January 28, 2020.

General Snus[®] Patterns of Use Study Month 6 (Wave 2), Year 1 Wave 3), Year 2 (Wave 4) Surveys – January 28, 2020

-LAST PAGE-



General Snus[®] Patterns of Use Study

Wave 4 Technical Report – Final

Swedish Match North America Protocol Number: SMU 19-01 GENS

(b) (4)

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Vendor	(b) (4)
Document Version Date Finalized	Version 1.0 04 November 2022
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SIGNATURES OF RESPONSIBLE PARTIES

SWEDISH MATCH NORTH AMERICA

(b) (6)



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Signing Reason: I approve this document
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09-Nov-2022

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(b) (4), (b) (6)

04-Nov-2022

Date Signed

07-Nov-2022

Date Signed

EXECUTIVE SUMMARY

General Snus[®] was used in the P30D by 87.3% (n=394) of those returning at Wave 4

- The pattern of *General Snus*[®] use **significantly differed** from Baseline ($p < 0.0001$) due to the proportion of respondents who had switched from every day to some day use by Wave 4

Every day *General Snus*[®] users used more pouches on days used than some day users (10.4 pouches/day vs. 6.7 pouches/day)

- Some day *General Snus*[®] users reported using the product an average of 13.1 days in the P30D, which **did not significantly differ** from that reported at Baseline ($p = 0.8367$)

Among returning *General Snus*[®] users at Wave 4, only 13.9% (n=63) reported smoking at Baseline and 13.5% (n=61) reported at Wave 4, which **did not significantly differ** ($p = 0.6232$)

Respondents correctly perceived that cigarette smoking contributed significant risks to health, associating it with moderate to very high chances of developing mouth cancer (78.5%, n=354), heart disease (93.8%, n=423), lung cancer (92.5%, n=417).

- Dual use of *General Snus*[®] and cigarettes was generally perceived as being just as risky to health as use of only cigarettes, suggesting that respondents understand that any use of cigarettes is associated with high risks to health
- Use of *General Snus*[®] was perceived as being less risky to health than cigarette smoking but that use of *General Snus*[®] was not without risks to health.

Respondents understood the MRTP claim that using *General Snus*[®] instead of cigarettes puts users at a lower risk for various diseases compared to cigarette smoking

- 77.8% (n=351) of respondents correctly endorsed that use of *General Snus*[®] presented less risk to health than cigarette smoking
- Most respondents who correctly endorsed that use of *General Snus*[®] presented less risk to health than cigarette smoking understood that no cigarettes can be smoked while using *General Snus*[®] to benefit from it being lower risk (79.8%, n=280)
- Results suggest that *General Snus*[®] users are aware of the need to completely substitute cigarettes for *General Snus*[®]

(b) (4)

DOCUMENT HISTORY

Document Version	Document Status	Version Date	Reason for and Description of Change	Changed By
v0.1	Draft	24OCT2022	Document created	EM
		25OCT2022	Edits to text, tables, formatting	EM, CN
		26OCT2022	Draft document shared with SMNA	EM
		03NOV2022	Draft document approved by SMNA	———
v1.0	Final	04NOV2022	Finalized and routed for signatures	EM

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LIST OF ABBREVIATIONS

Abbreviation	Definition
FDA	FDA Food and Drug Administration
MRTP	Modified Risk Tobacco Product
MRTPA	Modified Risk Tobacco Product Application
P30D	Past 30 Days
PATH	Population Assessment of Tobacco and Health
PMTA	Premarket Tobacco Product Application
SAP	Statistical Analysis Plan
SMNA	Swedish Match North America, LLC
TNP	Tobacco/Nicotine Product(s)
U.S.	United States

1. BACKGROUND & RATIONALE

In November 2015, Swedish Match USA, Inc. (SMU) received market authorization for *General Snus*[®], a moist tobacco product placed under the upper lip that does not involve spitting or chewing. In its first applications reviewed through the MRTP pathway, the FDA deferred final action on providing *General Snus*[®] a MRTP designation, providing guidance on how SMU could amend their application to provide greater support for a modified risk designation. SMU filed its amended MRTPA on 17 September 2018, and the FDA granted the risk modification order on 22 October 2019. The *General Snus*[®] Patterns of Use Study (the study) is for post-marketing surveillance reporting following the granted risk modification order.

2. STUDY OBJECTIVES

The overarching research questions for this study were the following:

1. How do *General Snus*[®] users use tobacco and nicotine products (TNP)?
2. How do *General Snus*[®] users perceive health risks associated with cigarettes and *General Snus*[®]?

These questions were studied using a self-reported survey examining patterns of past-30-day (P30D) TNP use among *General Snus*[®] users in a Baseline assessment (Wave 1) and again, among the same *General Snus*[®] users, at 6 months (Wave 2), 1 year (Wave 3) and 2 years (Wave 4) after Baseline.

2.1 PRIMARY OBJECTIVES

The primary objectives of the study were the following:

1. Compare patterns of TNP use between all 4 study waves by examining self-reported TNP use for participants, in aggregate, over time.
 - The study will report on frequency of use of *General Snus*[®] use, as well as other TNP, if multiple TNP use is reported. Of specific interest were patterns cigarette use.
 - Intent to quit and actual quitting of cigarettes was assessed at each wave of the study.
2. Among *General Snus*[®] users, compare consumption patterns of cigarettes and *General Snus*[®] in the P30D at Baseline with consumption patterns for both products at Wave 2 through Wave 4.
 - Of specific interest was whether use of *General Snus*[®] offsets use of cigarettes.
3. Characterize *General Snus*[®] users, especially new *General Snus*[®] users, in terms of prior TNP use and demographic characteristics and compare these findings to new users of smokeless TNP as reported in the Population Assessment of Tobacco and Health Study.
4. Compare the tendencies of *General Snus*[®] users to quit cigarettes or use *General Snus*[®] in an incremental fashion, in a supplemental fashion, or in complete substitution of cigarettes.

2.2 SECONDARY OBJECTIVES

The secondary objectives of the study were the following:

1. Assess perceptions of risk of certain health conditions (mouth cancer, heart disease and lung cancer, separately) among *General Snus*[®] users.
 - Asses the absolute risk attributed to using only *General Snus*[®] daily, smoking only cigarettes daily, dual use of *General Snus*[®] and cigarettes daily, and never having used any TNP.
2. Assess the extent to which *General Snus*[®] users, especially new users, understand the risk reduction as described in the modified risk claim

3. OVERVIEW OF RESEARCH METHODS

General Snus[®] users were recruited directly via invitation stickers placed directly on *General Snus*[®] tins. A third-party vendor (News America Marketing) was hired to place the study invitation stickers on product packaging (e.g., each individual *General Snus*[®] tins) for all varieties of *General Snus*[®] available at retail outlets. This took place from 25 July 2020 to 17 August 2020. The sticker initiative targeted approximately 10,600 retail stores carrying *General Snus*[®] across all locations where *General Snus*[®] was sold. The sticker presented a website where *General Snus*[®] users that were interested in participating could access the Baseline survey through a secure and unique survey link.

The first set of questions were used to screen potential respondents and were designed to qualify the respondent using the study inclusion and exclusion criteria. Once qualified, respondents were directed to the online survey. Respondents were asked to self-report TNP use within the P30D and various questions related to TNP use, risk perceptions, and understanding of the modified risk messaging for *General Snus*[®] products.

The study was a longitudinal, prospective assessment consisting of multiple survey waves to gain an understanding of how *General Snus*[®] and other TNP are used by the participating respondents. Respondents completed an initial survey at Baseline (Wave 1) and had the opportunity to participate again at 6 months (Wave 2), 1 year (Wave 3), and 2 years (Wave 4) from Baseline. All respondents at Baseline must have reported use of *General Snus*[®] at least once in the P30D and reported use every day (daily) or on some days (non-daily).

Full details of all research methods and study procedures can be found in the *General Snus*[®] Patterns of Use Study – Study Protocol.

3.1 INCLUSION CRITERIA

Respondents had to meet each of the following criteria to be included in the study:

1. Have used *General Snus*® at least once or more within the P30D and use it every day or on some days
2. Minimum age of 21 years
3. Agree to participate in four surveys over the 24-month period
4. Able to read and speak English
5. Currently a resident of the United States
6. Agreeing to provide informed consent and personal contact information

3.2 EXCLUSION CRITERIA

Respondents who met of the following criteria were excluded from the study:

1. Responded “don’t know” or “decline to answer” to questions asking their gender and geographic region
2. Unwilling or unable to provide electronic informed consent and personal contact information
3. Employed in any of the following fields or professions: market research, marketing, advertising, TNP manufacturing, or employed as a physician
4. Participated in a consumer research study on TNP in the 2 weeks prior to the Baseline survey

4. OVERVIEW OF ANALYSIS METHODS

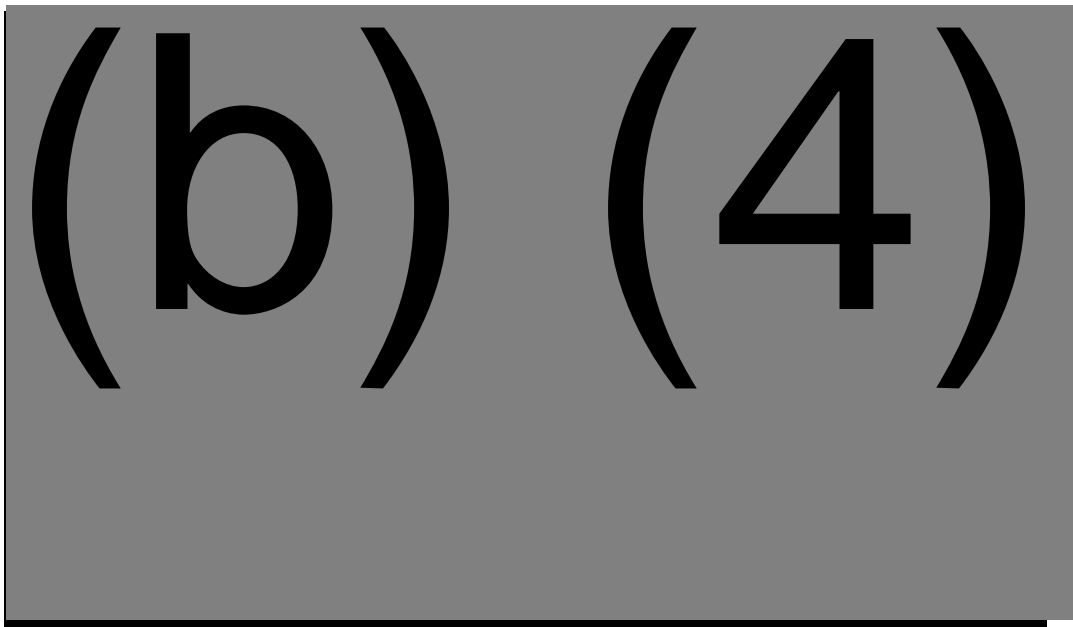
All analyses conducted were either descriptive or inferential. Descriptive analyses provided summary statistics for all variables. These statistics included counts and proportions for categorical variables and means, standard deviations, medians, minimums, and maximums for ordinal and continuous variables. Inferential statistical testing was conducted to evaluate changes in primary and secondary outcome measures (i.e., patterns of use, risk perceptions, understanding of claims) from baseline and each follow-up wave. Results comparing baseline data versus data from each follow-up wave was conducted using paired sample t-tests for continuous variables and McNemar tests for categorical variables.

5. WAVE 4 FIELDING SUMMARY

5.1 STUDY FIELDING SUMMARY

The fielding summary for number of respondents that entered the Wave 4 survey, those that did not complete the survey, those that were terminated (and the reasons for termination) are summarized below in [Table 1](#).

Table 1: Fielding Summary for the Wave 4 Survey



6. WAVE 4 STUDY RESULTS

6.1 DEMOGRAPHIC CHARACTERISTICS OF RESPONDENTS AT WAVE 4

The demographic characteristics of *General Snus*[®] users and the subset of new *General Snus*[®] users that returned for Wave 4 are summarized in [Table 2](#). Results represent data collected at Wave 4 as these demographic characteristics may have changed over the course of the study. Only results for the overall group of *General Snus*[®] users is discussed here given the small sample size. Findings for the subset of new *General Snus*[®] users can be found below in [Table 2](#).

Most respondents that returned for Wave 4 lived in the South (36.1%; n=163), while the least number of respondents lived in the Northeast (13.1%, n=59). Nearly all respondents were male (93.8%, n=423). The mean age of *General Snus*[®] users that returned for Wave 4 was 39.4 years (median: 38.0 years; range: 24.0 to 79.0 years). Most respondents were currently married (56.5%, n=255). There was a considerable number of respondents with high household incomes, as 42.8% (n=193) reported that they earned \$100,000 or more in the past 12 months.

Table 2: Demographic Characteristics of *General Snus*® Users and New *General Snus*® Users Who Returned for Wave 4

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6.2 WAVE 4 RESULTS FOR PRIMARY OBJECTIVES

6.2.1 TNP USE IN THE PAST 30 DAYS AT WAVE 4

Patterns of TNP use in the past 30 days (P30D) among all Wave 4 respondents are presented in [Table 3](#) below. At Baseline, TNP use in the P30D was asked to respondents that indicated they had ever regularly used any of eleven categories of TNP, including *General Snus*[®], and for those TNP to which they responded, “Don't know.” At Wave 4, TNP use in the P30D was asked to all respondents for the same eleven categories of TNP.

Among *General Snus*[®] users who returned for Wave 4, 87.3% (n=394) reported using *General Snus*[®] in the P30D, with 60.5% (n=273) using every day and 26.8% (n=121) using on some days. Some respondents that had regularly used *General Snus*[®] at Baseline had quit use of the product by Wave 4 (12.2%, n=55). The change in patterns of use for *General Snus*[®] from Baseline to Wave 4 **was significantly significant** ($p<0.0001$) given the differences in proportion of *General Snus*[®] users who used every day vs. some days at Wave 4 than at Baseline.

[Table 3](#) also presents P30D use for other categories of TNP among *General Snus*[®] users who returned for Wave 4. Only 13.5% (n=61) reported P30D cigarette smoking, with 4.7% (n=21) reporting smoking cigarettes every day and 8.9% (n=40) reporting smoking cigarettes on some days. Prevalence of P30D cigarette smoking among *General Snus*[®] users at Wave 4 **did not significantly differ** from prevalence of P30D cigarette smoking at Baseline ($p=0.6232$).

Prevalence of P30D use of nicotine pouches **significantly increased** among *General Snus*[®] users between Baseline and Wave 4 ($p<0.0001$) – 42.7% of *General Snus*[®] users reported using of nicotine pouches at Wave 4 (n=193), with 18.0% (n=81) reporting use every day and 24.8% (n=112) reporting use on some days. Additionally, the number of *General Snus*[®] users reporting use of aids to help stop smoking cigarettes also **significantly increased** between Baseline and Wave 4 ($p=0.0050$) – 6.7% (n=30) of *General Snus*[®] users reported P30D use of aids to help stop smoking cigarettes, with 2.7% (n=12) reporting use every day and 4.0% (n=18) reporting use on some days.

Table 3: TNP Use in the Past 30 Days at Wave 4

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6.2.2 TNP USE IN THE PAST 30 DAYS AT WAVE 4 AMONG RESPONDENTS WHO QUIT USING *GENERAL SNUS*[®]

TNP use in the P30D is reported in [Table 4](#) among respondents that initially used *General Snus*[®] at Baseline but had since quit using *General Snus*[®] by Wave 4. Though no formal statistical testing was conducted for this objective, results generally suggest that respondents that quit using *General Snus*[®] by Wave 4 did not substantially change their patterns of use for other TNP. The number of respondents reporting P30D use or no use in the P30D, for each category of TNP, differed between baseline and Wave 4 by very few respondents.

Table 4: TNP Use in the Past 30 Days at Wave 4 Among Respondents Who Quit Using *General Snus*[®]

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6.2.3 CIGARETTE QUITTING BEHAVIOR AT WAVE 4

Among *General Snus*[®] users who returned for Wave 4 who had smoked cigarettes, 18.1% (n=15) reported that they had completely quit smoking cigarettes in the P30D. Those who had not quit smoking were asked if they were trying to quit smoking. Among those who had not quit smoking, 39.2% (n=20) reported they had made a quit attempt in the P30D, and another 42.6% reported that they were currently making a quit attempt (n=29). Results for the number of respondents that had quit smoking **did not significantly differ** from that at Baseline (p=0.7728), nor were results for the number of respondents making a quit attempt at Wave 4 (p=1.0000). These results are presented in [Table 5](#) below.

Table 5: Cigarette Quitting Behaviors at Wave 4

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6.2.4 PERCENT OF DAYS IN THE PAST 30 DAYS THAT *GENERAL SNUS*[®] AND CIGARETTES WERE USED AND THE QUANTITY USED ON DAYS USED AT WAVE 4

Among the *General Snus*[®] users who returned for Wave 4, 60.5% (n=273) reported using *General Snus*[®] every day and 26.8% (n=121) reported using *General Snus*[®] on some days. Some day *General Snus*[®] users were asked on how many days out of the P30D that they used the product, while every day *General Snus*[®] users were assumed to have used the product on each of the P30D. Every day and some day users were then asked how many *General Snus*[®] pouches they used on the days that they used the product. These results are presented in [Table 6a](#) below.

Some day *General Snus*[®] users reported that they used the product 43.58% of days in the P30D (equating to 13.1 days). The percent of days *General Snus*[®] was used in the P30D among some day *General Snus*[®] users **did not significantly differ** from that reported at Baseline (p=0.8367).

Some day *General Snus*[®] users reported they used, on average, 6.7 pouches on the days they used the product. Every day *General Snus*[®] users reported using a greater number of pouches than did some day users, reporting they used 10.4 pouches each day, on average, within the P30D.

Among the *General Snus*[®] users who returned for Wave 4, 4.7% (n=21) reported smoking cigarettes every day and 8.9% (n=40) reported smoking cigarettes on some days. Some day cigarette smokers were asked on how many days out of the P30D that they smoked, while every day cigarette users were assumed to have smoked on each of the P30D. Every day and some day cigarette smokers were also asked how many cigarettes they used on the days that they smoked. These results are presented in [Table 6b](#) below.

Some day cigarette smokers reported that they smoked 22.83% of days in the P30D (equating to 6.8 days). The percent of days smoked in the P30D among some day cigarette smokers **did not significantly differ** from that reported at Baseline (p=0.2146).

Some day cigarette users reported they smoked, on average, 2.9 cigarettes on the days they smoked. Every day cigarette smokers reported smoking a greater number of cigarettes than did some day cigarette smokers, reporting they smoked 9.9 cigarettes each day, on average, within the P30D.

Table 6a: Percent of Days *General Snus*® Was Used in the Past 30 Days and Quantity of *General Snus*® Used on Days Used at Wave 4

(b) (4)

Table 6b: Percent of Days Cigarettes Were Smoked in the Past 30 Days and Quantity of Cigarettes Smoked on Days Smoked at Wave 4

(b) (4)

6.2.5 CHANGES IN PATTERNS OF USE OF *GENERAL* SNUS[®] AND CIGARETTES AT WAVE 4

Respondent patterns of use were measured by determining whether a given product was used every day, some days, or not at all within the P30D. Patterns of use for *General* Snus[®] and cigarettes were measured in both the baseline and Wave 4 surveys. Baseline and Wave 4 patterns of use for *General* Snus[®] and cigarettes were compared to understand changes in patterns of use over time and were measured separately among every day and some day users of the respective products at Baseline. Changes in patterns of use from Baseline to Wave 4 are presented in [Table 7](#) below.

Among the *General* Snus[®] users who returned for Wave 4, 65.0% (n=260) were every day *General* Snus[®] users at both Baseline and Wave 4, while 22.8% (n=91) had gone from every day use at Baseline to some day use at Wave 4. Others who were every day users at Baseline had quit use of *General* Snus[®] by Wave 4 (11.8%; n=47). Similarly, 58.8% (n=30) of some day *General* Snus[®] users at Baseline remained some day users at Wave 4, while 25.5% (n=13) had gone from some day use at Baseline to every day use at Wave 4. Others who were some day users at Baseline had quit use of *General* Snus[®] by Wave 4 (15.7%; n=8).

Most *General* Snus[®] users who returned for Wave 4 who had not smoked in the P30D at Baseline had also not smoked at Wave 4 (89.9%; n=160). Half of those who smoked every day at Baseline also smoked every day at Wave 4 (50.0%; n=12), while the other half either became some day smokers (33.3%; n=8) or had quit smoking (16.7%; n=4). Over half of those who were some day smokers at Baseline had quit smoking at Wave 4 (59.0%; n=23).

Table 7: Changes in Patterns of Use of *General Snus*® and Cigarettes from Baseline to Wave 4

(b) (4)

6.2.6 INCREMENTAL, SUPPLEMENTAL, OR COMPLETE SUBSTITUTION OF CIGARETTES FOR *GENERAL SNUS*[®] AMONG DUAL USERS OF BOTH CIGARETTES AND *GENERAL SNUS*[®] AT WAVE 4

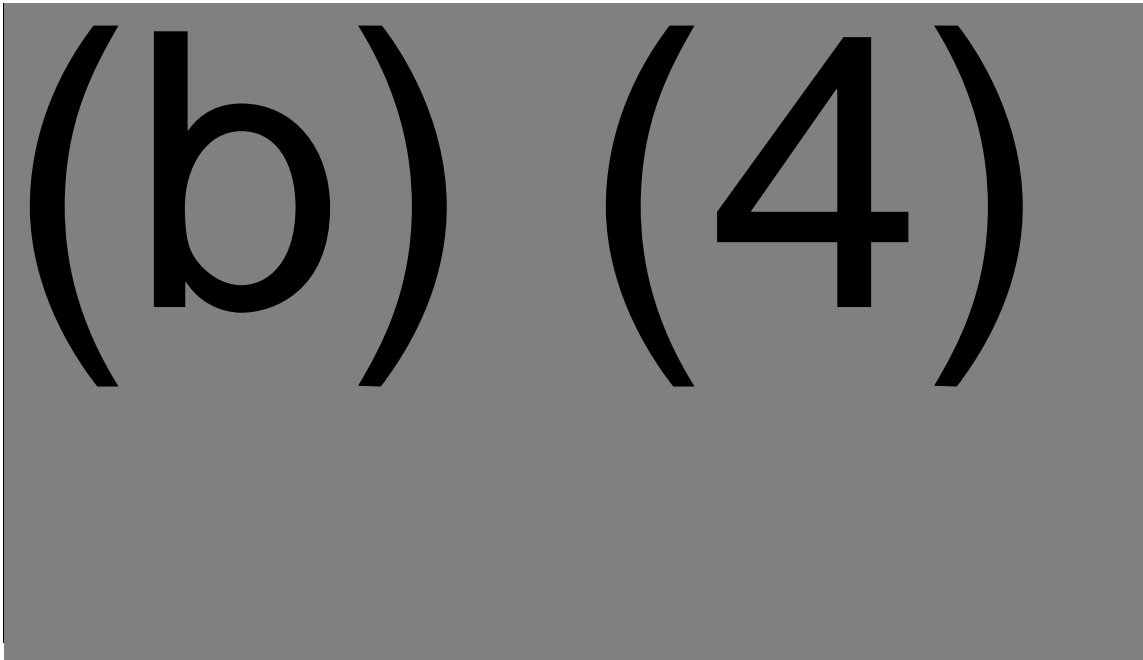
Incremental and supplemental use of cigarettes and *General Snus*[®] and complete substitution of cigarettes for *General Snus*[®] was evaluated among dual users of both cigarettes and *General Snus*[®] at Wave 4. Results were calculated by comparing frequency of use of both cigarettes and *General Snus*[®] at Baseline and subtracting frequency of use of the respective products at Wave 4. Frequency of use was measured by asking respondents the quantity of cigarettes and *General Snus*[®] used on days used. Respondents included in analyses measuring incremental and supplemental use were those that did not switch their pattern of use for either product between Baseline and Wave 4 – meaning, every day users of either cigarettes or *General Snus*[®] at Baseline who also reported every day use at Wave 4 and some day users of either cigarettes or *General Snus*[®] at Baseline who also reported some day use at Wave 4.

Incremental use was defined as using a greater or equal number of cigarettes or *General Snus*[®] at Wave 4 than at Baseline; a difference in frequency of use between baseline to Wave 4 resulting in a value that is positive or equal to zero was considered incremental use. Supplemental use was defined as using fewer cigarettes or *General Snus*[®] at Wave 4 than at Baseline; a difference in frequency of use between baseline to Wave 4 that is negative was considered supplemental use. Complete substitution was defined as fully replacing cigarette use and only using *General Snus*[®] or completely quitting use of both products. Results for incremental and supplemental use for both cigarettes and *General Snus*[®] are presented below in [Table 8a](#) and results for complete substitution are presented in [Table 8b](#).

There were no statistically significant changes in use behavior among dual users of cigarettes or *General Snus*[®] – either incremental or supplemental – at Wave 4 (range in p-values: 0.4144 – 0.6291). Additionally, there were only slight changes in use of either product among these respondents, as the change in magnitude of *General Snus*[®] pouches used was less than 1.0 pouch on for both every day (n=260) and some day (n=30) *General Snus*[®] users. and the change in magnitude for cigarettes used was 1.25 cigarettes among every day smokers (n=12) and 0.33 cigarettes among some day smokers (n=12). Results presented in [Table 8b](#) for complete substitution of cigarettes for *General Snus*[®] indicate that 6.0% (n=27) of *General Snus*[®] users who returned for Wave 4 had completely quit smoking cigarettes since Baseline. Among these respondents, 92.6% (n=25) reported that they exclusively used *General Snus*[®] to replace cigarettes.

Table 8a: Incremental or Supplemental Use of Cigarettes and *General Snus*® from Baseline to Wave 4

(b) (4)

Table 8b: Complete Substitution of Cigarettes for *General Snus*® at Wave 4

A large rectangular area of the document is completely redacted, covered by a solid gray block. Overlaid on this gray block is a large, semi-transparent watermark consisting of the text "(b) (4)" in a large, bold, black font.

6.3 WAVE 4 RESULTS FOR SECONDARY OBJECTIVES

6.3.1 PERCEPTIONS OF ABSOLUTE RISK FOR USE OF ONLY *GENERAL SNUS*® EVERY DAY AND USE OF ONLY CIGARETTES EVERY DAY

All respondents evaluated the absolute risk of developing three diseases—mouth cancer, heart disease, lung cancer—from use of only *General Snus*® every day or from use of only cigarettes every day. Perceptions of absolute risk were measured using a 5-point scale ranging from 1 (“Very low chance”) to 5 (“Very high chance”); “Don’t know” was also an available response option. These results are presented in [Table 9a](#) below.

General Snus® and other snus products contain markedly lower levels of harmful and potentially harmful constituents (HPHCs) compared to traditional smokeless tobacco. Numerous scientific publications have found no associations between use of snus products and development of mouth cancer^{1,2,3} or heart disease^{4,5,6}; this differs from use of traditional smokeless tobacco for which associations with these diseases have been found.

Findings at Wave 4 suggest that some *General Snus*® users may be misinformed about the health risks of using the product and may misattribute risks of traditional smokeless tobacco to *General Snus*®—about half perceived use of only *General Snus*® every day to be associated with a moderate to very high chance of developing mouth cancer (48.6%, n=219) and nearly half perceived use of only *General Snus*® every day to be associated with a moderate to very high chance of developing heart disease (44.8%, n=202).

¹ Luo J, Ye W, Zendehdel K, *et al.* Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung, and pancreas in male construction workers: a retrospective cohort study. *The Lancet*. Volume 369 (2007).

² Smita A, Labani S, Kailash U, *et al.* Association of smokeless tobacco use and oral cancer: a systematic global review and meta-analysis. *Nicotine & Tobacco Research*. Volume 21, Issue 9 (2019).

³ Araghi M, Galanti MR, Lundberg M, *et al.* No association between moist oral snuff (snus) use and oral cancer: pooled analysis of nine prospective observational studies. *Scandinavian Journal of Public Health*. Volume 28, Issue 8 (2021).

⁴ Lee P. Summary of the epidemiological evidence relating snus to health: an updated review based on recent publications. *Harm Reduction Journal*. Volume 10, Issue 36 (2013).

⁵ Hansson J, Galanti MR, Hergens MP, *et al.* Use of snus and acute myocardial infarction: pooled analysis of eight prospective observational studies. *European Journal of Epidemiology*. Volume 27 (2012).

⁶ Wennberg P, Eliasson M, Hallmans G, *et al.* The risk of myocardial infarction and sudden cardiac death amongst snuff users with or without a previous history of smoking. *Journal of Internal Medicine*. Volume 262, Issue 3 (2007).

General Snus[®] users who returned for Wave 4 (n=451) correctly perceived that use of only *General Snus*[®] every day carried lower risks to health than use of only cigarettes every day across the three diseases assessed. This is also evidenced by results for perceived risk of developing lung cancer, as 88.5% (n=399) of respondents at Wave 4 associated use of only *General Snus*[®] every day to be associated with a low to very low chance of developing lung cancer, which is also evidenced in scientific literature.⁷

General Snus[®] products can be marketed in the U.S. with the following modified risk messaging: “Using *General Snus*[®] instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”⁸ Risk perceptions among *General Snus*[®] users at Wave 4 provide evidence that respondents understand that *General Snus*[®] is a reduced risk tobacco product (compared to cigarettes) but that use of *General Snus*[®] is not without risks to health. Findings also provide evidence that respondents can correctly attribute use of only *General Snus*[®] to reductions in risk of developing specific diseases stated in the modified risk messaging.

Among *General Snus*[®] users who returned for Wave 4 (n=451), use of only cigarettes every day was perceived to carry much higher risks to health than use of only *General Snus*[®] every day across the three diseases assessed. Large majorities of respondents at Wave 4 perceived use of only cigarettes every day to be associated with a moderate to very high chance of developing each of the three disease states assessed—mouth cancer (78.5%, n=354), heart disease (93.8%, n=423), lung cancer (92.5%, n=417). This suggests these respondents understand that use of cigarettes contributes very high risks to health and to the development of mouth cancer, heart disease, and lung cancer, specifically.

⁷ Clarke E., Thompson K., Weaver S., *et al.* **Snus: a compelling harm reduction alternative to cigarettes.** *Harm Reduction Journal*. Volume 16, Issue 62 (2019).

⁸ U.S. Food and Drug Administration. **FDA grants first-ever modified risk orders to eight smokeless tobacco products.** Press Release (2019).

Table 9a: Perceptions of Absolute Risk for Use of Only *General Snus*® Every Day and Use of Only Cigarettes Every Day

(b) (4)

(b) (4)

6.3.2 PERCEPTIONS OF ABSOLUTE RISK FOR USE OF BOTH *GENERAL* SNUS[®] AND CIGARETTES EVERY DAY AND NEVER HAVING USED ANY TNP

All respondents evaluated the absolute risk of developing three diseases—mouth cancer, heart disease, lung cancer—from use of both *General Snus*[®] and cigarettes every day or from never having used any TNP. Perceptions of absolute risk were measured using a 5-point scale ranging from 1 (“Very low chance”) to 5 (“Very high chance”); “Don’t know” was also an available response option. These results are presented in [Table 9b](#).

Among *General Snus*[®] users who returned for Wave 4 (n=451), large majorities of respondents perceived use of both *General Snus*[®] and cigarettes every day (dual use) to be associated with a moderate to very high chance of developing each of the three disease states assessed—mouth cancer (85.4%, n=385), heart disease (91.6%, n=413), lung cancer (92.5%, n=417). As *General Snus*[®] is a modified risk tobacco product (MRTP) and carries a modified risk message⁹, this finding provides evidence that respondents do not perceive that supplementing cigarette use with *General Snus*[®] (dual use) reduces risks for developing diseases from cigarette use—perceived risks associated with dual use of *General Snus*[®] and cigarettes every day were similar in magnitude to perceived risks associated with use of only cigarettes every day ([Table 9a](#)). Thus, these results do not provide evidence of a “halo effect” related to use of *General Snus*[®], a concern that has recently been raised by both public health researchers and FDA.¹⁰

Among *General Snus*[®] users at baseline that returned for Wave 4 (n=451), never having used any TNP was perceived as having minimal risk of developing cancer. Large majorities of respondents at Wave 4 associated never having used any TNP with low or very low chances of developing mouth cancer (89.6%, n=404) and lung cancer (84.9%, n=383). Perceived risk of developing heart disease from never having used any TNP was considerably higher, as more than half of respondents associated never having used any TNP with a moderate to very high chance of developing heart disease (57.2%, n=258).

⁹ The modified risk messaging approved for *General Snus*[®] states the following: “Using *General Snus*[®] instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.” U.S. Food and Drug Administration. **FDA grants first-ever modified risk orders to eight smokeless tobacco products**. Press Release (2019).

¹⁰ Seidenberg AB, Popova L, Ashley DL, *et al.* **Inferences beyond a claim: a typology of potential halo effects related to modified risk tobacco product claims**. *Tobacco Control*. Volume 30 (2021).

Table 9b: Perceptions of Absolute Risk for Use of Both *General Snus*[®] and Cigarettes Every Day and Never Having Used Any TNP

(b) (4)

(b) (4)

6.3.3 UNDERSTANDING OF THE MODIFIED RISK CLAIM FOR *GENERAL* SNUS[®]

Understanding of the modified risk claim for *General* Snus[®] was assessed among all *General* Snus[®] users at Baseline who returned for Wave 4 (N=451). Two questions were asked. The first asked respondents to correctly identify the language used in the modified risk claim. Response options included “lower risk,” “higher risk,” or “the same risk” of developing certain diseases from using *General* Snus[®] compared to smoking cigarettes.¹¹

Respondents who correctly answered this question (i.e., endorsed “lower risk”) were presented with a second question asking how many cigarettes that can be smoked per day while using *General* Snus[®] and still benefit from the reduction in risk of developing the diseases stated in the modified risk claim. Response options included “Zero cigarettes,” “Up to 5 cigarettes,” “Up to 20 cigarettes,” and “As many as you want to smoke.” “Don’t know” and “Decline to answer” were also available response options. The correct response option, based on language used in the modified risk claim, is “Zero cigarettes,” as the claim states a user must use *General* Snus[®] *instead of cigarettes*.

Results are presented in [Table 10](#) below and are separated between *General* Snus[®] users overall and new *General* Snus[®] users (defined as first using *General* Snus[®] in the 30 days prior to the Baseline survey). Only results for the overall group of *General* Snus[®] users are described here given the small sample size of new *General* Snus[®] users.

Most respondents correctly reported that use of *General* Snus[®] instead of cigarettes presents a lower risk of developing the diseases stated in the modified risk claim (77.8%, n=351). Also, most respondents who correctly responded to the modified risk claim messaging (n=351) then correctly reported that cigarettes could not be smoked (i.e., endorsed “Zero cigarettes”) and still benefit from the reduction in risk of developing the diseases stated in the modified risk claim (79.8%, n=280). These findings suggest that *General* Snus[®] users understand that use of *General* Snus[®] instead of cigarettes puts them at a lower risk of developing various tobacco-related diseases and that this reduction in risk is predicated on not smoking cigarettes (“Using *General* Snus[®] instead of cigarette[s]”).

¹¹ Diseases included on the modified risk claim are the following: mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Table 10: Understanding of the MRTP Claim Related to Reduced Risk Among *General Snus*® Users and New *General Snus*® Users

(b) (4)

7. SUMMARY OF WAVE 4 RESULTS

General Snus[®] was used in the P30D by 87.3% (n=394) of those returning at Wave 4

- The pattern of *General Snus*[®] use **significantly differed** from Baseline (p<0.0001) due to the proportion of respondents who had switched from every day to some day use by Wave 4

Every day *General Snus*[®] users used more pouches on days used than some day users (10.4 pouches/day vs. 6.7 pouches/day)

- Some day *General Snus*[®] users reported using the product an average of 13.1 days in the P30D, which **did not significantly differ** from that reported at Baseline (p=0.8367)

Among returning *General Snus*[®] users at Wave 4, only 13.9% (n=63) reported smoking at Baseline and 13.5% (n=61) reported at Wave 4, which **did not significantly differ** (p=0.6232)

Respondents correctly perceived that cigarette smoking contributed significant risks to health, associating it with moderate to very high chances of developing mouth cancer (78.5%, n=354), heart disease (93.8%, n=423), lung cancer (92.5%, n=417).

- Dual use of *General Snus*[®] and cigarettes was generally perceived as being just as risky to health as use of only cigarettes, suggesting that respondents understand that any use of cigarettes is associated with high risks to health
- Use of *General Snus*[®] was perceived as being less risky to health than cigarette smoking but that use of *General Snus*[®] was not without risks to health.

Respondents understood the MRTP claim that using *General Snus*[®] instead of cigarettes puts users at a lower risk for various diseases compared to cigarette smoking

- 77.8% (n=351) of respondents correctly endorsed that use of *General Snus*[®] presented less risk to health than cigarette smoking
 - Most respondents who correctly endorsed that use of *General Snus*[®] presented less risk to health than cigarette smoking understood that no cigarettes can be smoked while using *General Snus*[®] to benefit from it being lower risk (79.8%, n=280)
 - Results suggest that *General Snus*[®] users are aware of the need to completely substitute cigarettes for *General Snus*[®]
-

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In Person Signer Events	Signature	Timestamp
Editor Delivery Events	Status	Timestamp
Agent Delivery Events	Status	Timestamp
Intermediary Delivery Events	Status	Timestamp
Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
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Certified Delivered	Security Checked	09-Nov-2022 08:48
Signing Complete	Security Checked	09-Nov-2022 08:48
Completed	Security Checked	09-Nov-2022 14:56
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General Snus MRTP Marketing Support Plan

Relative Size of Snus Category and General Snus Brand:

(b) (4)

¹ MSA Total US, Q1 – Q3 2023

Responsible Marketing Practices:

(b) (4)

(b) (4)

(b) (4)

3 Swedish Match Salesforce Database November 2022 – September 2023
4 Havas digital media plans November 2022 – October 2023
5 Facebook Analytics November 2022 – October 2023

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2023 MRTP Annual Report

CATEGORY: SNUS

BRAND: GENERAL SNUS

November 2022 – October 2023

Appendix 2A (1)

All Website Pages



General Snus Elevated Stories: November [BEHIND AGE GATE] 11-8-22 - current

FIND YOUR HYGGE THIS SEASON

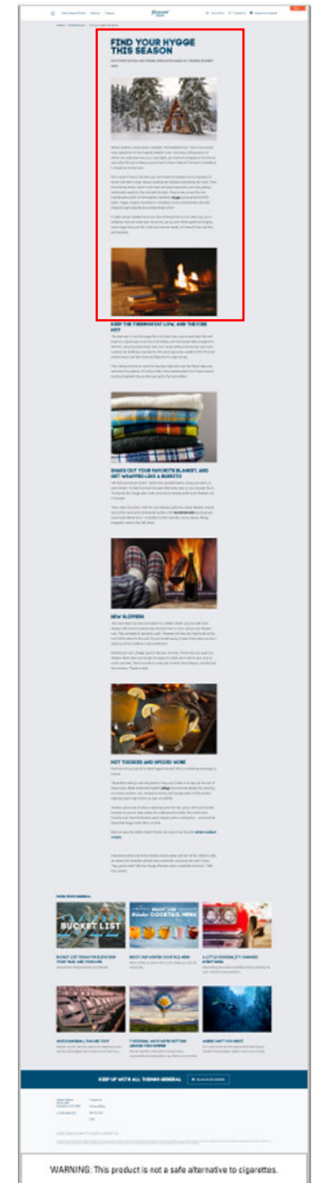
Don't hide from the cold. Instead, embrace the season in a timeless Swedish style.



Winter weather comes early to Sweden. And Swedes know—even if you're the most upbeat fan of the Original Swedish Snus—the slow, hulking march of winter can really bum you out. Long nights can have you longing for the time of year when the sun is always around, and it doesn't take 20 minutes to bundle up to simply go to the store.

But it doesn't have to be that way. Our friends in Sweden are no strangers to winter with their snowy season starting late October and lasting into April. They know facing winter doesn't only mean physical preparation, but also getting emotionally ready for the cold and the dark. There's even a word for this Scandinavian spirit of cold-weather positivity: **hygge** (pronounced /HYOO-guh/). Hygge roughly translates to "a feeling of cozy contentment and well-being through enjoying the simple things in life."

In other words, Swedes know you must embrace the cozy to stay cozy. So, in solidarity, here are some easy ways you can up your winter game by bringing some hygge into your life. Grab your favorite variety of General Snus, and let's get prepping.




General Snus Elevated Stories: November con't [BEHIND AGE GATE] 11-8-22 - current

KEEP THE THERMOSTAT LOW, AND THE FIRE HOT

The best way to live the hygge life is to stand your ground and meet the cold head on. A great way to do this is by letting your thermostat take a break for a little bit. Leave the temp lower than your usual setting and harness your inner caveman by building a roaring fire. The warm glow and crackle of the fire is the perfect way to set the mood and keep the icy night at bay.


Plus, taking the time to stack the logs just right and coax the flame helps you welcome the *outdoors* of it all just like a true Swede would. Don't have a wood-burning fireplace? Fire up that gas log for the same effect.



SHAKE OUT YOUR FAVORITE BLANKET, AND GET WRAPPED LIKE A BURRITO

The best part about winter—aside from snowball fights, skiing, and deals on swim trunks—is that it arrives the same time every year, so you can plan for it. To execute this hygge plan, make sure you've already pulled your blankets out of storage.

Then, when the winter cold hits your latitude, grab the coziest blanket, stretch out on the couch, and roll yourself up like a hot **tunnbrödsrulle** (pronounced /toon-brud-SROO-luh/)—a Swedish street food with various hearty fillings wrapped in warm, thin, flat bread.



FIND YOUR HYGGE THIS SEASON

Hygge is the Danish word for a feeling of coziness and comfort. It's the art of slowing down and savoring the simple pleasures of life. This season, embrace the hygge lifestyle and make the most of the winter months.



Hygge is all about creating a warm and inviting atmosphere. It's about taking the time to enjoy the little things in life, like a cup of coffee or a warm blanket. This season, make the most of the winter months and embrace the hygge lifestyle.



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NEW SLIPPERS

This next step is an easy no-brainer for a better winter: buy yourself some slippers. We know it sounds crazy, but just hear us out. Look at your slippers now. They probably fit perfectly, right? However, do they also have holes in the toes? What about in the sole? Do you dread having to wear them when you do a quick jog to the mailbox in wet conditions?

Nothing can ruin a hygge session like wet, cold feet. That's why you need nice slippers. Most heat may escape through your head, but it warms your core to cover your feet. Treat yourself to a new pair of warm, lined slippers, and slip into the coziness. Thank us later.



HOT TODDIES AND SPICED WINE

Now how do you top off an ideal hygge evening? With a comforting beverage, of course.

Thankfully making a warming drink to hug your insides is as easy as the rest of these steps. Make traditional Swedish **glögg** (pronounced /glahg/) by warming port wine, bourbon, rum, cinnamon, cloves, and orange peels. It's the perfect nightcap when night seems to start at 3:00PM.

Another tasty treat involves combining some hot tea, spices, and your favorite bourbon in a pot or slow cooker for a delicious hot toddy. Pair it with your favorite snus, favorite blanket, warm slippers, plus a roaring fire — and you'll be living that hygge-matic life in no time.


Want an easy hot toddy recipe? Check out some of our favorite **winter cocktail recipes**.

Everyone on this side of the Atlantic knows being cold isn't all fun. Which is why we admire the Swedish attitude that essentially outsmarts the cold. It says, "Hey, guess what? We live a hygge lifestyle: warm, contented and cozy". Take that, winter!




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MORE FROM GENERAL




A LITTLE ORIGINALITY CHANGES EVERYTHING
Appreciating the unique ingredients that turn boring into wow—and the science behind it.




WHERE CAN'T YOU SNUS?
A fun look at the very few places where the Original Swedish Snus probably ought to stay in your pocket



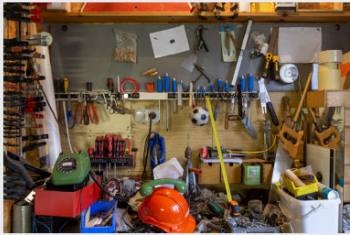
A HIGHER STANDARD
Giving you an elevated tobacco experience also means elevating our principles and practices



FIVE FUNNY SWEDISH SAYINGS
A short (and seriously silly) guide to sounding like a Swede



THE UNSPOKEN RULES & CURIOUS CUSTOMS OF GOLF
Plus a Quick Look at Golf in the Land of the Original Swedish Snus



ORGANIZE YOUR SPACE: SWEDISH STYLE
Enjoy the Benefits of a Less-Stuff Life

FIND YOUR HYGGE THIS SEASON



HOW THE HIGHEST QUALITY SNUS CAN HELP



HOW TO GET THE MOST OUT OF YOUR SNUS



HOW TO GET THE MOST OUT OF YOUR SNUS



HOW TO GET THE MOST OUT OF YOUR SNUS



HOW TO GET THE MOST OUT OF YOUR SNUS



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General Snus Elevated Stories: December [BEHIND AGE GATE] 12-6-22 - current

HOW TO ENTERTAIN WHILE WAITING TO ENTERTAIN

Cookies in the oven? Chili in the slow cooker? But the guests are here? We've got ideas on activities to fill the time.



You've got everything planned out for your holiday party. You're baking some cookies, slow cooking chili, or frying latkes before guests arrive. Unfortunately, your day started later than you anticipated, and now you've got guests in your living room and a bowl of cookie dough on the counter. What can you do to make sure your guests aren't bored while the cookies crisp? Don't worry. We've got you covered. Here are some great ideas to keep the party rolling depending on how much wait time (1 hour, 2 hours, 30 minutes) you have.

T-Minus 30 Minutes – Fill Your Cup

This one should be the easiest. You've got everything ready, but you're just waiting on the final crisping of your latkes. What to do for 30min or less? Get everyone ready to eat! Go around to every person at your party, and make sure they have a full drink. Carry around a pitcher of water or a non-alcoholic libation for those that don't drink, or have drinks close at hand for those that do. Make sure you greet each person with a hug or handshake or fist bump, ask them how they're doing, and thank them for coming. This is a great way to set the stage for a party that's welcoming and loving. Simple. Friendly. Memorable. Let's eat!



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KEEP UP WITH ALL THINGS SWEDISH MATCH

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General Snus Elevated Stories:

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T-Minus One Hour – Celebrity/Hat Game/Monikers

This party game comes in many different names—Celebrity, Hat Game, Fish Bowl, Monikers—but the game play is generally the same. It's an exciting, fast paced game that easy to learn regardless of skill level.

- Create at least two teams of (ideally) 3-6 players per team. You can have more than two teams, but more than 6 people per team can get complicated and extra noisy.
- Pass out 3-5 slips of paper to each person (the more people per team the less slips of paper per person) along with a pen. Each person then writes down a noun (person, place, or thing) on to each slip of paper, and puts the completed slip into a bowl, hat, or some kind of dish. For even faster set-up, you can write out the slips ahead of time for everyone.
- To start, each team picks a person to be the first presenter. The presenter will have 30-seconds to get their team to guess as many slips in the bowl as they can. Once their 30-seconds is up, the next team then goes with the remaining slips. The teams alternate this way until all slips are gone, which ends the round. The number of slips each team correctly guessed are added up. The next round starts with whichever team is next, and the person presenting switches.
- The game lasts this way for three rounds with each round having different rules. For the first round, the presenter can describe the clue in any way they like, but cannot say the word itself. The second round has the presenter only being able to say ONE word to describe the noun. Finally, the third round is no words at all and only Charade rules. The team that guesses the most clues is the winner! There are all kinds of variations of this game out there as well if you'd like to spice it up.



T-Minus Two Hours – Living Scrapbook

We've all left a party and thought, "I should have taken some pictures!" or "I didn't get a chance to talk to everyone!" Well, regret no more! Grab some supplies and get to snapping to create a living scrapbook. It's an easy and original way to not only have documentation of the evening, but to also make time to talk with everyone you'd like.

The set-up is easy:

- Split your guests into groups—any size and number of groups—and then give them some art supplies like paper, markers, stickers, etc. Ask them to create captions, draw designs, or whatever they want to make to add flair to their group pictures. While they're creating encourage them to ask each other about their days, their plans for the new year, or anything else.
- As the groups are ready, bring them up and take their pictures. Also, make sure you get pictures of everyone drawing and creating so you have posed and candid shots.



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- Once every group is done, split them up again so they're with someone new and repeat. They can create all new flair or use what's already been made.

Later you can take all those pictures and share with your guests so they can pick their favorites. This way you get a full record of the party and guests, and you get to have at least one conversation with everyone. No more party regrets!



We hope these tips and games will help you round out your holiday spectacular in high fashion. Your friends and family are sure to enjoy and remember you as a true original and loving. Simple. Friendly. Memorable. Let's eat!

HOW TO ENTERTAIN WHILE WAITING TO ENTERTAIN

When you're waiting for your next Swedish Match product, here are some ideas to keep you entertained.



When you're waiting for your next Swedish Match product, here are some ideas to keep you entertained.

Play a Game

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More Games

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KEEP UP WITH ALL THINGS SWEDISH MATCH

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General Snus Elevated Stories: December con't [BEHIND AGE GATE]

12-6-22 - current

MORE FROM GENERAL

ENJOY OUR WINTER COCKTAIL MENU

We've crafted a cocktail menu sure to keep you warm all winter long.

HOW ORIGINALS LOVE THEIR GEAR

The gear we use says a lot about us...so does how we take care it.

REALISTIC RESOLUTIONS

New Year's resolutions shouldn't be intimidating. We're making sure you stay cool and calm by setting realistic...

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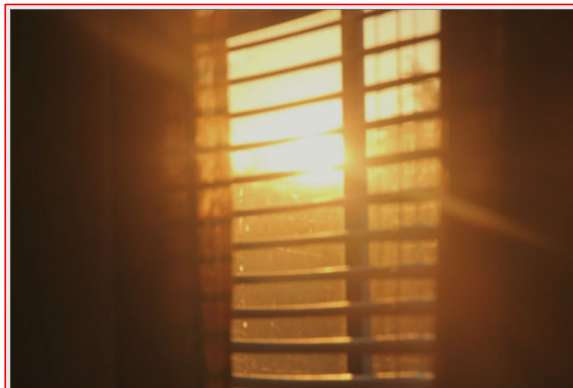
1-3-23 - current

REALISTIC RESOLUTIONS

New Year's resolutions shouldn't be intimidating. We're making sure you stay cool and calm by setting realistic and achievable goals for your New Year.



The pressure to make and stick to New Year's resolutions is quickly spreading earlier into December than ever before. Gyms, food companies, bottled water brands, and more want you to drop pounds, change your routine, and learn to multiply yourself so you can be everywhere at once. It can be a lot! That's why we've created some realistic, small, achievable goals so you don't have to feel anxious in the New Year. Not reading this until after the New Year? Don't worry. These goals work just as well on January 21st as January 1st.



WAKE-UP 15MIN EARLIER THAN NORMAL.

Look, we understand that sleep is awesome. Closing our eyes at night and peacefully drifting off to Dream Town is one of the best parts of the day. However, giving yourself an extra 15 minutes in the morning can be just as awesome. Use that time to do some reading or journaling to quietly wake up your mind for the day ahead. You could also do some light stretching or meditation to ease into your day. Lighting up your muscles, joints, and brain, and focusing on your day with intention can really start things off on the right foot. Even using the extra 15 minutes to simply get an early start on your morning routine can help reduce stress and do wonders for your body and mind.

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TAKE A BREAK AND FIND SOME SPACE

FIND SOME QUIET

LISTEN TO YOUR MOTHER SAY SOME THINGS

GET YOUR DAILY ESSENTIALS

SHOP OF VITAL ALL THINGS

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

General Snus Elevated Stories: January con't [BEHIND AGE GATE] 1-3-23 - current



TAKE A BREAK AND TAKE SOME STEPS.


We've all been told about the long-term damage sitting at a desk all day can do to our bodies and brains. Between staring at a screen, sitting in a non-ergonomic chair, and lightly tanning under fluorescent lights, the impact of a low-key desk job is surprisingly high. But you can easily counteract some of that by adding some movement to your day. Every hour or two get up from your desk and let curiosity be your trainer. You can take the stairs to say hi to a co-worker on another floor, make your next meeting a walking meeting to a nearby coffee shop, or just grab a handful of papers and a folder and walk around the office with purpose. If you are carrying a folder with papers in it and a determined look on your face, then no one will question where you're going—somewhere important, obviously. You get a little exercise, give your eyes a break, and get some new air in your lungs.




FIND SOME QUIET.

Our lives can be noisy. TVs, traffic, music in elevators, and Jerry from Shipping telling you all about his new fishing boat, all add up to a lot of ambient noise all around us. It can be great for stress levels and peace of mind to just find a little bit of quiet every day wherever you can. Maybe it's taking time at night to sit in a room with lights low and all screens and notifications off. Maybe it involves sitting in your car for a couple minutes at the start or end of your commute with the radio and car off. Maybe you need to walk into the woods, find a good tree to sit under, and be very still for a few minutes. Either way, give your senses a chance to breathe with some nice silence.

REALISTIC RESOLUTIONS




It's the start of a new year, and with it comes a new set of resolutions. But what if you could make resolutions that are actually realistic? That's the idea behind the Realistic Resolutions campaign. It's a series of articles and videos that offer practical advice on how to set and achieve goals that are both challenging and achievable. From finding time to exercise to improving your productivity, these resolutions are designed to help you make the most of the new year.




MAKING YOUR RESOLUTIONS A REALITY

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KEEP UP WITH ALL THINGS GENERAL

ABOUT

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PRIVACY

TERMS

FAQ

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

General Snus Elevated Stories: January con't [BEHIND AGE GATE]

1-3-23 - current



LISTEN TO YOUR MOTHER. EAT SOME VEGGIES.

We don't want to tell you how to fully live your life, but it's time you start listening to your mother's advice and add some veggies to your plate. No, french fries or mashed potatoes don't count (much to our own chagrin) because of the salt, fat, et cetera. We're talking some good old-fashioned broccoli, spinach, carrots, and more. You don't have to go full vegetarian, but just adding a few veggies to your weekly dinner (or lunch) plates can go a long way for your health. You can even branch out and try the Swedish staple, *Pressgurka* (/press-GER-kuh/), a pressed and pickled cucumber side dish. Small steps are a good way to create big change, so give it a shot. Sautéing some broccoli to go along with a steak or chicken is easy, and, we'd bet, much tastier than you remember.



GET WAY INTO SPIRITUAL HOMEOPATHY, OPEN A LUXURY CRYSTAL SHOP, AND BECOME A GURU.

This may seem pretty far out there compared to everything else on this list, but the healing powers of crystals really are a wonderful way to align your chakras and heal your spirit by — Just kidding. Don't do this.

Happiest of New Years to you all. We're pulling for you, and best of luck on those resolutions!

REALISTIC RESOLUTIONS

1. **BE HEALTHY**

2. **SAVE UP MONEY BEFORE YOUR MOTHER**

3. **READ A BOOK AND FIND SOME SPIRIT**

4. **FIND SOME GUTS**

5. **LISTEN TO YOUR MOTHER EAT SOME VEGGIES**

6. **GET WAY INTO SPIRITUAL HOMEOPATHY, OPEN A LUXURY CRYSTAL SHOP, AND BECOME A GURU**

7. **HAPPY NEW YEAR**

8. **BE A HIGH SCHOOL**

9. **A FINEST CHANCE**

10. **BEHIND THE SCENES**

11. **KEEP UP WITH ALL THOSE CRIBS**

12. **BE A GURU**

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

1-3-23 - current

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General Snus Elevated Stories: February [BEHIND AGE GATE] 2-14-23 - current

HOW ORIGINALS LOVE THEIR GEAR

The gear we use says a lot about us...so does how we take care it.



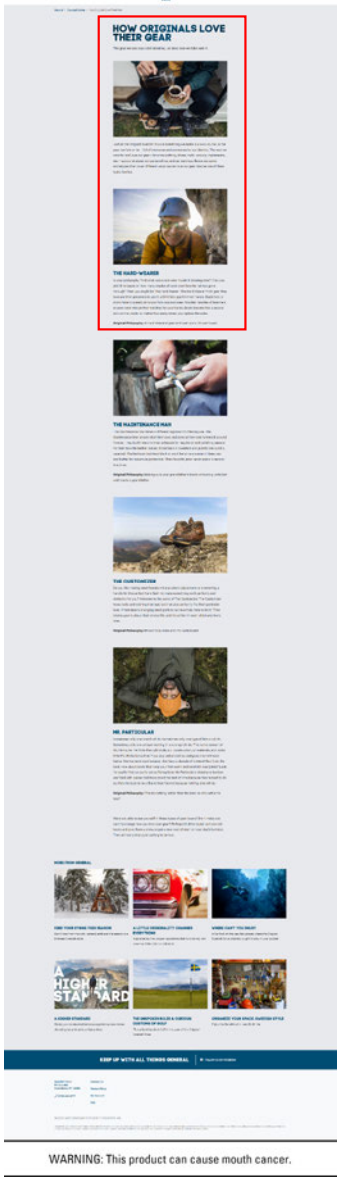
Just as the Original Swedish Snus is something we make our own, so, too, is the gear we hold on to—full of memories and connected to our identity. The way we care for and love our gear—favorite clothing, shoes, tools, cooking implements, etc.—says a lot about our personalities and our journeys. Below are some archetypes that cover different ways we can love our gear. Maybe one of them looks familiar.



THE HARD-WEARER

Is your philosophy “find what works and wear it until it disintegrates”? Can you plot time based on how many shades of color your favorite hat has gone through? Then you might be The Hard-Wearer. The Hard-Wearer finds gear they love and then proceeds to use it until it falls apart in their hands. Black hats or shirts fade to a medium brown from sun and wear. Wooden handles of hammers or axes wear into perfect matches for your hands. Boots become like a second skin on the inside no matter how many times you replace the soles.

Original Philosophy: A Hard-Wearers' gear isn't well-worn, it's well-loved.



General Snus Elevated Stories: February con't [BEHIND AGE GATE] 2-14-23 - current



THE MAINTENANCE MAN

The Maintenance Man takes a different approach to lifelong use. The Maintenance Man knows what they love, and does all they can to keep it around forever. They build time into their schedule for regular oil and polishing session for their favorite leather pieces. Small tears in sweaters and jackets are quickly repaired. The heirloom butchers block or work bench are coated in bees wax and buffed for maximum protection. Their favorite jeans never spend a second in a dryer.

Original Philosophy: Making sure your grandfather's boots or hunting knife last until you're a grandfather.




THE CUSTOMIZER


Do you like making small tweaks—like a tailor's adjustment or shortening a handle for the perfect hand feel—to make something work perfectly and distinctly for you? Welcome to the world of The Customizer. The Customizer loves tools and clothing that last, but that also perfectly fits their particular lives. If that means changing small parts to achieve that, then so be it. Their choice gear is about their choice life, and it's written in each stitch and ivory inlay.

Original Philosophy: It's not truly mine until it's customized.

HOW ORIGINALS LOVE THEIR GEAR




When you're an original, you know your gear is more than just a tool—it's a part of you. That's why you take care of it, you love it, and you make it work for you. It's not just about the gear, it's about the life you live with it.




THE GEAR LOVER

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THE PARTICULAR


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THE GEAR LOVER




THE CUSTOMIZER




THE MAINTENANCE MAN




THE PARTICULAR




THE GEAR LOVER




THE CUSTOMIZER



THE MAINTENANCE MAN



THE PARTICULAR



THE GEAR LOVER

KEEP UP WITH ALL THINGS ORIGINALS

WARNING: This product can cause mouth cancer.

General Snus Elevated Stories:

February con't [BEHIND AGE GATE]

2-14-23 - current



MR. PARTICULAR

Sometimes only one brand will do. Sometimes only one type of fabric will do. Sometimes only one artisan working in one shop will do. This is the domain of Mr. Particular. He finds the right style, cut, construction, or materials, and rocks it for life. He believes that if you buy better clothes and gear, they will wear better. Want a warm wool sweater that lasts a decade of winters? Buy from the best. How about boots that keep your feet warm and won't kill your joints? Look for quality first so you're not suffering later. Mr. Particular's closet and toolbox are filled with pieces that have stood the test of time because they're built to do so. He's the type to be a Brand Man forever because nothing else will do.

Original Philosophy: There's nothing better than the best, so why settle for less?

Were you able to see yourself in these types of gear lovers? Did it make you want to change how you love your gear? Perhaps it's time to pull out your old boots and give them a shine, or put a new coat of stain on your dad's humidor. They all hold a story just waiting to be told.

MORE FROM GENERAL



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Don't hide from the cold. Instead, embrace the season in a timeless Swedish style.



A LITTLE ORIGINALITY CHANGES EVERYTHING

Appreciating the unique ingredients that turn boring into wow—and the science behind it.



WHERE CAN'T YOU SNUS?

A fun look at the very few places where the Original Swedish Snus probably ought to stay in your pocket



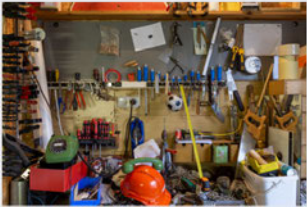
A HIGHER STANDARD

Giving you an elevated tobacco experience also means elevating our principles and practices



THE UNSPOKEN RULES & CURIOUS CUSTOMS OF GOLF

Plus a Quick Look at Golf in the Land of the Original Swedish Snus



ORGANIZE YOUR SPACE: SWEDISH STYLE

Enjoy the Benefits of a Less-Stuff Life

HOW ORIGINALS LOVE THEIR GEAR

When you're an original, you know your gear is your best friend. It's the stuff that keeps you going, the stuff that makes you feel like you're in control. That's why originals love their gear. They love the way it feels, the way it looks, the way it works. They love the way it makes them feel like they're in control. That's why originals love their gear. They love the way it feels, the way it looks, the way it works. They love the way it makes them feel like they're in control.

THE HUNT FOR THE PERFECT SNUS

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KEEP UP WITH ALL THE NEWS


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WARNING: This product can cause mouth cancer.

General Snus Elevated Stories: March [BEHIND AGE GATE] 3-21-23 - current

ALL ABOUT ALLEMANSRÄTTEN

The freedom to roam is an essential right in the land of the Original Swedish Snus




Imagine being able to pack up your favorite variety of General, strap on your favorite hiking boots, and head out into the wild over fence, over glade, over glen...with hardly any limits on where your legs can take you or your head can rest.

Imagine being able to pack up your favorite variety of General, strap on your favorite hiking boots, and head out into the wild over fence, over glade, over glen...with hardly any limits on where your legs can take you or your head can rest.


Sounds pretty amazing, right? This is the guiding principle of *allmansrätten* (/ah-leh-manz-REHT-ten/), or “the everyman’s right,” a freedom granted and codified by the constitution of Sweden. It means when you’re in Sweden you have the right to walk, cycle, ride, float, ski, and camp on basically any land you’d like with the exception of private gardens, near a dwelling or house, or land under cultivation. Swedes often refer to it as the “Freedom to Roam,” and it is a major part of Swedish life.

These Outdoor Access Rights—as they’re also called—were written into the Swedish constitution in 1994, and state that, notwithstanding the right to own property, “everyone shall have access to nature in accordance with *allmansrätten*.” It further explains that this encompasses “actions that are not crimes, will not make a person liable to pay damages, nor can be prohibited by any authority.” It also includes the right to gather wild berries, mushrooms, and flowers (with some exceptions), and fish in the five big lakes and along the coastline. There are some restrictions to the right: such as certain nature preserves, species of plants and flowers, proximity to private homes (known as the “hemfridszonen” or “peace-at-home-zone”), etc. You can read more from the Swedish Environmental Protection Agency.


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READY FOR AHEAD? CHECK OUT THE NEW




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READY FOR AHEAD? CHECK OUT THE NEW



READY FOR AHEAD? CHECK OUT THE NEW

KEEP UP WITH ALL THINGS GENERAL

WARNING: This product can cause mouth cancer.

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General Snus Elevated Stories: March [BEHIND AGE GATE]

3-21-23 - current

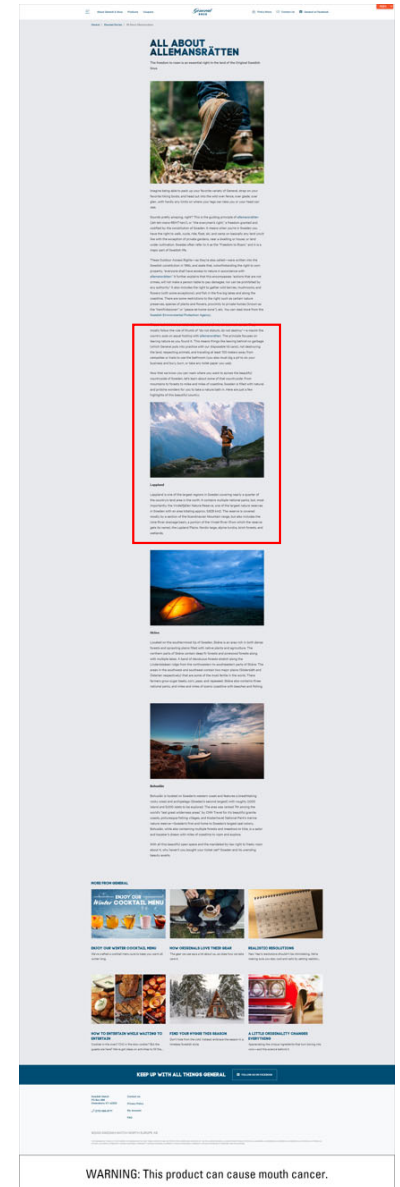
These restrictions are relatively minor, and all rely on common sense. They mostly follow the rule of thumb of “do not disturb, do not destroy”—a maxim the country puts on equal footing with *allemansrätten*. The principle focuses on leaving nature as you found it. This means things like leaving behind no garbage (which General puts into practice with our disposable lid cans), not destroying the land, respecting animals, and traveling at least 100 meters away from campsites or trails to use the bathroom (you also must dig a pit to do your business and bury, burn, or take any toilet paper you use).

Now that we know you can roam where you want to across the beautiful countryside of Sweden, let's learn about some of that countryside. From mountains to forests to miles and miles of coastline, Sweden is filled with natural and pristine wonders for you to take a nature bath in. Here are just a few highlights of this beautiful country:



Lappland

Lapland is one of the largest regions in Sweden covering nearly a quarter of the country's land area in the north. It contains multiple national parks, but, most importantly, the Vindelfjällen Nature Reserve, one of the largest nature reserves in Sweden with an area totaling approx. 5,628 km². The reserve is covered mostly by a section of the Scandinavian Mountain range, but also includes the Ume River drainage basin, a portion of the Vindel River (from which the reserve gets its name), the Lapland Plains, Nordic taiga, alpine tundra, birch forests, and wetlands.



General Snus Elevated Stories: March [BEHIND AGE GATE]

3-21-23 - current



Skåne

Located on the southernmost tip of Sweden, Skåne is an area rich in both dense forests and sprawling plains filled with native plants and agriculture. The northern parts of Skåne contain deep fir forests and pinewood forests along with multiple lakes. A band of deciduous forests stretch along the Linderödsåsen ridge from the northwestern to southeastern parts of Skåne. The areas in the southwest and southeast contain two major plains (Söderslätt and Österlen respectively) that are some of the most fertile in the world. There farmers grow sugar beets, corn, peas, and rapeseed. Skåne also contains three national parks, and miles and miles of scenic coastline with beaches and fishing.



Bohuslän


Bohuslän is located on Sweden's western coast and features a breathtaking rocky coast and archipelago (Sweden's second largest) with roughly 3,000 islands and 5,000 islets to be explored. The area was ranked 7th among the world's "last great wilderness areas" by CNN Travel for its beautiful granite coasts, picturesque fishing villages, and Kosterhavet National Park's marine nature reserve—Sweden's first and home to Sweden's largest seal colony. Bohuslän, while also containing multiple forests and meadows to hike, is a sailor and kayaker's dream with miles of coastline to roam and explore.

With all this beautiful open space and the mandated-by-law right to freely roam about it, why haven't you bought your ticket yet? Sweden and its unending beauty awaits.

[illegible]


General Snus Elevated Stories: March [BEHIND AGE GATE] 3-21-23 - current

MORE FROM GENERAL




ENJOY OUR WINTER COCKTAIL MENU

We've crafted a cocktail menu sure to keep you warm all winter long.




HOW ORIGINALS LOVE THEIR GEAR

The gear we use says a lot about us...so does how we take care of it.




REALISTIC RESOLUTIONS

New Year's resolutions shouldn't be intimidating. We're making sure you stay cool and calm by setting realistic...




HOW TO ENTERTAIN WHILE WAITING TO ENTERTAIN

Cookies in the oven? Chili in the slow cooker? But the guests are here? We've got ideas on activities to fill the...



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A LITTLE ORIGINALITY CHANGES EVERYTHING

Appreciating the unique ingredients that turn boring into wow—and the science behind it.

ALL ABOUT ALLEMANGRÄTTEN

The Allemangrätten is a traditional Swedish dish made of meat and potatoes. It's a popular dish in Sweden and is often served at family gatherings and celebrations. The dish is made by cooking meat in a pot with potatoes and vegetables. The meat is usually pork or beef, and the potatoes are boiled. The vegetables are typically carrots and peas. The dish is served with a sauce made of meat juices and cream. It's a hearty and comforting dish that is perfect for cold weather.



KEEP UP WITH ALL THINGS GENERAL

Sign up for our newsletter to receive the latest news and updates from General Snus.

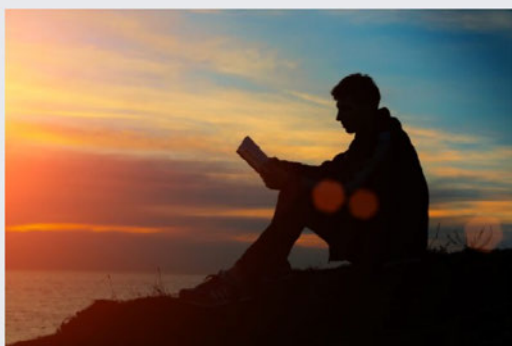
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April [BEHIND AGE GATE]

4-4-23 - current

SELF-IMPROVEMENT FOR ORIGINALS

Maverick hacks the world didn't see coming

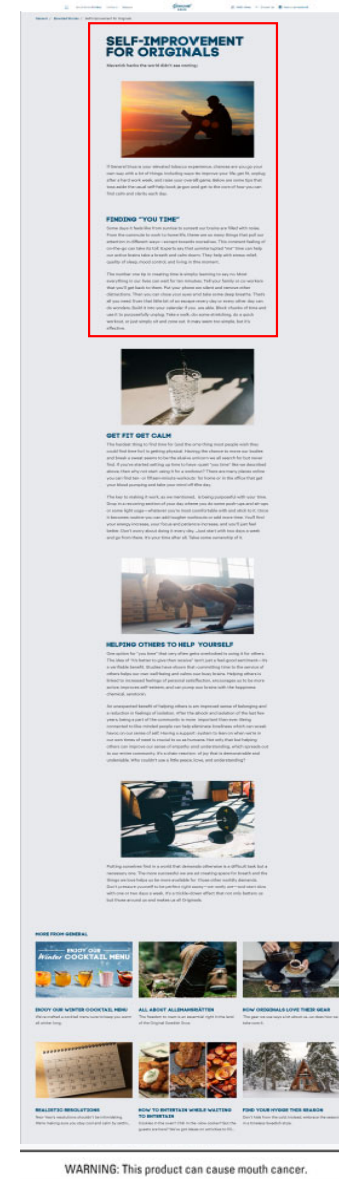


If General Snus is your elevated tobacco experience, chances are you go your own way with a lot of things. Including ways to improve your life, get fit, unplug after a hard work week, and raise your overall game. Below are some tips that toss aside the usual self-help book jargon and get to the core of how you can find calm and clarity each day.

FINDING "YOU TIME"

Some days it feels like from sunrise to sunset our brains are filled with noise. From the commute to work to home life, there are so many things that pull our attention in different ways—except towards ourselves. This constant feeling of on-the-go can take its toll. Experts say that uninterrupted “me” time can help our active brains take a breath and calm down. They help with stress relief, quality of sleep, mood control, and living in the moment.

The number one tip in creating time is simply learning to say no. Most everything in our lives can wait for ten minutes. Tell your family or co-workers that you'll get back to them. Put your phone on silent and remove other distractions. Then you can close your eyes and take some deep breaths. That's all you need. Even that little bit of an escape every day or every other day can do wonders. Build it into your calendar if you are able. Block chunks of time and use it to purposefully unplug. Take a walk, do some stretching, do a quick workout, or just simply sit and zone out. It may seem too simple, but it's effective.



General Snus Elevated Stories: April con't [BEHIND AGE GATE] 4-4-23 - current



GET FIT GET CALM

The hardest thing to find time for (and the one thing most people wish they could find time for) is getting physical. Having the chance to move our bodies and break a sweat seems to be the elusive unicorn we all search for but never find. If you've started setting up time to have quiet "you time" like we described above, then why not start using it for a workout? There are many places online you can find ten- or fifteen-minute workouts for home or in the office that get your blood pumping and take your mind off the day.

The key to making it work, as we mentioned, is being purposeful with your time. Drop in a recurring section of your day where you do some push-ups and sit-ups or some light yoga—whatever you're most comfortable with and stick to it. Once it becomes routine you can add tougher workouts or add more time. You'll find your energy increase, your focus and patience increase, and you'll just feel better. Don't worry about doing it every day. Just start with two days a week and go from there. It's your time after all. Take some ownership of it.




HELPING OTHERS TO HELP YOURSELF

One option for "you time" that very often gets overlooked is using it for others. The idea of "it's better to give than receive" isn't just a feel-good sentiment—it's a verifiable benefit. Studies have shown that committing time to the service of others helps our own well-being and calms our busy brains. Helping others is linked to increased feelings of personal satisfaction, encourages us to be more active, improves self-esteem, and can pump our brains with the happiness chemical, serotonin.

An unexpected benefit of helping others is an improved sense of belonging and a reduction in feelings of isolation. After the shock and isolation of the last few years, being a part of the community is more important than ever. Being connected to like-minded people can help eliminate loneliness which can wreak havoc on our sense of self. Having a support system to lean on when we're in our own times of need is crucial to us as humans. Not only that but helping others can improve our sense of empathy and understanding, which spreads out to our entire community. It's a chain reaction of joy that is demonstrable and undeniable. Who couldn't use a little peace, love, and understanding?

SELF-IMPROVEMENT FOR ORIGINALS

Research backs the words "be a better you."



If there's one thing we've learned in the past few years, it's that we can't control everything. But we can control how we respond to what we can't control. That's the key to being a better you. It's not about being perfect. It's about being better than you were yesterday. And that's a goal we can all agree on.

FINDING "YOU TIME"

Some days it feels like there's no time to be a better you. But there is. It's just a matter of finding it. And that's the key to being a better you. It's not about being perfect. It's about being better than you were yesterday. And that's a goal we can all agree on.

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MORE FROM GENERAL




BEHIND OUR WATER COOLERS

How we've been keeping up with the world's most popular beverage.



ALL ABOUT COMMUNITIES


The power of being part of something bigger than yourself.



HOW ORIGINALS LIVE THEIR LIFE


The key to being a better you is to be a better person.

RELATED RESOURCES




HOW TO IMPROVE YOURSELF

How to be a better you in 30 days.



HOW TO IMPROVE YOURSELF

How to be a better you in 30 days.



HOW TO IMPROVE YOURSELF

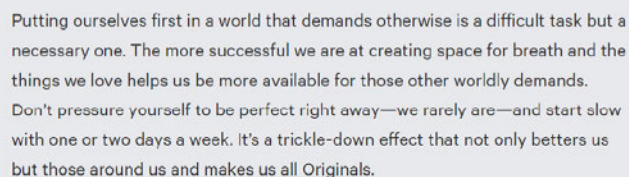
How to be a better you in 30 days.

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4-4-23 - current



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May [BEHIND AGE GATE]

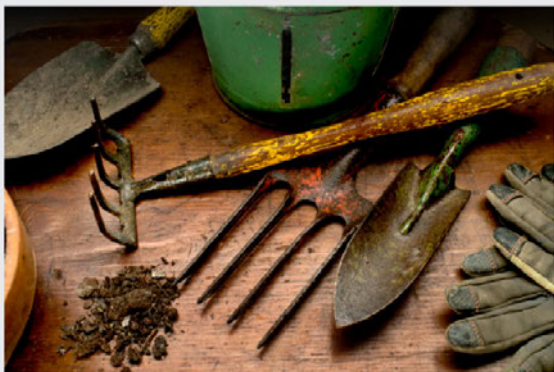
5-9-23 - current

GARDEN LIKE AN ORIGINAL

Elevate your lifestyle with your own food and flowers.



May is *Gifts from the Garden* month—as declared by celebrated gardener, CL Fornari—a time to celebrate the food and beauty you can harvest from your own backyard. There's something wonderfully satisfying about growing something from a simple seed in the ground. Cultivating the soil and providing the right amount of nourishment can really get you in touch with your roots. It can be a challenge, but the payoff is well worth the effort. Here are some tips for maintaining your garden so you can enjoy a delicious garden that pays off year-round.



MAINTAINING YOUR GARDEN

Now that you've spent all spring planting and organizing your garden, here's some watering, plant maintenance, and pest protection steps you can take between now and harvest to make sure your flowers and veggies are bright and beautiful and plump:

PROPER WATERING:

Water only as often as necessary for your specific plants. Overwatering can lead to fungi growth, leaf spots, and unhealthy plants. A good rule of thumb: let the soil dry between waterings so you don't oversaturate (1-2 times per week).

Water the soil around your plants rather than on the plants themselves. This lessens the chances of fungi growth.

Best times to water are early morning or early evening when the soil is cooler. This lowers evaporation rates during the heat of the day.



MAINTAINING YOUR GARDEN

[illegible]

Pruning is the removal of dead, damaged, or diseased plant material. Pruning is also used to shape the plant, to remove unwanted growth, and to improve the plant's health. Pruning is a common horticultural practice that is used on a wide variety of plants, including trees, shrubs, and flowering plants. Pruning is done at different times of the year, depending on the plant and the climate. Pruning is done to remove dead, damaged, or diseased wood, to shape the plant, to remove unwanted growth, and to improve the plant's health. Pruning is a common horticultural practice that is used on a wide variety of plants, including trees, shrubs, and flowering plants. Pruning is done at different times of the year, depending on the plant and the climate.

- Both can have directly or indirectly for water in storage
- Use a steady stream to release air as you stand at the top, so they can't breathe
- Use 2" of forehead, upper chest area press down from growing the lungs, all the air in your chest stays with you and you suffocate

- **Substantive**
 - Built on a math foundation, our gender is independent from us, and girls
 - Born strong, our nature is to be brave, gentle, and to be a part of our family
 - Following a higher level of study, there is a reward in our mind, our gender is a balance of both sides



- **Be sure to seal the perimeter and repair any leaks.** A leaking air leak is the most common cause of air conditioning problems. Check the air filter, the condenser coils, and the evaporator coils. If the air filter is dirty, it will restrict the airflow and the system will not cool properly. If the condenser coils are dirty, they will not absorb heat properly. If the evaporator coils are dirty, they will not release heat properly. If there is a leak in the refrigerant, the system will not cool properly.
- **Check the thermostat.** Make sure the thermostat is set to the correct temperature and that it is working properly. If the thermostat is not working, it will not send the correct signals to the air conditioning system.
- **Check the condenser coils.** The condenser coils are located outside the house. They should be cleaned regularly to remove dirt and debris. If the coils are dirty, they will not absorb heat properly.
- **Check the evaporator coils.** The evaporator coils are located inside the house. They should be cleaned regularly to remove dirt and debris. If the coils are dirty, they will not release heat properly.
- **Check the refrigerant level.** The refrigerant is the fluid that circulates through the air conditioning system. If the level is low, the system will not cool properly. A professional technician should check the level and recharge the system if necessary.
- **Check the ductwork.** The ductwork is the system of pipes that carries the air from the air conditioning unit to the rooms. If there are leaks or blockages in the ductwork, the air will not reach the rooms properly. A professional technician should check the ductwork and seal any leaks or remove any blockages.
- **Check the fan motor.** The fan motor is the part of the air conditioning unit that circulates the air. If the motor is not working, the air will not be circulated properly. A professional technician should check the motor and replace it if necessary.
- **Check the compressor.** The compressor is the part of the air conditioning unit that pumps the refrigerant. If the compressor is not working, the system will not cool properly. A professional technician should check the compressor and replace it if necessary.

SEASONAL BARRIER CHECK-LIST (YEA! NATIVE BACKYARD)

- `getSystemProperties()`

- Transport possible with the system
- power and fluids stream possible to share
- From power side the heat distribution is more simple



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General Snus Elevated Stories:

May con't [BEHIND AGE GATE]

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PLANT MAINTENANCE:

Pinching off old flower blooms or leaves, or **deadheading**, encourages new growth in your plants. Deadhead at the beginning or middle of summer to trick your plants to keep producing.

Prune your plants by cutting back branches to control and make room for growth, reduce shade spots, and increase air circulation around your plants.

Culling is great to create more space for your plants and vegetables to grow. Clean up unhealthy parts of plants and remove dead plants so they aren't pulling nutrients from healthier plants in your garden.

PEST PROTECTION:

Weeds:

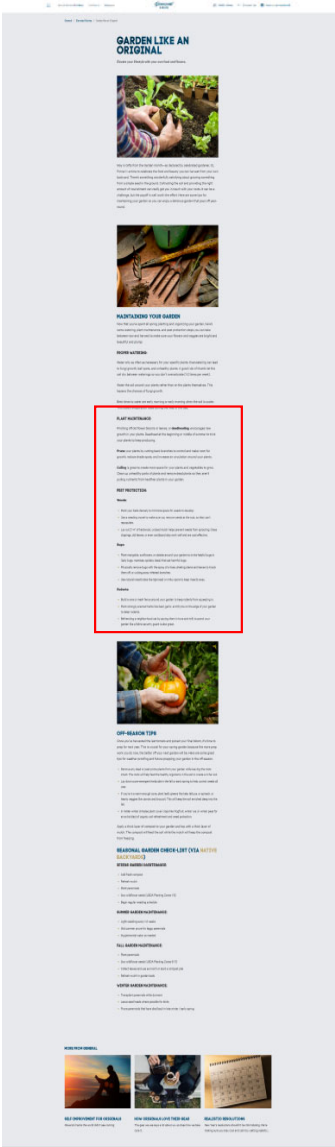
- Plant your beds densely to minimize space for weeds to develop.
- Use a weeding trowel to make sure you remove weeds at the root, so they can't repopulate.
- Lay out 2"-4" of hardwood, undyed mulch helps prevent weeds from sprouting. Grass clippings, old leaves, or even cardboard also work well and are cost effective.

Bugs:

- Plant marigolds, sunflowers, or daisies around your garden to invite helpful bugs in (lady bugs, mantises, spiders, bees) that eat harmful bugs.
- Physically remove bugs with the spray of a hose, shaking stems and leaves to knock them off, or cutting away infested branches.
- Use natural insecticides like Spinosad or milky spore to keep insects away.

Rodents:

- Build a wire or mesh fence around your garden to keep rodents from squeezing in.
- Plant strongly scented herbs like basil, garlic, and thyme on the edge of your garden to deter rodents.
- Befriending a neighborhood cat by paying them in tuna and milk to patrol your garden like a feline security guard is also great.



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OFF-SEASON TIPS

Once you've harvested the last tomato and picked your final bloom, it's time to prep for next year. This is crucial for your spring garden because the more prep work you do now, the better off your next garden will be. Here are some great tips for weather-proofing and future-prepping your garden in the off-season.

- Remove any dead or past-prime plants from your garden while leaving the roots intact. The roots will help feed the healthy organisms in the soil to create a richer soil.
- Lay down a pre-emergent herbicide in the fall or early spring to help control weeds all year.
- If you're in a warm enough zone, plant leafy greens like kale, lettuce, or spinach, or hearty veggies like carrots and broccoli. This will keep the soil enriched deep into the fall.
- In milder winter climates plant cover crops like frogfruit, winter rye, or winter peas for an extra blast of organic soil refreshment and weed protection.

Apply a thick layer of compost to your garden and top with a thick layer of mulch. The compost will feed the soil while the mulch will keep the compost from freezing.

SEASONAL GARDEN CHECK-LIST (VIA NATIVE BACKYARDS)

SPRING GARDEN MAINTENANCE:

- Add fresh compost
- Refresh mulch
- Plant perennials
- Sow wildflower seeds (USDA Planting Zones 1-5)
- Begin regular weeding schedule

SUMMER GARDEN MAINTENANCE:

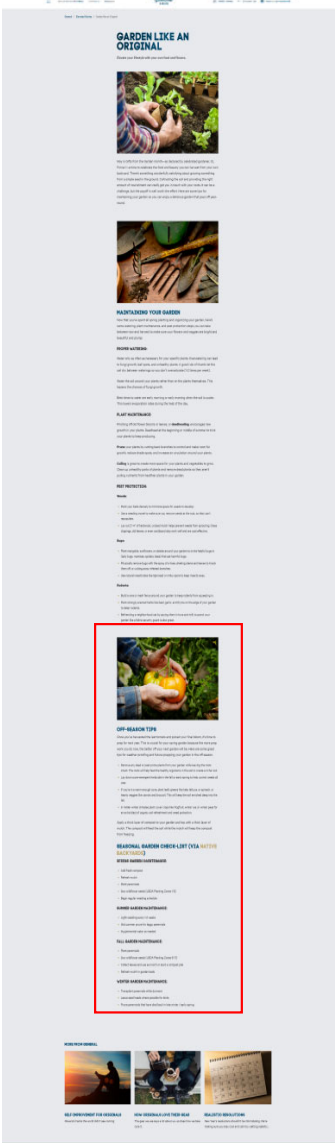
- Light weeding every 1-2 weeks
- Mid summer prune for leggy perennials
- Supplemental water as needed

FALL GARDEN MAINTENANCE:

- Plant perennials
- Sow wildflower seeds (USDA Planting Zones 6-11)
- Collect leaves and use as mulch or start a compost pile
- Refresh mulch in garden beds

WINTER GARDEN MAINTENANCE:


- Transplant perennials while dormant
- Leave seed heads where possible for birds
- Prune perennials that have died back in late winter / early spring




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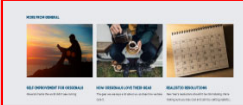
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General Snus Elevated Stories: June [BEHIND AGE GATE] 6-6-23 - current

TO SLEEP IN NATURE IS TO KNOW NATURE

Camping can be a calming way to celebrate, and be one with, nature



It's safe to say that nearly everyone loves nature—right up to the point where they need to sleep outside in it. For most taking a hike in the woods is one thing, while pitching a tent and building a fire is another entirely. There's no need to fear camping if you're prepared, however. For National Camping Week we want to help you change your view on camping. Getting the right supplies and preparing for surprises can turn your camping experience into a relaxing connection with nature and unlock a new love for the environment around you.

Note: These gear recommendations and tips are centered around “car camping,” or camping at designated campsites, rather than backpack camping where you're hiking and setting up camps along the way. If you're looking for tips on more rustic camping like that, we suggest checking out brands like REI that have great camping guides.

CAMPING GEAR ESSENTIALS


Before you head to the great outdoors, make sure you're prepared. Nothing's worse than getting to the campsite and realizing you forgot a place to sit or sleep. This is a list of bare essentials you'll need, but not exhaustive list. If you know you won't need some items, feel free to ignore. Also, much of this equipment (especially expensive pieces like tent and sleeping bag) can be rented from an outdoor store so you don't have to invest too much money right away if you want to test your love of camping first.

TENT

Arguably the most important part of your camping collection, you want a tent that keeps you protected from the elements and is big enough for you and your crew to sleep comfortably. If you've got a larger budget, opt for a slightly larger tent for some extra breathing room. You may also want to check the height of the tent if you want room to stand-up for more movement. There are myriad options for number of doors, vents, storage room, etc. so do a little research for your ideal choice. Also, as a tip, practice setting up your tent at home first, so you don't waste time and energy getting frustrated at the camp site.

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SLEEPING BAG

When it comes to sleeping bags, there are a few things to consider. First, the temperature rating. This is the lowest temperature the bag is designed to keep you warm. If you're camping in a warm climate, a bag with a higher rating is fine. If you're camping in a cold climate, you'll want a bag with a lower rating. Second, the weight. A lighter bag is easier to carry, but a heavier bag might be more comfortable. Third, the material. Some bags are made of synthetic materials, while others are made of natural materials like wool. Each has its own pros and cons.

STOVE

A camp stove is a great way to cook your food and keep yourself warm. There are a few different types of camp stoves, including propane, alcohol, and wood-burning. Each has its own pros and cons. Propane stoves are the most common, but they can be expensive. Alcohol stoves are a good option if you're on a budget. Wood-burning stoves are a great option if you're camping in a wooded area.

TRAILER

A trailer is a great way to transport your camping gear. There are a few different types of trailers, including car trailers, horse trailers, and boat trailers. Each has its own pros and cons. Car trailers are the most common, but they can be expensive. Horse trailers are a good option if you're camping with horses. Boat trailers are a good option if you're camping near a body of water.

NEW TO SLEEP

There are a few different ways to sleep in nature. You can sleep in a tent, a sleeping bag, or a hammock. Each has its own pros and cons. Tents are the most common, but they can be expensive. Sleeping bags are a good option if you're on a budget. Hammocks are a great option if you're camping in a wooded area.

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SLEEPING BAG & PAD

Your sleeping bag can be the difference between a good night's sleep or a nightmare of sweat or chills. Check the weather around your trip and grab a sleeping bag with the right temperature rating. For most trips, a summer-style bag should do the trick. However, if it's fall or early spring and the weather fluctuates, then look to 3-season bags to keep you comfortable. You'll also want to grab a sleeping pad to put under your bag for some extra cushion. Forgo large air mattresses, and instead look for pads of thicker foam with a little insulation. They're easier to pack, and you won't have to worry about the hassle of inflating them.

CAMPING STOVE

If you are already comfortable building a fire and using it to cook and make morning coffee, then you won't need to worry about a camping stove. But for the rest of us, having these easy to use stoves are a life saver—especially when you're blurry-eyed in the morning and just need that first hot cup of coffee. A standard two burner stove is great to cook breakfast and heat coffee at the same time. Grab a couple canisters of fuel and a long stove lighter, and you'll start your day on the right foot—preferably one filled with coffee.

LANTERNS & HEADLAMPS

Since most camp sites don't include mood lighting and campfires only illuminate so far, you'll want to bring along your own lighting. Grabbing a lantern or two for ambient light around the campsite or in your tent is a great idea. Same can be said for a small headlamp. Headlamps are great for keeping your hands free for setting up food or supplies, or late-night trips to the bathroom.

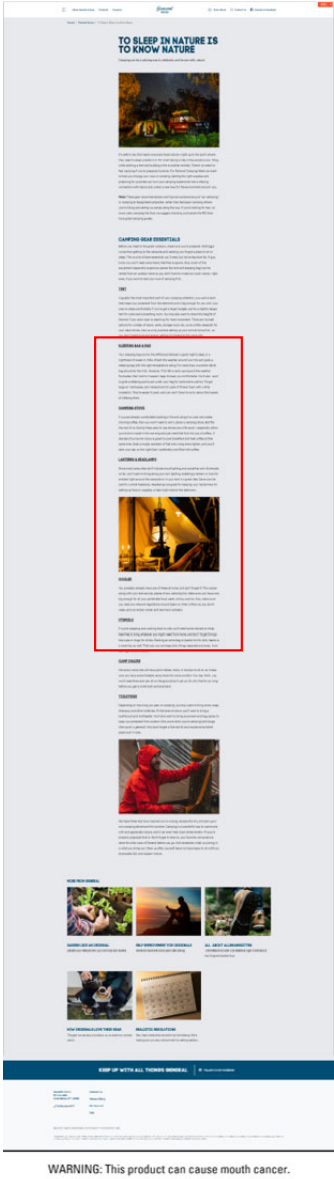


COOLER

You probably already have one of these at home, but don't forget it! The cooler along with your tent are key pieces of any camping trip. Make sure you have one big enough for all your perishable food, water, drinks, and ice. Also, make sure you read any relevant regulations around bears or other critters so you don't wake up to an empty cooler and new hairy campers.

UTENSILS

If you're prepping and cooking food on site, you'll need some utensils to help. Feel free to bring whatever you might need from home, and don't forget things like cups or mugs for drinks. Packing an extra bag or plastic bin for dirty items is a smart tip, as well. That way you can keep dirty things separate and away from late night animal visitors.



General Snus Elevated Stories: June con't [BEHIND AGE GATE]

CAMP CHAIRS

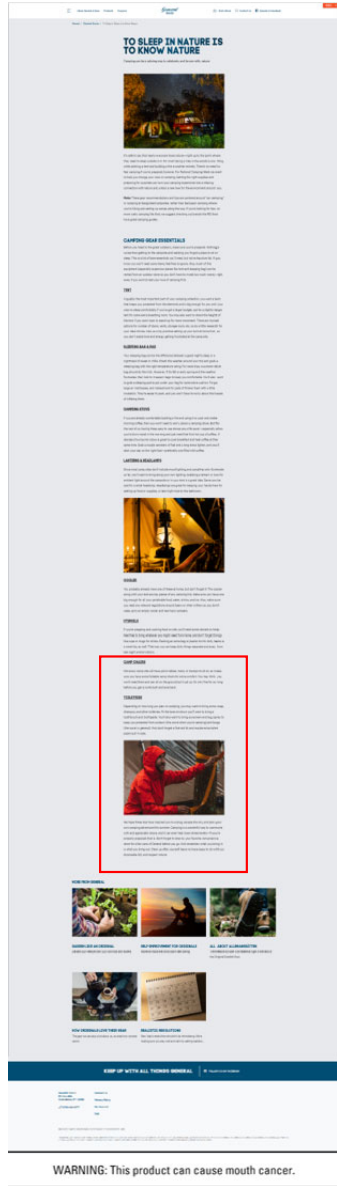
Not every camp site will have picnic tables, rocks, or stumps to sit on, so make sure you have some foldable camp chairs for extra comfort. You may think you won't need them and can sit on the ground but trust us: it's only fine for so long before you get a numb butt and sore back.

TOILETRIES

Depending on how long you plan on camping, you may want to bring some soap, shampoo, and other toiletries. At the bare minimum you'll want to bring a toothbrush and toothpaste. You'll also want to bring sunscreen and bug spray to keep you protected from sunburn (the worst when you're camping) and bugs (the worst in general). And don't forget a first-aid kit and maybe extra toilet paper just in case.




We hope these tips have inspired you to unplug, escape the city, and plan your own camping adventure this summer. Camping is a wonderful way to commune with and appreciate nature, and it can even help lower stress levels—if you're properly prepared, that is. Don't forget to stop by your favorite convenience store for a few cans of General before you go. And remember: what you bring in is what you bring out. Clean up after yourself, leave no trace (easy to do with our disposable lid), and respect nature!




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July [BEHIND AGE GATE]

7-4-23 - current

ULTRAMARATHONS – LIKE MARATHONS BUT FOREVER

Most think marathons are a crazy feat. But let's meet a true sporting original: Ultramarathons.



For many casual runners and weekend road warriors, surviving the 26.1 miles of chaffing, exhaustion, and the constant "why did I do this again?" of a marathon is a great water cooler story and "fun" way of exploring cities and landscapes. However, some folks run marathons and think, "I should go...further!" Thus, the invention of a true original: ultramarathons. These 50K, 100K, and 100+ mile races test physical and mental endurance and take runners through all sorts of terrains and elevations. Ultramarathons have become more popular in the last couple decades, and intrepid adventurers are taking up this extreme sport that even regular marathoners think is crazy.



ORIGINS

The modern history of ultramarathons is often dated back to around the 19th century when exploits of runners covering large distances were breathlessly reported as heroic stories of daredevil deeds and bravery. People like Edward Payson "The Pedestrian" Weston—who walked from Boston to Washington, DC in 10.5 days for Abraham Lincoln's inauguration in 1861 and from New York to San Francisco in 100 days in 1909—were made into celebrities across the US.

One of the first official ultramarathons in the US took place in 1911, in Bellingham, Washington. The 50K race sent runners 10,000 ft up Mount Baker and back. In 1920, a 100K ultramarathon was part of the Central American Games in Mexico. The winners—two members of the Tarahumara (or *Rarámuri*) people indigenous to Mexico known for their long-distance running ability—finished first in a time of 9hrs 37min. The popularity of the race has since gained traction across the globe with numerous world sanctioned races of 50K and 100K as well as timed races (24hr and 48hr) set up by the International Association of Ultrarunners (IAU) founded in 1984.

[illegible]

7-4-23 - current



The IAU organizes world championships in 50K, 100K, 24hr, and Trail distances, as well as European, Asian, and Americas championships, and other qualifying races around the world. There are also many popular ultramarathons that occur yearly. One of the oldest is the 55-mile Comrades Marathon in South Africa that's been run since 1921. The world's oldest 100-mile trail run is the Western States Endurance Run in California that's been held every year since 1977.


It takes a certain amount of grit and determination to run an ultramarathon, but the payoff can be extremely satisfying (we assume). If you're crazy and original enough to want to do it, here is [a link](#) for some gear tips, and just find the nearest race to start training. Godspeed. We'll be along the trail cheering you on from our lawn chair and waiting with a beer at the end.




General Snus Elevated Stories: July con't [BEHIND AGE GATE]

7-4-23 - current


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Camping can be a calming way to celebrate, and be one with, nature




GARDEN LIKE AN ORIGINAL
Elevate your lifestyle with your own food and flowers.



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Maverick hacks the world didn't see coming



HOW ORIGINALS LOVE THEIR GEAR
The gear we use says a lot about us...so does how we take care it.



REALISTIC RESOLUTIONS
New Year's resolutions shouldn't be intimidating. We're making sure you stay cool and calm by setting realistic...

ULTRAMARATHONS - LIKE MARATHONS BUT FOREVER



CRISIS



POPULAR FACTS



TO SLEEP IN NATURE IS TO KNOW NATURE

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HOW ORIGINALS LOVE THEIR GEAR

REALISTIC RESOLUTIONS

KEEP UP WITH ALL THINGS ORIGINAL

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General Snus Elevated Stories: August [BEHIND AGE GATE]

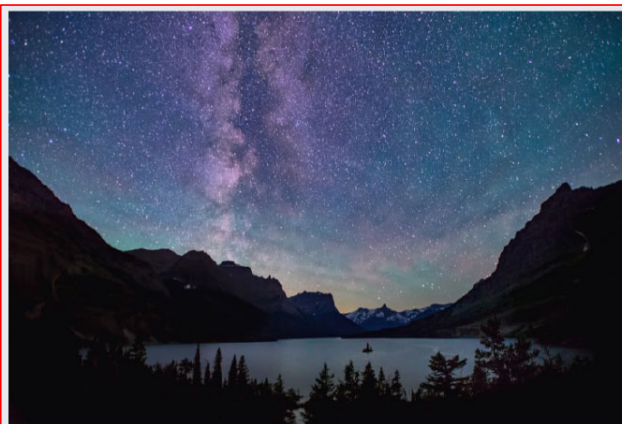
8-8-23 - current

DARK PARK, BRIGHT UNIVERSE

Get out beyond the city glow for stargazing like an Original



If you live in a large city (or even a medium-sized one) you have probably noticed that you can't see many stars in the night sky. The light pollution from streetlamps, buildings, and car headlights create an ambient glow that blocks out most of the stars visible to us on Earth. Get just outside of town, however, and watch the sky explode with light. Thankfully, there is an organization called The International Dark-Sky Association (IDA) that wants to preserve our night sky and the awe-inspiring lights it contains. These dark sky places are great to visit and camp, a great way to learn more about the stars, and a great way to blow your mind without leaving the comfort of the Solar System.



WHAT MAKES A DARK SKY PLACE?

The IDA's main mission is preserving the night sky and advocating against light pollution caused by artificial lighting which affects humans, wildlife, and our climate. On their [website](#), the IDA lists five distinctions within their International Dark Sky Places program. Each distinction has its own set of guidelines for designation based on "land management, size, and sky quality," and are meant to preserve and protect dark sites from harmful light pollution through responsible lighting policies and education. Every space goes through a rigorous 1-3 year certification process before becoming official.

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General Snus Elevated Stories:

August con't [BEHIND AGE GATE]

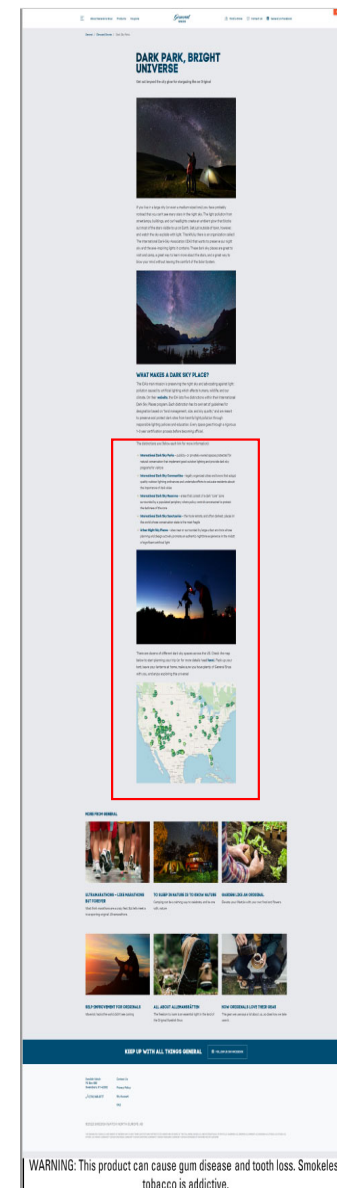
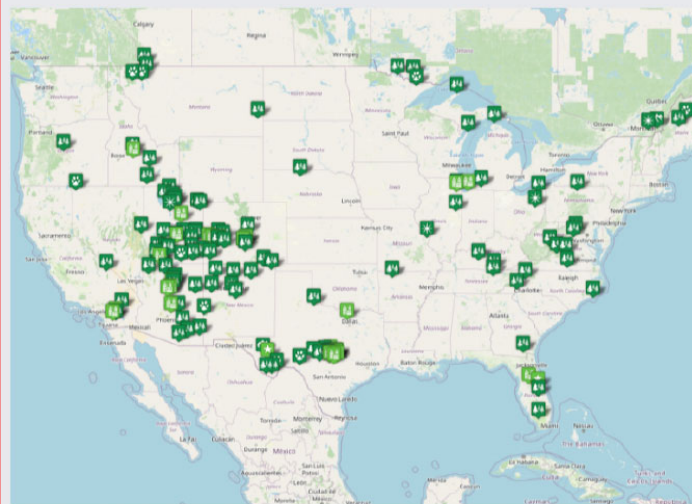
8-8-23 - current

The distinctions are (follow each link for more information):

- **International Dark Sky Parks** – publicly- or privately-owned spaces protected for natural conservation that implement good outdoor lighting and provide dark sky programs for visitors
- **International Dark Sky Communities** – legally organized cities and towns that adopt quality outdoor lighting ordinances and undertake efforts to educate residents about the importance of dark skies
- **International Dark Sky Reserves** – areas that consist of a dark “core” zone surrounded by a populated periphery where policy controls are enacted to protect the darkness of the core
- **International Dark Sky Sanctuaries** – the more remote, and often darkest, places in the world whose conservation state is the most fragile
- **Urban Night Sky Places** – sites near or surrounded by large urban environs whose planning and design actively promote an authentic nighttime experience in the midst of significant artificial light



There are dozens of different dark sky spaces across the US. Check the map below to start planning your trip (or for more details head [here](#)). Pack up your tent, leave your lanterns at home, make sure you have plenty of General Snus with you, and enjoy exploring the universe!



General Snus Elevated Stories: August con't [BEHIND AGE GATE]

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MORE FROM GENERAL

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ALL ABOUT ALLEMANSRÄTTEN

The freedom to roam is an essential right in the land of the Original Swedish Snus

HOW ORIGINALS LOVE THEIR GEAR

The gear we use says a lot about us...so does how we take care it.


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20 Photos
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Dark Park, Bright Universe

How a small group of people changed the world



For those who love the night, the dark sky is a treasure trove of wonders. The night sky is a vast, dark canvas, filled with stars, galaxies, and other celestial objects. The night sky is a source of inspiration and wonder for many people. The night sky is a source of beauty and awe. The night sky is a source of knowledge and discovery. The night sky is a source of hope and faith. The night sky is a source of love and life.



What Makes a Dark Sky Place?

Dark sky places are areas where the night sky is visible to the naked eye. They are places where the light pollution is low enough to see the stars and other celestial objects. Dark sky places are places where the night sky is a source of beauty and awe. Dark sky places are places where the night sky is a source of knowledge and discovery. Dark sky places are places where the night sky is a source of hope and faith. Dark sky places are places where the night sky is a source of love and life.



Dark Sky Places Around the World

There are many dark sky places around the world. Some of the most famous dark sky places are in the United States, Canada, and Europe. There are also many dark sky places in Asia, Africa, and South America. Dark sky places are places where the night sky is a source of beauty and awe. Dark sky places are places where the night sky is a source of knowledge and discovery. Dark sky places are places where the night sky is a source of hope and faith. Dark sky places are places where the night sky is a source of love and life.



Dark Sky Places



Dark Sky Places
A list of dark sky places around the world.



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General Snus Elevated Stories: September [BEHIND AGE GATE]

9-5-23 - current

HONORING THE TRUE LEADER OF FALL - APPLES

Whether you bake them, juice them, or just eat them off the branch, apples are the rightful kings of Fall.



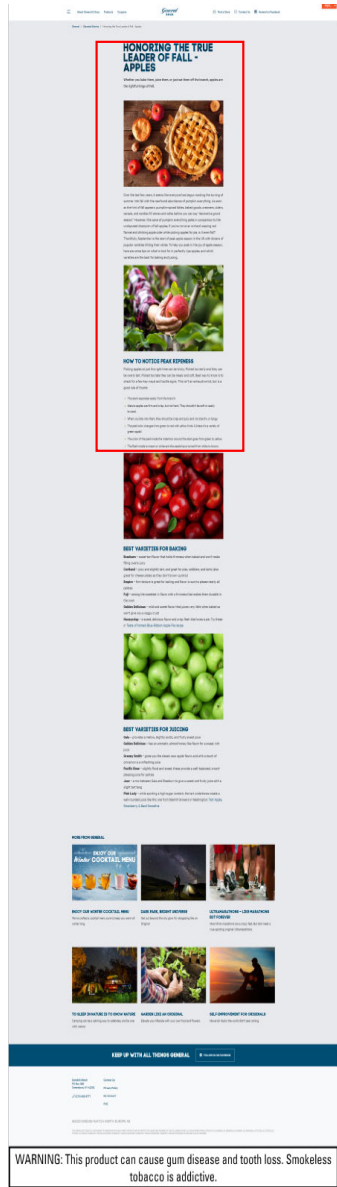
Over the last few years, it seems like everyone has begun marking the turning of summer into fall with the newfound abundance of pumpkin everything. As soon as the hint of fall appears, pumpkin-spiced lattes, baked goods, creamers, ciders, cereals, and candles fill stores and cafes before you can say “decorative gourd season.” However, this wave of pumpkin everything pales in comparison to the undisputed champion of fall: apples. If you’re not at an orchard wearing red flannel and drinking apple cider while picking apples for pie, is it even fall? Thankfully, September is the start of peak apple season in the US with dozens of popular varieties hitting their stride. To help you soak in the joy of apple season, here are some tips on what to look for in perfectly ripe apples, and which varieties are the best for baking and juicing.



HOW TO NOTICE PEAK RIPENESS

Picking apples at just the right time can be tricky. Picked too early and they can be overly tart. Picked too late they can be mealy and soft. Best way to know is to check for a few key visual and tactile signs. This isn't an exhaustive list, but is a good rule of thumb:

- The stem separates easily from the branch.
- Mature apples are firm and crisp, but not hard. They shouldn't be soft or easily bruised.
- When you bite into them, they should be crisp and juicy and not starchy or tangy.
- The peel color changes from green to red with yellow hints. (Unless it's a variety of green apple)
- The color of the peel inside the indentation around the stem goes from green to yellow.
- The flesh inside is cream or white and the seeds have turned from white to brown.



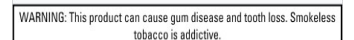
9-5-23 - current



Honeycrisp – a sweet, delicious flavor and crisp flesh that loves a pie. Try these in Taste of Home's Blue-Ribbon Apple Pie recipe




Pink Lady – while sporting a high sugar content, the tart undertones create a well-rounded juice like this one from Stemilt Growers in Washington: [Tart Apple Strawberry, & Basil Smoothie](#)



General Snus Elevated Stories: September con't [BEHIND AGE GATE]


9-5-23 - current

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We've crafted a cocktail menu sure to keep you warm all winter long.




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HONORING THE TRUE LEADER OF FALL - APPLES




HOW TO NOTICE PEAK SPENDING




BEST TARGETS FOR BUDGETING




BEST TARGETS FOR BUDGETING




WINTER WISDOM




ENJOY OUR WINTER COCKTAIL MENU




DARK PARK, BRIGHT UNIVERSE




ULTRAMARATHONS – LIKE MARATHONS BUT FOREVER



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GARDEN LIKE AN ORIGINAL



SELF-IMPROVEMENT FOR ORIGINALS

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General Snus Website Tobacco User Screener

[OUTSIDE AGE GATE] 4-25-23 - current

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General Snus products are only for current tobacco or nicotine users, age 21+. Since you're not a current tobacco or nicotine user, there's no need to register on our website because General isn't for you.

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General / Privacy Policy

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Swedish Match is committed to ensuring that our consumers' privacy is protected and you can be assured that such information will only be used in accordance with this privacy statement.

Swedish Match has a policy of protecting the confidentiality and security of information we collect from consumers and does not share your non-public personal information with unaffiliated third parties. Information is only shared with your consent except for the specific purposes below, in accordance with all applicable laws.

This privacy policy was last updated on September 27, 2023. Please review it carefully and check this page periodically, as Swedish Match may modify its privacy policy from time to time and use customer information for new, unanticipated uses not previously disclosed.

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HOW WE COLLECT INFORMATION

USE AND SHARING OF INFORMATION

DISPATCH FROM

INTERNATIONAL DATA TRANSFER

COOKIES AND TRACKING TECHNOLOGIES

SECURITY

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For each visitor, our web server automatically recognizes only the consumer's domain name. We collect the domain name, personal and contact information (including name, address, date of birth, email address and telephone number, where possible) of visitors to our website, aggregate information on what pages consumers access or visit, and information volunteered by the consumer, such as survey information and/or site registrations.

When registering on our websites, we collect certain personal information including your legal first name, preferred first name, last name, address (including street, city, state, and zip code), telephone number (if you choose to provide), your date of birth, email, and whether you use tobacco or nicotine products.

In addition, we may collect various types of personal information about you, whether through our Websites or in other contexts in connection with our Products and Services:

- information about your orders, including information necessary to fulfill them
- information necessary to verify your age
- information you give us in communications (e.g., calls, e-mails, chats) you have with contact centers
- information you give us to participate in loyalty rewards programs
- information about your experiences using our Products and Services
- information about your preferences and interests (including information that we infer from other information, for example from statistical information)
- statistical information about you (for example, statistical information about people in certain geographical areas)

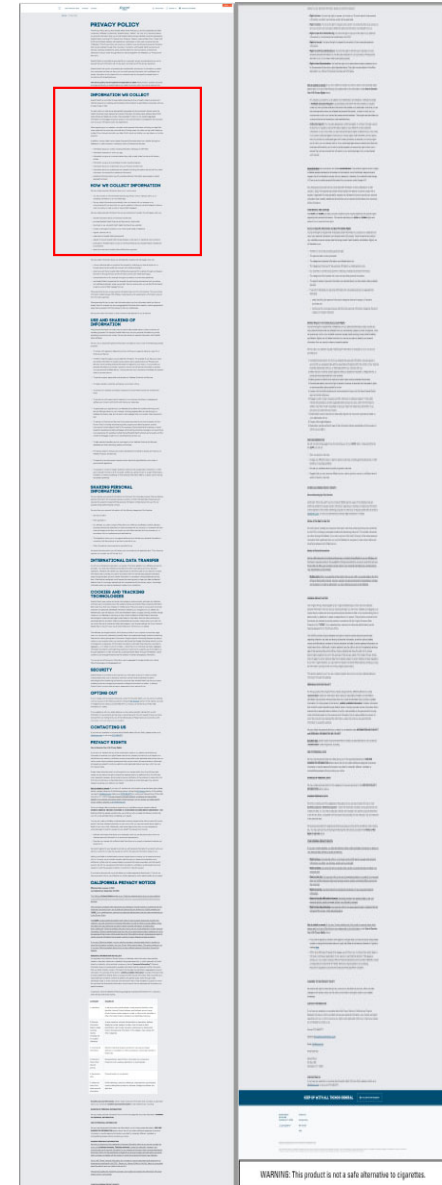
HOW WE COLLECT INFORMATION

We may collect personal information about you in various ways:

- You may provide us with information directly (e.g., filling in a form, making a call to us, or uploading information to us via a mobile app)
- We may collect information automatically when you interact with our systems or we communicate with you (e.g., when you use our website or, where we use technologies to observe when you receive or open e-mails or receive SMS messages)

We may collect personal information that you provide directly. Typically, this will happen when you:

- request information about our Products and Services
- purchase Swedish Match Products and Services at a retail outlet
- download, or use, a Swedish Match digital touchpoint (e.g., website)
- contact us through a touchpoint, or by e-mail, social media or telephone
- register a device with us
- subscribe to a Swedish Match panel portal
- register to receive Swedish Match press releases, e-mail alerts, or marketing communications
- participate in Swedish Match surveys or (where permitted by law) Swedish Match competitions or promotions
- attend an event that a Swedish Match affiliate has organized



General Snus Website Privacy Policy

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10-5-23 - current

We may collect information about you automatically. Typically, this will happen when you:

- visit an outlet that sells our products (for example, by collecting your data at check-out, or through sensors at the outlet that connect with mobile technology)
- attend an event that a Swedish Match affiliate has organized (for example, through purchases at the event or through sensors at the event that connect with mobile technology)
- communicate with us (for example, through a touchpoint, or social media platforms)
- use Swedish Match touchpoints (for example, through tracking mechanisms (such as cookies and web beacons/pixels), where we use them, that you receive when you use the PMI touchpoint or get an e-mail or SMS message from us)

Where permitted by law, we may acquire information about you from third parties. This may include information shared between PMI affiliates, marketing lists, and supplementary information acquired from third party agencies.

Where permitted by law, we may infer information about you from information about you that we already have. For example, we may use aggregated information about people in certain geographical areas, that we acquire from third parties, to infer your preferences.

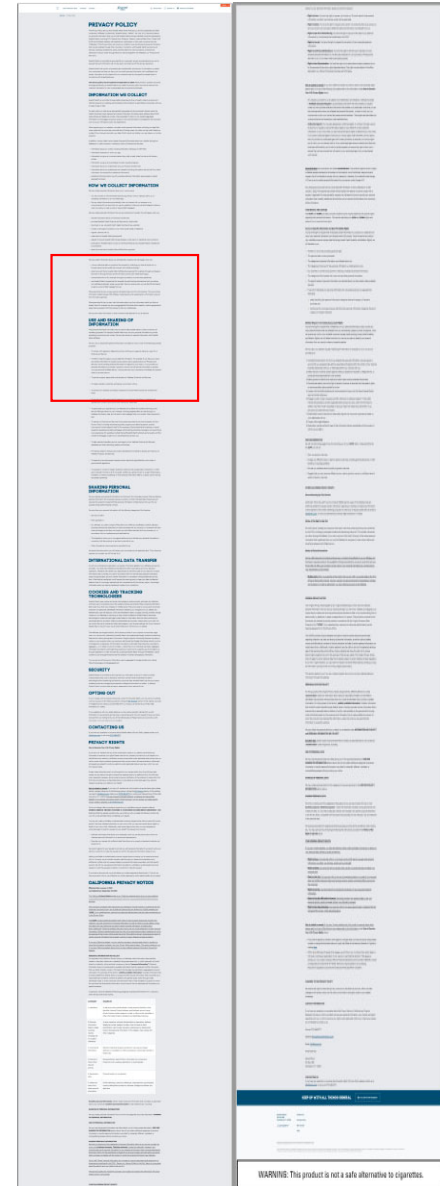
We may also collect information in other contexts made apparent to you at the time.

USE AND SHARING OF INFORMATION

The personal information we collect may be used to help Swedish Match contact consumers for marketing purposes. For example, Swedish Match may use your personal information to provide advertising, promotions, and content. We may also share your personal information with Swedish Match affiliates.

We may use, or disclose the personal information we collect for one or more of the following business purposes:

- To comply with regulatory obligations, such as verifying your age and status as a user of our Products and Service
- To fulfill or meet the reason you provided the information. For example, if you share your name and contact information to request a price quote or ask a question about our Products and Services, we will use that personal information to respond to your inquiry. If you provide your personal information to purchase a product or service, we will use that information to process your payment and facilitate delivery. We may also save your information to facilitate new product orders or process returns.
- To provide, support, personalize, and develop our Websites, Products, and Services.
- To create, maintain, customize, and secure your account with us.
- To process your requests, purchases, transactions, and payments and prevent transactional fraud.



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- To provide you with support and to respond to your inquiries, including to investigate and address your concerns and monitor and improve our responses.
- To personalize your experience on our Websites and to deliver the content and Product and Service offerings relevant to your interests, including targeted offers and ads through our Websites, third-party sites, and via email or text message (with your consent, where required by law).
- To market our Products and Services (to the extent permitted by law and consistent with this Privacy Policy), including administering loyalty programs and referral programs, product improvement, market research (and for the purposes of demonstrating fair practices in market research), developing marketing strategies, administering marketing campaigns, and customizing your experiences, for example at outlets that sell Swedish Match products and at events, and the content of messages we send you or advertisements we show you
- To help maintain the safety, security, and integrity of our Website, Products and Services, databases and other technology assets, and business.
- For testing, research, analysis, and product development, including to develop and improve our Website, Products, and Services.
- To respond to law enforcement requests and as required by applicable law, court order, or governmental regulations.
- To evaluate or conduct a merger, divestiture, restructuring, reorganization, dissolution, or other sale or transfer of some or all of our assets, whether as a going concern or as part of bankruptcy, liquidation, or similar proceeding, in which personal information held by us about users is among the assets transferred.

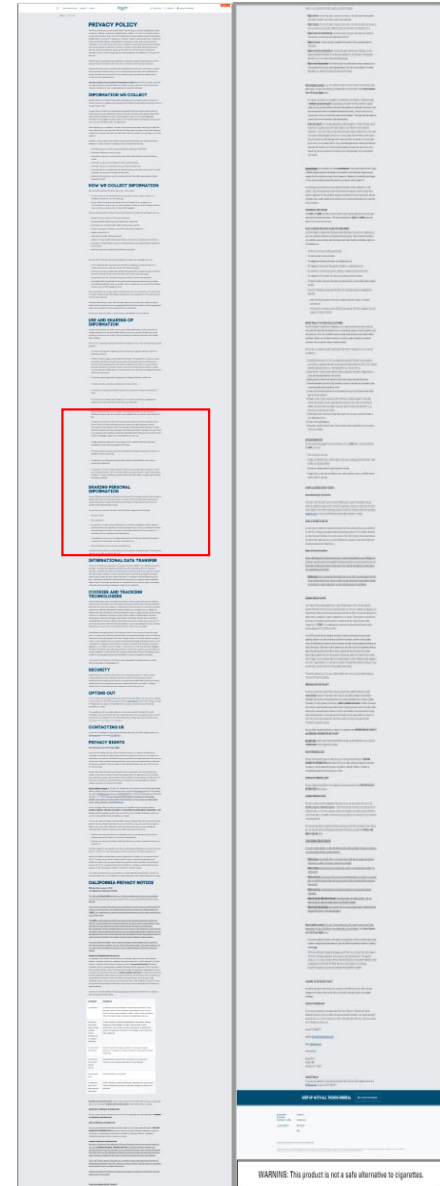
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We may share your personal information with the following categories of third parties:

- Service providers.
- Data aggregators.
- Our affiliates, our parent company Philip Morris Intl. (PMI) and its affiliates' carefully selected business partners and advertisers (in areas connected with our products, or consistent with their style and image) so that they can contact you with offers that they think may interest you, in accordance with your preferences and applicable law
- Third parties to whom you or your agents authorize us to disclose your personal information in connection with the products or services we provide to you.
- Other third parties, where required or permitted by law

We share information about you with others only in accordance with applicable laws. Thus, where law requires your consent, we will first ask for it.



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As with any multinational organization, we transfer information globally to our affiliates and service providers. Your data may therefore be transferred to other countries as part of our standard operations. Whenever we transfer your data abroad, we will limit access to your data only to those who need to see it, process your data in accordance with our internal data protection standards, protect it appropriately, and only transfer information in compliance with applicable data privacy laws. When data is transferred, we will require the receiving party to keep your data confidential, delete it when it is no longer required, and act in accordance with this privacy notice. Accordingly, information about you may be transferred outside of your jurisdiction.

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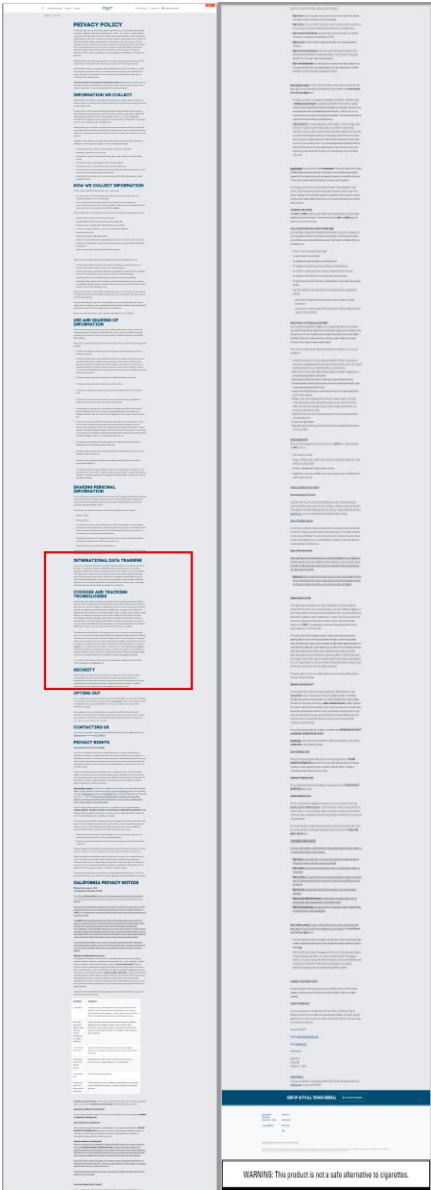
Swedish Match uses cookies and similar technologies to analyze trends, administer the Websites, and track users' movements around the website. Cookies are small text files containing information that is sent to us from your computer or mobile device. They are unique to your account or browser and store non-personally identifiable information related to your navigation on our website. Our Websites also uses web beacons, which are embedded invisibly on pages and help us better manage content on our Websites by informing us what content is effective. Swedish Match uses these technologies to customize web page content based on information that the visitor sends and to record past activity at a site in order to provide better service when visitors return to our site. You can control the use of cookies and other technologies in your browser settings, but if you choose to disable them, it may limit your use of certain features or functions on our website.

The Websites use Google Analytics, which places a cookie on your computer to track site usage when you visit this site. Additionally, Swedish Match has implemented Google Analytics Advertising Features for tracking demographic information. Google Analytics Advertising Features may place a cookie on your computer when you are shown ads through the Google Advertising network, such as on Google.com or elsewhere. All information provided to us through these networks is provided in aggregate — or in totals or sums of numbers — rather than on an individual user basis. Aggregate information provided to us through these networks is never tied to a specific user, if provided to us through registration or other channels. By accessing Swedish Match through the Websites, visitors consent to use of Google Analytics and the collection of certain demographic information.

You may opt-out of having your information used in aggregate for Google Analytics by visiting <https://tools.google.com/dlpage/gaoptout/>.

SECURITY

Swedish Match is committed to ensuring that your information is secure. In order to prevent unauthorized access, use, or disclosure, we always use the industry-standard encryption technologies when transferring and receiving consumer data. Swedish Match has also put in place suitable physical and managerial procedures to safeguard information we collect. In addition, Swedish Match conducts data protection assessments when required by law.



General Snus Website Privacy Policy

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OPTING OUT

If you no longer wish to receive commercial e-mails from Swedish Match, you may opt out by letting us know using any of the following options: visiting the [My Account](#) section of this website, via email to info@smna.com; calling us at (270) 685-8777; or, writing us at General Snus, PO Box 986, Owensboro, KY, 42302.

If you supplied us with your postal address, you may receive periodic mailings from us with information on new products and services or upcoming events. You can request to have your name removed from our mailing list by any of the methods above. Please make sure to provide us with your proper name and address when doing so.

CONTACTING US

If you have any questions or concerns about Swedish Match's Privacy Policy, please contact us at info@smna.com or call us at (270) 685-8777.

PRIVACY RIGHTS

How to Exercise Your U.S. Privacy Rights

If you are a U.S. resident and any of the notices below apply to you, please use the following information to exercise your rights. Please note that any request you submit to us is subject to an identification and residency verification process as permitted under applicable state privacy laws, as well as certain other procedural requirements that may be noted in the sections below. Additionally, all requests are subject to certain exceptions under applicable state privacy laws, which may vary from state to state.

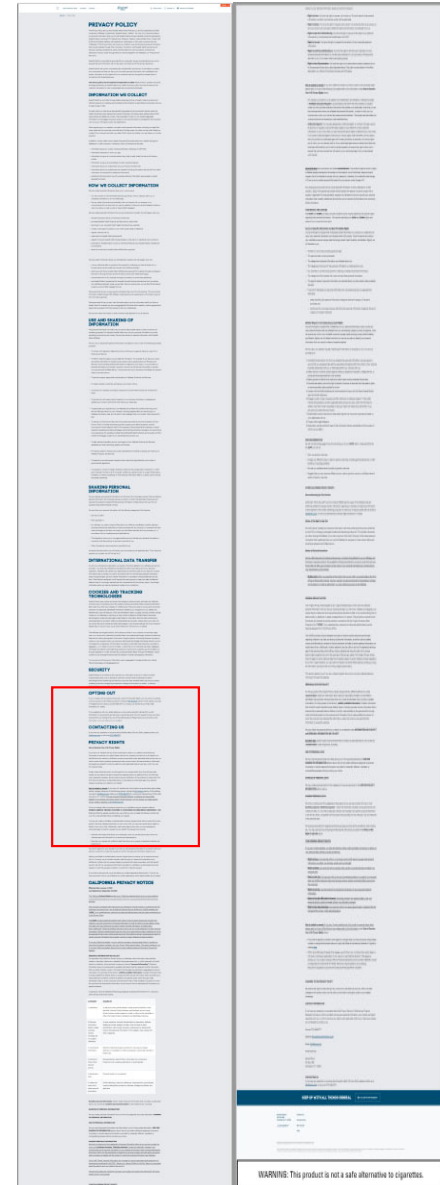
Except where otherwise noted, we will respond to your request within forty-five (45) days after receipt and we reserve the right to extend the response time by an additional forty-five (45) days when reasonably necessary and provided consumer notification of the extension is made within the first forty-five (45) days. As described below, in some states an authorized agent may submit a request to exercise your rights on your behalf.

How to submit a request. If you are a U.S. resident and wish to seek to exercise these rights, please submit a request using any of the following options: visiting the [My Account](#) section of this website, via email to info@smna.com; calling us at (270) 685-8777; or, writing us at General Snus, PO Box 986, Owensboro, KY, 42302. If you are a visually-impaired customer, a customer who has another disability or a customer who seek support in other language, you may access your state-specific privacy rights by emailing us at info@smna.com.

We do not charge a fee to process or respond to your verifiable consumer request unless its excessive, repetitive, manifestly unfounded, or in accordance with state-specific requirements. If we determine that the request warrants a fee, we will tell you why we made that decision and provide you with a cost estimate before completing your request.

You may only make a verifiable or authenticated consumer request twice within a twelve (12) month period. If we have collected information on your minor child, you may exercise the above rights on behalf of your minor child. Additionally, under some state privacy laws, you may designate an authorized agent to submit a request on your behalf. The request must include:

- Sufficient information that allows us to reasonably verify you are the person about whom we collected personal information or an authorized representative.
- Describe your request with sufficient detail that allows us to properly understand, evaluate, and respond to it.



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We cannot respond to your request or provide you with personal information if we cannot verify your identity or authority to make the request and confirm the personal information relates to you.

Making a verifiable or authenticated consumer request does not require you to create an account with us. However, we do consider requests made through your password protected account sufficiently verified when the request relates to personal information associated with that specific account. We will only use personal information provided in a verifiable or authenticated consumer request to verify the requestor's identity or authority to make the request.

If you have an account with us, we will deliver our written response to that account. If you do not have an account with us, we will deliver our written response by mail or electronically, at your option.

CALIFORNIA PRIVACY NOTICE

Effective Date: January 1, 2023

Last Updated on: September 27, 2023

This California Privacy Notice applies to any California residents about whom we have collected personal information from any source, including through your use of our Websites, Products, and Services.

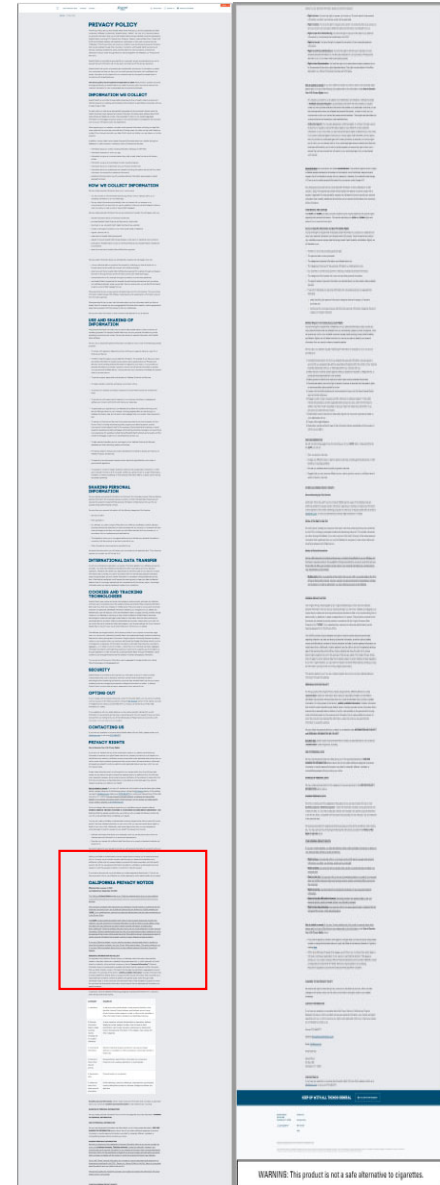
The provisions contained within this section are intended to provide notices in compliance with the California Consumer Privacy Act of 2018 and California Privacy Rights Act of 2020 (together, the "CCPA"). Any capitalized term used and not otherwise defined below has the meaning assigned to it in this Privacy Policy.

The CCPA provides California residents with rights to receive certain disclosures regarding the collection, use, sale, and sharing of personal information, as well as rights to access, delete, correct, and restrict the use, disclosure, and sale of certain personal information we collect about them. Additionally, California residents have the right to opt-out of the sale/sharing of their personal information. California residents also have the right not to receive discriminatory treatment by us for the exercise of their privacy rights under the CCPA. This California Privacy Notice does not apply to certain personal information that is already subject to certain federal and state regulation.

If you are a California resident, you may submit a request to exercise these rights by emailing us using the information provided in the Your Privacy Rights section below. This section applies to you if you are a California resident about whom we have collected personal information through the Website.

PERSONAL INFORMATION WE COLLECT

For purposes of this California Privacy Notice, our Websites collect information that identifies, relates to, describes, references, is capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or device ("personal information"). Personal information does not include publicly available information; lawfully obtained, truthful information that is a matter of public concern; information that has been de-identified; or aggregated consumer information. For purposes of this section, "publicly available information" includes: information that is made available from federal, state, or local government records; information that a business has a reasonable basis to believe is lawfully available to the general public, either through widely distributed media, or by the consumer; and information that is made available by a person to whom the consumer has disclosed the information if the consumer has not restricted the information to a specific audience.



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In particular, we have collected the following categories of personal information from consumers within the last twelve (12) months:

CATEGORY	EXAMPLES
A. Identifiers.	A real name, alias, postal address, unique personal identifier, online identifier, Internet Protocol address, email address, account name, driver's license number, passport number, or other similar identifiers or other information linked or linkable to an identifiable individual.
B. Personal information listed in states customer records, including Cal. Civ. Code § 1798.80(a).	A name, signature, physical characteristics or description, address, telephone number, passport number, driver's license or state identification card number, education, employment or employment history. Some personal information in this category may overlap with other categories.
C. Commercial information.	Records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.
D. Internet or other similar network activity.	Browsing history, search history, information on a consumer's interaction with a website, application, or advertisement.
E. Geolocation data.	Physical location or movements.
F. Inferences drawn from other personal information.	Profile reflecting a person's preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.

Sensitive personal information. Certain types of personal information that we collect, as described above, may constitute "sensitive personal information" under California law, including:

SOURCES OF PERSONAL INFORMATION

We may collect personal information from you from the categories of sources described in **SHARING OF PERSONAL INFORMATION**.

USE OF PERSONAL INFORMATION

We may use the personal information we collect about you for the purposes described in **USE AND SHARING OF INFORMATION** section above. We will not collect additional categories of personal information or use the personal information we collect for materially different, unrelated, or incompatible purposes without providing you notice.

SHARING PERSONAL INFORMATION

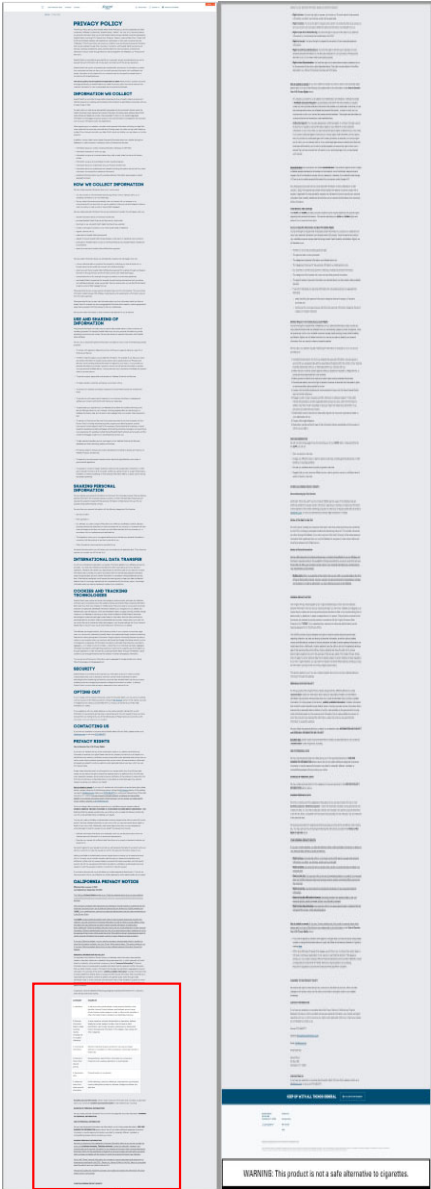
We limit our disclosure of the categories of personal information above to our service providers for one or more business purposes. "Business purposes" means the reasonably necessary and proportionate use of personal information for our operational purposes, other purposes described in this Privacy Policy, for the operational purposes of our service providers and contractors, as well as other purposes compatible with the context in which the personal information was collected.

We do "sell"/"share" personal information for purposes of cross-context behavioral advertising, as those terms are defined by the CCPA. Review our "Notice of Right to Opt-Out" below for more detail about this activity and your rights to opt-out of it.

The above excludes text messaging originator opt-in data and consent; this information will not be shared with any third parties.

YOUR CALIFORNIA PRIVACY RIGHTS

If you are a California resident, you have the following rights under applicable California law in



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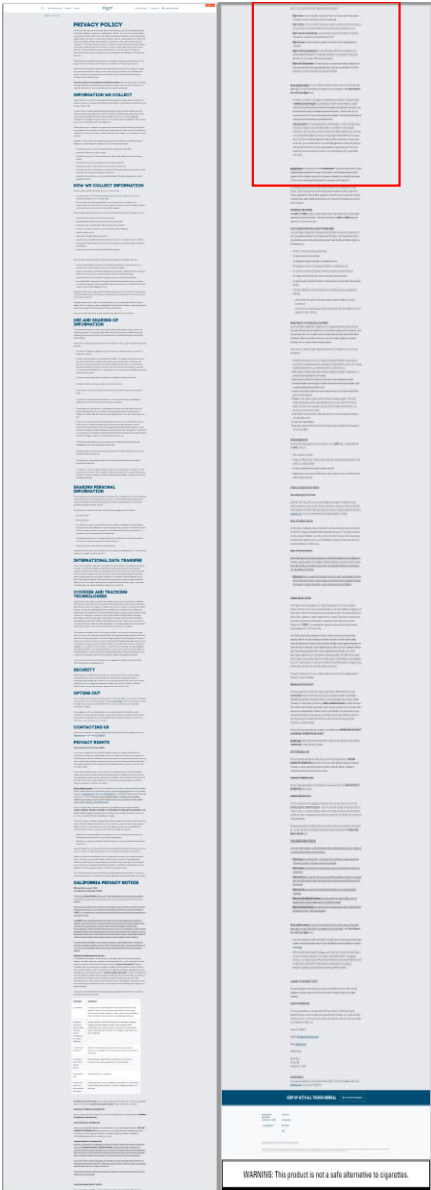
relation to your personal information, subject to certain exceptions:

- **Right to Know.** You have the right to request, up to twice in a 12-month period, what personal information we collect, use, disclose, and/or sell, as applicable.
- **Right to Delete.** You have the right to request under certain circumstances that we as well as our service providers and contractors delete the personal information we collected from you.
- **Right to Opt-Out of Sale/Sharing.** You have the right to opt-out of the sale of your personal information by us as those terms are defined by the CCPA.
- **Right to Correct.** You have the right to request the correction of your inaccurate personal information.
- **Right to Limit Use and Disclosure.** You have the right to limit the use or disclosure of your sensitive personal information to only the uses necessary for us to provide our Products and Services to you, or for certain other authorized purposes.
- **Right to Non-Discrimination.** You have the right not to receive discriminatory treatment by us for the exercise of the privacy rights described above. This right may be subject to the offers described in our Notice of Financial Incentives, set forth below.

How to submit a request. If you are a California resident and wish to seek to exercise these rights, please reach us in one of the following ways please refer to the information under **How to Exercise Your U.S. Privacy Rights** above.

- Any request you submit to us is subject to an identification and residency verification process (“**Verifiable Consumer Request**”) as permitted by the CCPA. We will not fulfill your request unless you have provided sufficient information that enables us to reasonably verify that you are the consumer about whom we collected the personal information. In order to verify you, you must provide us with your first and last name and email address. These rights are also subject to various exclusions and exceptions under applicable laws.
- **Authorized Agents.** You may also designate an authorized agent, in writing or through a power of attorney, to request to exercise the above rights on your behalf. If we have collected information on your minor child, you may exercise the above rights on behalf of your minor child. If you use an authorized agent to exercise your various rights under the CCPA, we may require that you provide your authorized agent with written permission to exercise your various rights and to verify your own identity with us. If your authorized agent does not submit proof that they have been authorized by you to submit verified requests, we reserve the right to deny such a request that we have received and will explain to your authorized agent why we have denied such request.

Household Data. We currently do not collect **household data**. If we receive a Right to Know or Right to Delete request submitted by all members of a household, we will individually respond to each request. We will not be able to comply with any request by a member of a household under the age of 13, as we do not collect personal information from any person under the age of 13.



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Any disclosures we provide will only cover personal information we have collected on or after January 1, 2022. The response we provide will also explain the reasons we cannot comply with a request, if applicable. For data portability requests, we will select a format to provide your personal information that is readily useable and should allow you to transmit the information from one entity without hindrance.

YOUR RIGHTS AND CHOICES

The **CCPA** and **VCDPA** provides consumers (California and Virginia residents) with specific rights regarding their personal information. This section describes your **CCPA** and **VCDPA** rights and explains how to exercise those rights.

Access to Specific Information and Data Portability Rights

You have the right to request that we disclose certain information to you about our collection and use of your personal information over the past twelve (12) months. Once we receive and confirm your verifiable consumer request (see Exercising Access, Data Portability, and Deletion Rights), we will disclose to you:

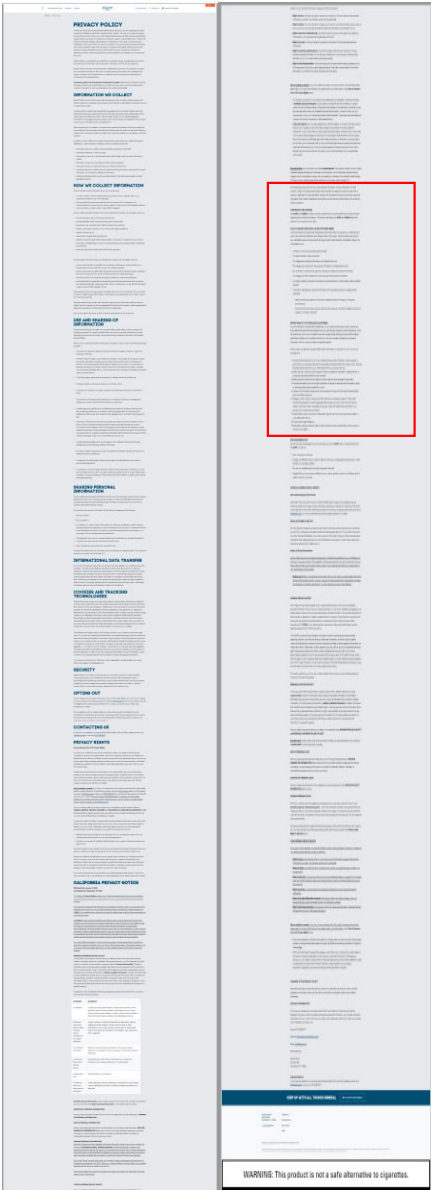
- Whether or not we are processing personal data
- The personal data we have processed
- The categories of personal information we collected about you.
- The categories of sources for the personal information we collected about you.
- Our business or commercial purpose for collecting or selling the personal information.
- The categories of third parties with whom we share that personal information.
- The specific pieces of personal information we collected about you (also called a data portability request).
- If we sold or disclosed your personal information for a business purpose, two separate lists disclosing:
 - sales, identifying the personal information categories that each category of recipient purchase; and
 - disclosures for a business purpose, identifying the personal information categories that each category of recipient obtained.

Deletion Request / Correcting Inaccuracies Rights

You have the right to request that we delete any of your personal information and/or correct any inaccurate information that we collected from you and retained, subject to certain exceptions. Once we receive and confirm your verifiable consumer request (see Exercising Access, Data Portability, and Deletion Rights), we will delete (and direct our service providers to delete) your personal information from our records, unless an exception applies.

We may deny your deletion request if retaining the information is necessary to us or our service provider(s) to:

1. Complete the transaction for which we collected the personal information, provide a good or service that you requested, take actions reasonably anticipated within the context of our ongoing business relationship with you, or otherwise perform our contract with you.
2. Detect security incidents, protect against malicious, deceptive, fraudulent, or illegal activity, or prosecute those responsible for such activities.
3. Debug product to identify and repair errors that impair existing intended functionality.
4. Exercise free speech, ensure the right of another consumer to exercise their free speech rights, or exercise another right provided for by law.
5. Comply with the California Electronic Communications Privacy Act (Cal. Penal Code § 1546 et seq.) and similar state laws.
6. Engage in public or peer-reviewed scientific, historical, or statistical research in the public interest that adheres to all other applicable ethics and privacy laws, when the information's deletion may likely render impossible or seriously impair the research's achievement, if you previously provided informed consent.
7. Enable solely internal uses that are reasonably aligned with consumer expectations based on your relationship with us.
8. Comply with a legal obligation.
9. Make other internal and lawful uses of that information that are compatible with the context in which you provided it.



General Snus Website Privacy Policy

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10-5-23 - current

NON-DISCRIMINATION

We will not discriminate against you for exercising any of your **CCPA** rights. Unless permitted by the **CCPA**, we will not:

- Deny you goods or services.
- Charge you different prices or rates for goods or services, including granting discounts or other benefits, or imposing penalties.
- Provide you a different level of quality of goods or services.
- Suggest that you may receive a different price or rate for goods or service or a different level or quality of goods or services.

OTHER CALIFORNIA PRIVACY RIGHTS

Direct Marketing By Third Parties

California's "Shine the Light" law (Civil Code § 1798.83) permits users of the Websites that are California residents to request certain information regarding our disclosure of personal information to third parties for their direct marketing purposes. To make such a request, please send an email to info@smna.com, or write us at General Snus, P.O. Box 986, Owensboro, KY 42302.

Notice of the Right to Opt-Out

We "sell"/"share" a limited set of personal information with third parties as those terms are defined by the CCPA, including to participate in behavioral advertising networks. This includes information we collect through the Website. If you wish to opt-out of the "sale"/"sharing" of the limited personal information that is gathered when you visit the Websites for purposes of cross-context behavioral advertising, please email info@smna.com.

Notice of Financial Incentives

We may offer discounts on products and services – including those offered by us, our affiliates, and third-party business partners. The availability of these promotions to you at any given time will vary. If and when we offer such programs, we may ask for your personal information as a prerequisite to your participation in the program.

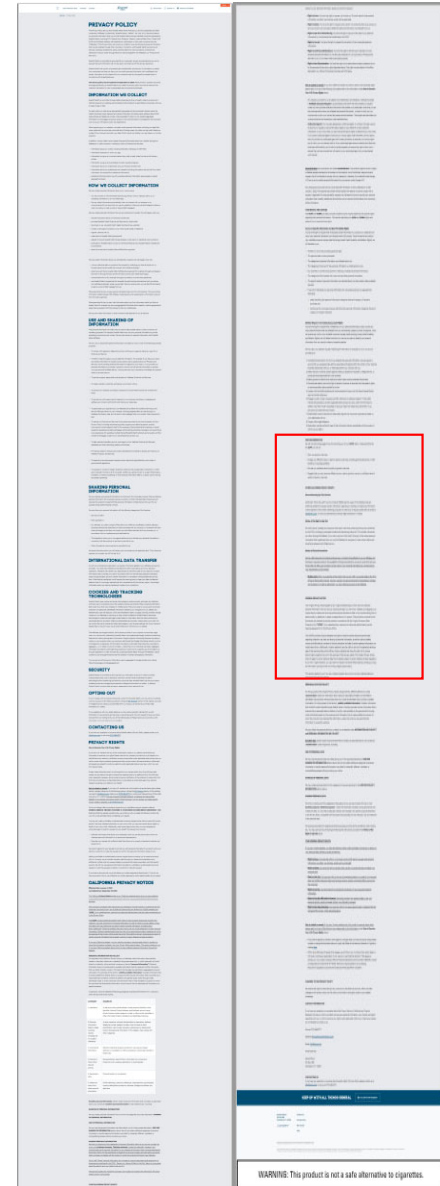
- **Mailing Lists.** When you subscribe to the mailing lists, we may offer you special deals in the form of free or discounted products, coupons, rewards, and announcements of sweepstakes, contests, and giveaways. In order to participate, you must create an account on the Website.

VIRGINIA PRIVACY NOTICE

This Virginia Privacy Notice applies to any Virginia residents about whom we have collected personal information from any source, including through your use of our websites, by engaging us to inquire about or obtain the various products and services that we offer, or by communicating with us electronically, by telephone, in paper correspondence, or in person. The provisions contained within this section are intended to provide notices in compliance with the Virginia Consumer Data Protection Act ("VCDPA"). Any capitalized term used and not otherwise defined below has the meaning assigned to it in this Privacy Policy.

The VCDPA provides Virginia residents with rights to receive certain disclosures and access regarding collection, use, sale, and sharing of personal information, as well as rights to delete, correct, and affirmatively consent to the use, disclosure, and sale of certain personal information we collect about them. Additionally, Virginia residents have the right to opt-out of targeted advertising, sale of their personal data, and profiling. Virginia residents also have the right not to receive discriminatory treatment by us for the exercise of their privacy rights. This Virginia Privacy Notice does not apply to certain personal data that is already subject to certain federal and state regulation. If you are a Virginia resident, you may submit a request to exercise these rights by emailing us using the information provided in the Your Privacy Rights section below.

This section applies to you if you are a Virginia resident about whom we have collected personal information through the websites.



General Snus Website Privacy Policy

Con't [OUTSIDE AGE GATE] 10-5-23 - current

10-5-23 - current

PERSONAL DATA WE COLLECT

For the purposes of this Virginia Privacy Notice, except where a different definition is noted, **"personal data"** means any information that is linked or reasonably linkable to an identified or identifiable natural person. Personal data does not include de-identified data or publicly available information. For the purposes of this section, **"publicly available information"** includes: information that is lawfully made available through federal, state, or local government records; information that a business has a reasonable basis to believe is lawfully made available to the general public through widely distributed media, by the consumer; and information that is made available by a person to whom the consumer has disclosed the information, unless the consumer has restricted the information to a specific audience.

We may collect the personal data from or about you as detailed under **INFORMATION WE COLLECT** and **PERSONAL INFORMATION WE COLLECT**.

Sensitive data. Certain types of personal data that we collect, as described above, may constitute **"sensitive data"** under Virginia law, including:

USE OF PERSONAL DATA

We may use the personal data we collect about you for the purposes described in **USE AND SHARING OF INFORMATION** section above. We will not collect additional categories of personal information or use the personal information we collect for materially different, unrelated, or incompatible purposes without providing you notice.

SOURCES OF PERSONAL DATA

We may collect personal data from the categories of sources described in the **HOW WE COLLECT INFORMATION** section above.

SHARING PERSONAL DATA

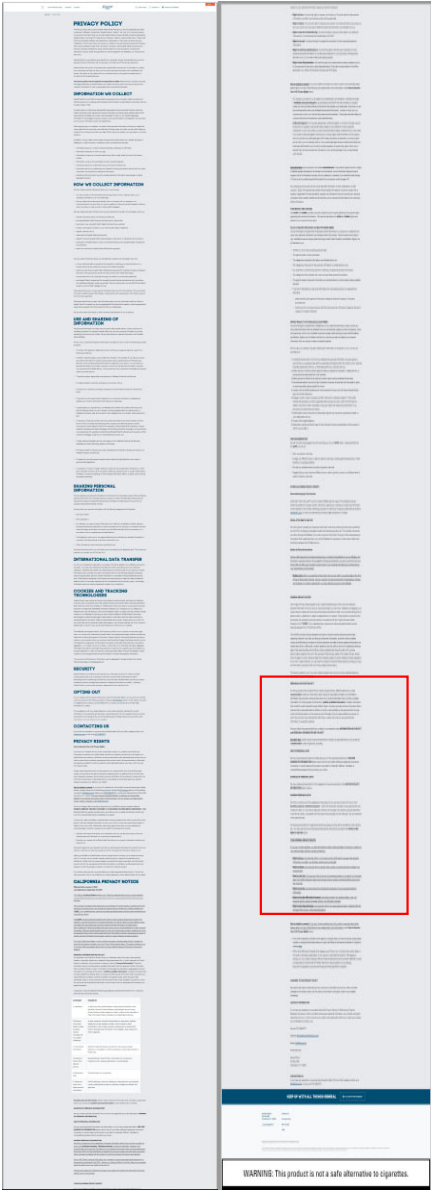
We limit our disclosure of the categories of data above to our service providers for one or more **business purposes**. **"Business purposes"** means the reasonably necessary and proportionate use of personal data, in a way that is adequate, relevant, and necessary for specific purposes described in this Privacy Policy, compatible with the nature and purpose(s) for the collection, use, and retention of the personal data.

We share personal data for targeted advertising purposes as those terms are defined under Virginia law. You may opt-out of such sharing by following the instructions provided in the **Notice of the Right to Opt-Out** above.

YOUR VIRGINIA PRIVACY RIGHTS

If you are a Virginia resident, you have the following rights under applicable Virginia law in relation to your personal data, subject to certain exceptions:

- **Right to Know.** You have the right to, up to twice in a 12-month period, request what personal information we collect, use, disclose, and/or sell, as applicable.
- **Right to Delete.** You have the right to request under certain circumstances that we delete your personal data.
- **Right to Opt-Out.** You have the right to opt-out of targeted advertising, our sale of your personal data, and profiling decisions that could produce legal or similarly significant effects concerning the consumer.
- **Right to Correct.** You have the right to request the correction of your inaccurate personal information.
- **Right to Provide Affirmative Consent.** We cannot process your sensitive data or use your personal data for certain purposes without your affirmative consent.
- **Right to Non-Discrimination.** You have the right to not receive discriminatory treatment for the exercise of the privacy rights described above.



General Snus Website Privacy Policy

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10-5-23 - current

How to submit a request. If you are a Virginia resident and wish to seek to exercise these rights, please reach us in one of the following ways please refer to the information under **How to Exercise Your U.S. Privacy Rights** above.

- If you wish to appeal our decision with regard to a request that you have previously made, please contact us using the information above or notify the Office of the Attorney General of Virginia by clicking [here](#).
- Within sixty (60) days of receipt of an appeal, we will inform you in writing of any action taken or not taken, including an explanation of our reasons in reaching the decision. If the appeal is denied, you may contact Virginia's Office of Attorney General by phone at (804) 786-2071, written correspondence to 202 North 9th Street, Richmond, Virginia 23219, or by accessing: <https://www.oag.state.va.us/consumer-protection/index.php/file-a-complaint>.

CHANGES TO OUR PRIVACY POLICY

We reserve the right to amend this privacy notice at our discretion at any time. When we make changes to this privacy notice, we will notify you by email or through a notice on our website homepage.

CONTACT INFORMATION

If you have any questions or comments about this Privacy Notice for California and Virginia Residents, the ways in which we collect and use your personal information, your choices, and rights regarding such use, or wish to exercise your rights under applicable California or Virginia law, please do not hesitate to contact us at:

Phone: (270) 685-8777

Website: <https://www.generalsnus.com/>

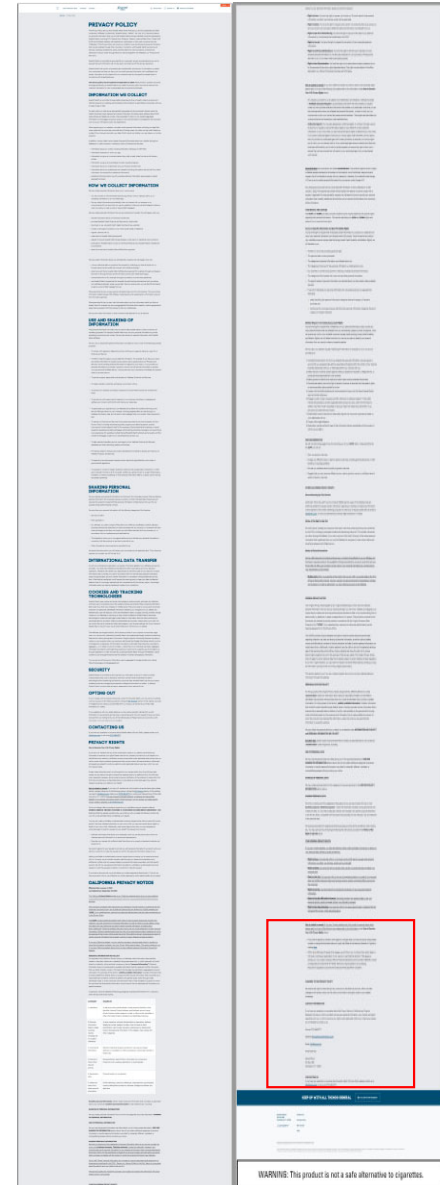
Email: info@smna.com

Postal Address:

General Snus
P.O. Box 986
Owensboro, KY 42302

CONTACTING US

If you have any questions or concerns about Swedish Match's Privacy Policy, please contact us at info@smna.com or call us at (270) 685-8777.



General Snus Find The Original Sweepstakes: Menu Page [OUTSIDE AGE GATE]

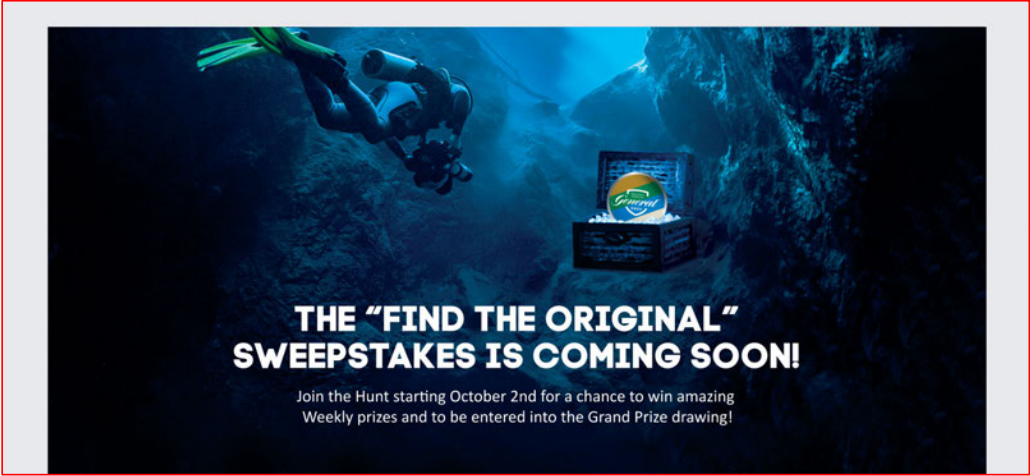
10-2-23 – 11-12-23



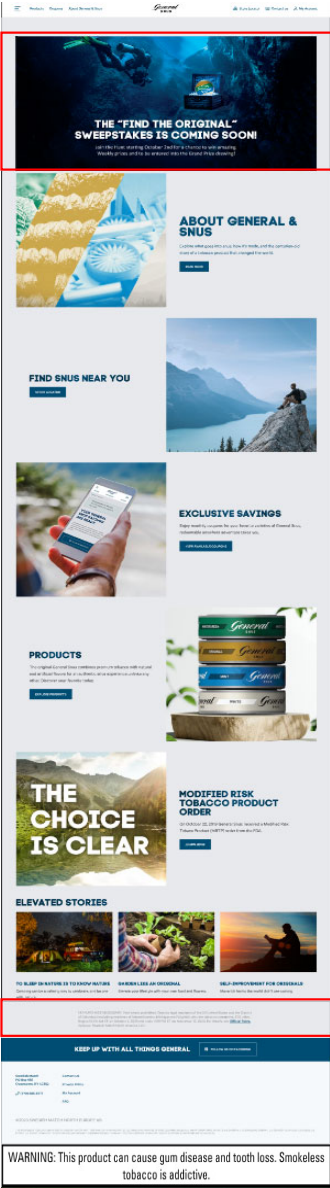
WARNING: This product is not a safe alternative to cigarettes.

General Snus Find The Original Sweepstakes: Home Page [BEHIND AGE GATE]

9-27-23 – 10-2-23

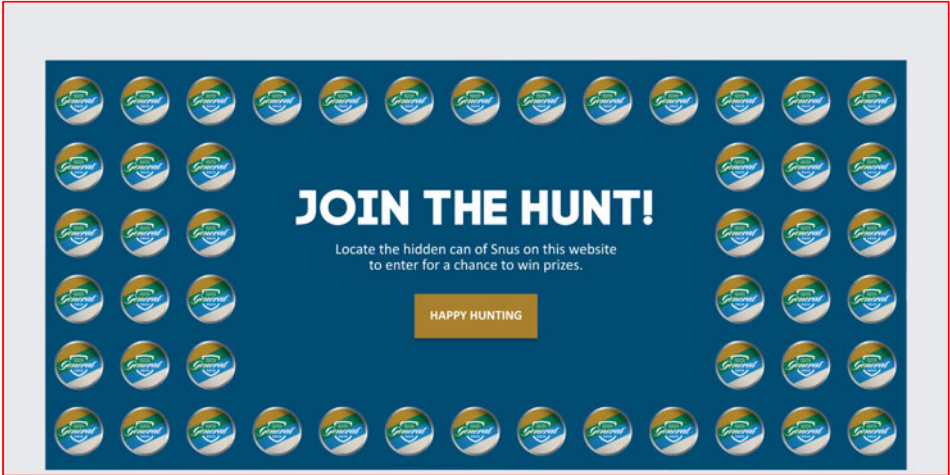


NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.

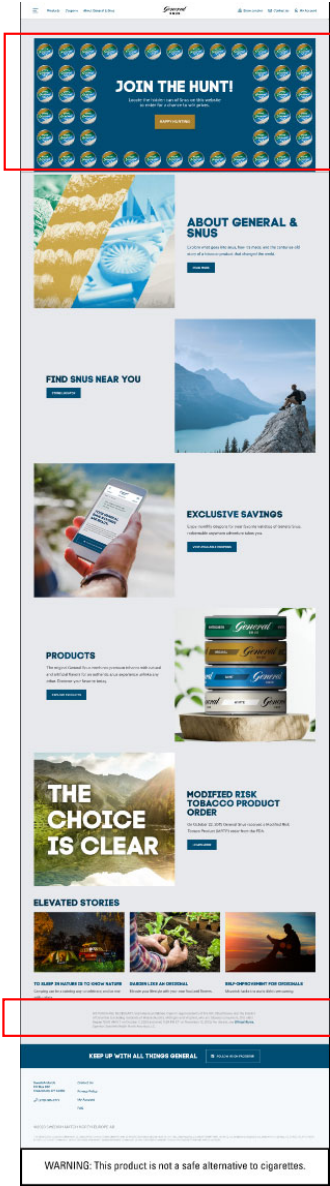


General Snus Find The Original Sweepstakes: Home Page [BEHIND AGE GATE]

10-2-23 – 11-12-23



NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.



General Snus Find The Original Sweepstakes: Landing Page [BEHIND AGE GATE]

10-2-23 – 11-12-23

About General & Snus

Products

Coupons

General
SNUS

Find a Store

Contact Us

General on Facebook

SEE THIS ONE-OF-A-KIND CAN OF GENERAL SNUS?
Every week on the General Snus website it will be hiding someplace different. Find it and you could enter to win one of these prizes.

WEEK 1

Multi-Tool

WEEK 2

Trail-Running Headlamp

WEEK 3

8x42 Binoculars

WEEK 4

Hiking Backpack

WEEK 5

36-Can Cooler

WEEK 6

Hammock

Products

General
SNUS

Find a Store

Contact Us

General on Facebook

SEE THIS ONE-OF-A-KIND CAN OF GENERAL SNUS?
Every week on the General Snus website it will be hiding someplace different. Find it and you could enter to win one of these prizes.

WEEK 1

Multi-Tool

WEEK 2

Trail-Running Headlamp

WEEK 3

8x42 Binoculars

WEEK 4

Hiking Backpack

WEEK 5

36-Can Cooler

WEEK 6

Hammock

GRAND PRIZE

Every week you enter gives you a better chance of winning the Grand Prize.

15' Inflatable Boat

So what are you still doing here? Get out there and get hunting. And remember to come back every week for a new hunt and another chance to win.

KEEP UP WITH ALL THINGS GENERAL

Follow us on Facebook

Twitter

Instagram

YouTube

LinkedIn

Facebook

100% SWEETENED TOBACCO

100% SWEETENED TOBACCO

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

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10-2-23 – 11-12-23

10-2-23 – 11-12-23

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

General Snus Find The Original Sweepstakes: Week 1 Hidden Can [BEHIND AGE GATE]

10-2-23 – 10-8-23

1866

GENERAL DEBUTS

After four years of painstakingly crafting his recipe, Boman introduces an elevated tobacco experience to his home country. Crafted using only the finest ingredients, it was an upper-lip snus unlike anything seen before.

NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.

The authentic Swedish

1862 THE JOURNEY BEGINS

1866 GENERAL DEBUTS

1866 GENERAL DEBUTS

Late 1800s COMING TO AMERICA

Late 1800s COMING TO AMERICA

1970 THE PERFECT PORTION

1970 THE PERFECT PORTION

Late 1990s A MODERN STANDARD

Late 1990s A MODERN STANDARD

2003 NEXT LEVEL CLEAN

2003 NEXT LEVEL CLEAN

2004 THE FIRST OF ITS KIND

2004 THE FIRST OF ITS KIND

2005 A STAR IS BORN

2005 A STAR IS BORN

2006 SNUS EXPANDS

2006 SNUS EXPANDS

2016 THE LEGACY CONTINUES

2016 THE LEGACY CONTINUES

THE CHOICE IS CLEAR

THE CHOICE IS CLEAR

2018 ANCHORING FIRST

2018 ANCHORING FIRST

HOW TO ENJOY SNUS

HOW TO ENJOY SNUS

GET SNUS COMPENSATION

GET SNUS COMPENSATION

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

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

General Snus Find The Original Sweepstakes: Week 1 Removed [BEHIND AGE GATE]

10-9-23 – current

1866

GENERAL DEBUTS

After four years of painstakingly crafting his recipe, Boman introduces an elevated tobacco experience to his home country. Crafted using only the finest ingredients, it was an upper-lip snus unlike anything seen before.

The mission Swedish snus

1867
THE JOURNEY BEGINS

1866
GENERAL DEBUTS

Late 1800s
GOING TO AMERICA

1970
THE PERFECT PORTION

Late 1990s
A NEWER STANDARD

2001
NEXT LEVEL CLEAN

2004
THE FIRST OF ITS KIND

2005
A STAR IS BORN

2006
SNUS EXPANDS

2016
THE LEGACY CONTINUES

THE CHOICE IS CLEAR

2019
ANOTHER FIRST

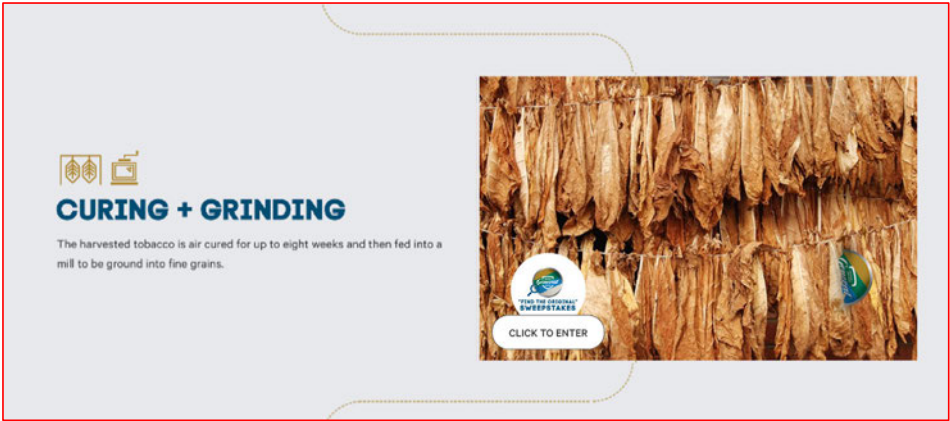
HOW TO USE SNUS
HOW TO GET SNUS
GET SNUS COUPONS

FAST UP WITH ALL THOSE OTHERS

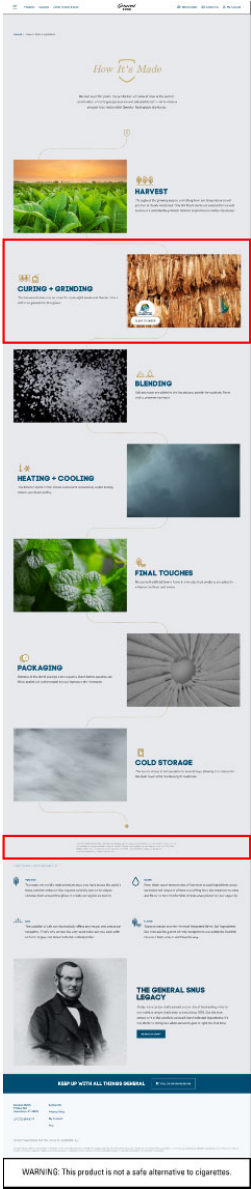
WARNING: This product is not a safe alternative to cigarettes.

General Snus Find The Original Sweepstakes: Week 2 Hidden Can [BEHIND AGE GATE]

10-9-23 – 10-15-23



NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.

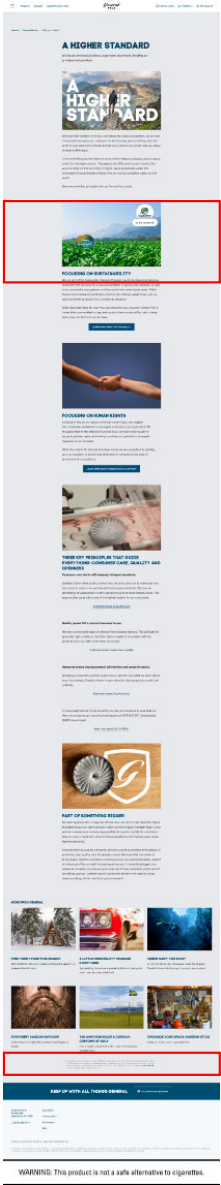


General Snus Find The Original Sweepstakes: Week 3 Hidden Can [BEHIND AGE GATE]

10-16-23 – 10-22-23



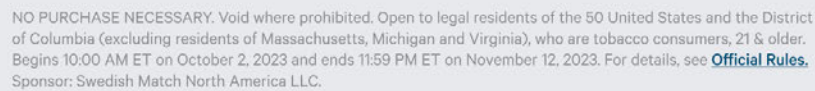
NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.



10-23-23 – current



10-23-23 – 10-29-23



[Products](#)
[Contact Us](#)
[About General & Snus](#)

[Store Locator](#)
[Contact Us](#)
[My Account](#)

[Sign up](#) | [Track Order](#)

THE CHOICE IS CLEAR

General Snus is committed to a future free from cigarette smoke – a future where the choice is always clear.

On October 23, 2019 General Snus received a Modified Risk Tobacco Product (MRTTP) order, which allows us to say:

Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.

Even though we've already made history, our story remains firmly fixed on the future – a future free from cigarette smoke, where the choice is always clear.

AABOUT GENERAL & SNUS

**HOW TO USE
SNUS**

[LEARN MORE](#)

**HOW SNUS
IS MADE**

[LEARN MORE](#)

**GET SNUS
COUPONS**

[CLICK HERE](#)

NOT FOR SALE IN THE U.S. General Snus is a tobacco-free oral nicotine pouch. It does not contain tobacco or any other products of tobacco origin. Although it may help reduce your exposure to some harmful chemicals found in cigarettes, it does not protect against the risks associated with smoking. Smoking causes many health problems, such as heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. Quitting now greatly reduces serious risks to your health. ©2023 SWEDISH MATCH AB. All rights reserved.

KEEP UP WITH ALL THINGS GENERAL

[FOLLOW US ON FACEBOOK](#)

Swedish Match PO Box 500 Gustavsberg, NY 12535 ☎ (518) 688-4970	Contact Us Privacy Policy My Account FAQ
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WARNING: This product is not a safe alternative to cigarettes.

Week 4 Removed [BEHIND AGE GATE]


10-30-23 – current



General Snus Find The Original Sweepstakes: Week 5 Hidden Can [BEHIND AGE GATE]

10-30-23 – 11-5-23

Where can't you snus? As it turns out, it's a pretty short list. Unless you get a little creative.



1. SCUBA DIVING

Anytime you need a mouthpiece to breathe probably isn't the best time to be snusing, just as a rule of thumb.

NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.

WHERE CAN'T YOU SNUS?

1. SCUBA DIVING

2. HARBORCRA SOLO

3. HOT-DOG EATING CONTEST?

4. MEETING THE QUEEN

5. BOXING

6. WHISTLE-OW

7. OPERATIC AREA

8. SKYDIVING

KEEP UP WITH ALL THINGS GENERAL

KEEP UP WITH ALL THINGS GENERAL

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

11-6-23 – current

Where can't you snus? As it turns out, it's a pretty short list. Unless you get a little creative.




Anytime you need a mouthpiece to breathe probably isn't the best time to be snusing, just as a rule of thumb.



General Snus Find The Original Sweepstakes: Week 6 Hidden Can [BEHIND AGE GATE]

11-6-23 – 11-12-23


Appreciating the unique ingredients that turn boring into wow—and the science behind it.



Our minds need originality. We crave it. But why? From the color of your car to the unsurpassed blend of tobaccos in your favorite variety of snus, you choose the things you prefer because of something that — for you, at least — stands out.


NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see [Official Rules](#). Sponsor: Swedish Match North America LLC.

A LITTLE ORIGINALITY CHANGES EVERYTHING




PATTERN-SEEKING PEOPLE

DISRUPTING THE NATION




BEYOND RED



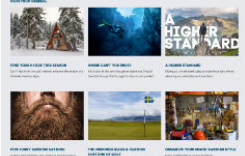
THE SECRET OF SWEET

NOT JUST A NEW CITY ORIGINALITY



BEYOND THE SECRET OF ORIGINALITY

THE NEW ORIGINAL




KEEP UP WITH ALL THINGS ORIGINAL

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

General Snus Find The Original Sweepstakes: Week 6 Removed [BEHIND AGE GATE]

11-13-23 – current

Appreciating the unique ingredients that turn boring into wow—and the science behind it.



Our minds need originality. We crave it. But why? From the color of your car to the unsurpassed blend of tobaccos in your favorite variety of snus, you choose the things you prefer because of something that — for you, at least — stands out.

A LITTLE ORIGINALITY CHANGES EVERYTHING



PATTERN-SEEKING PEOPLE

Pattern-seeking people are the ones who see the world in terms of patterns. They are the ones who see the world in terms of patterns. They are the ones who see the world in terms of patterns.

DISRUPTING THE PATTERN

Disrupting the pattern is the only way to see the world in terms of patterns. Disrupting the pattern is the only way to see the world in terms of patterns. Disrupting the pattern is the only way to see the world in terms of patterns.



SEEKING RED

Seeking red is the only way to see the world in terms of patterns. Seeking red is the only way to see the world in terms of patterns. Seeking red is the only way to see the world in terms of patterns.



THE DELICIOUS OF SPEED

The delicious of speed is the only way to see the world in terms of patterns. The delicious of speed is the only way to see the world in terms of patterns. The delicious of speed is the only way to see the world in terms of patterns.



WANT TO BE THE ORIGINALITY

Want to be the originality is the only way to see the world in terms of patterns. Want to be the originality is the only way to see the world in terms of patterns. Want to be the originality is the only way to see the world in terms of patterns.



BEHOLD, THE SHORTCUT TO ORIGINALITY

Behold, the shortcut to originality is the only way to see the world in terms of patterns. Behold, the shortcut to originality is the only way to see the world in terms of patterns. Behold, the shortcut to originality is the only way to see the world in terms of patterns.



THE NEW STANDARD

The new standard is the only way to see the world in terms of patterns. The new standard is the only way to see the world in terms of patterns. The new standard is the only way to see the world in terms of patterns.



A HIGHER STANDARD

A higher standard is the only way to see the world in terms of patterns. A higher standard is the only way to see the world in terms of patterns. A higher standard is the only way to see the world in terms of patterns.



THE NEW STANDARD

The new standard is the only way to see the world in terms of patterns. The new standard is the only way to see the world in terms of patterns. The new standard is the only way to see the world in terms of patterns.



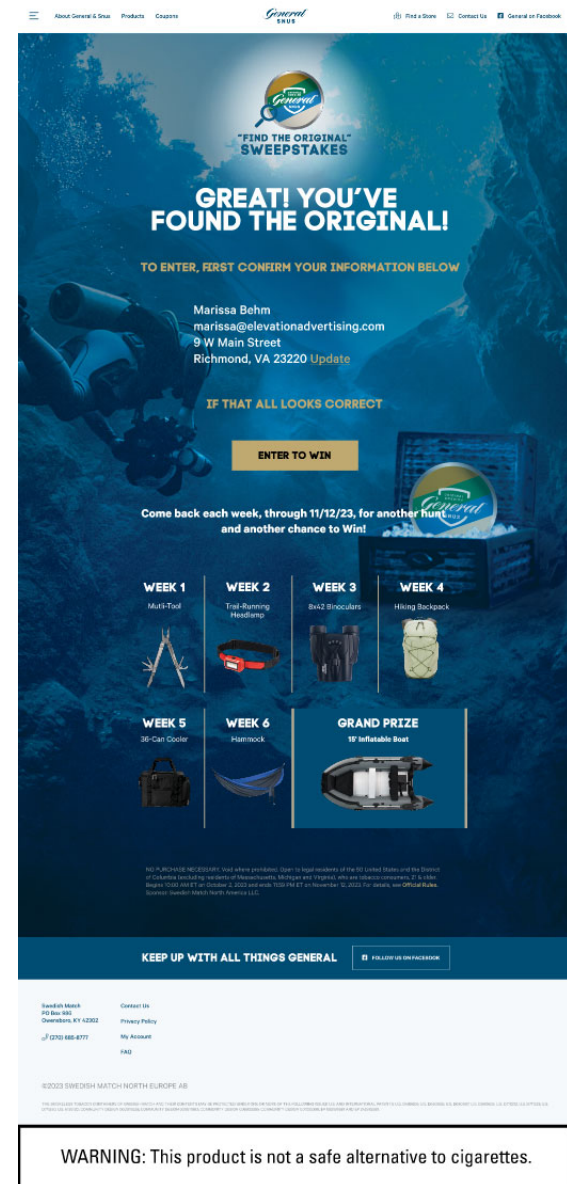
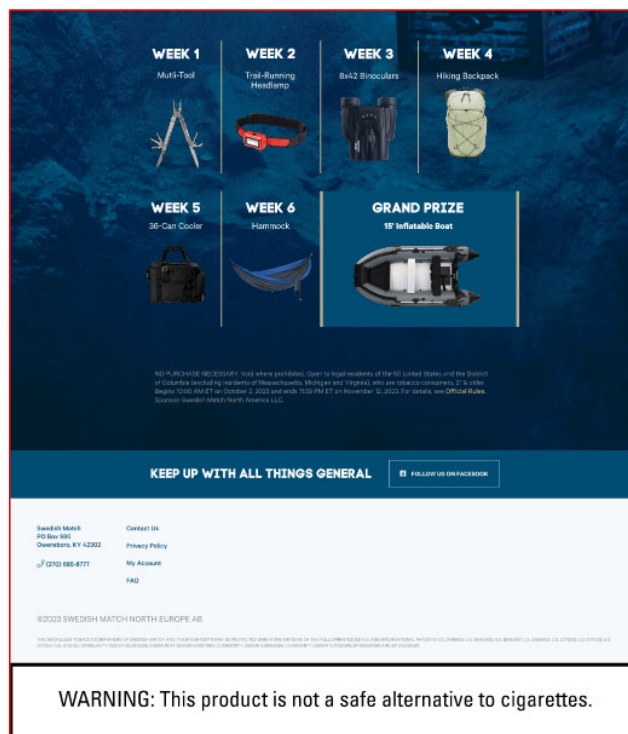
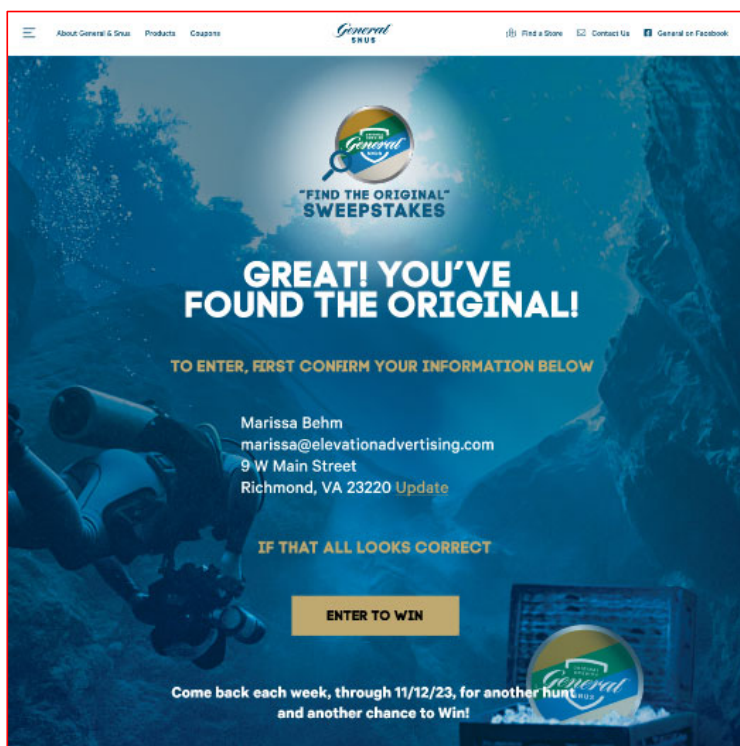
A HIGHER STANDARD

A higher standard is the only way to see the world in terms of patterns. A higher standard is the only way to see the world in terms of patterns. A higher standard is the only way to see the world in terms of patterns.

KEEP UP WITH ALL THINGS ORIGINAL

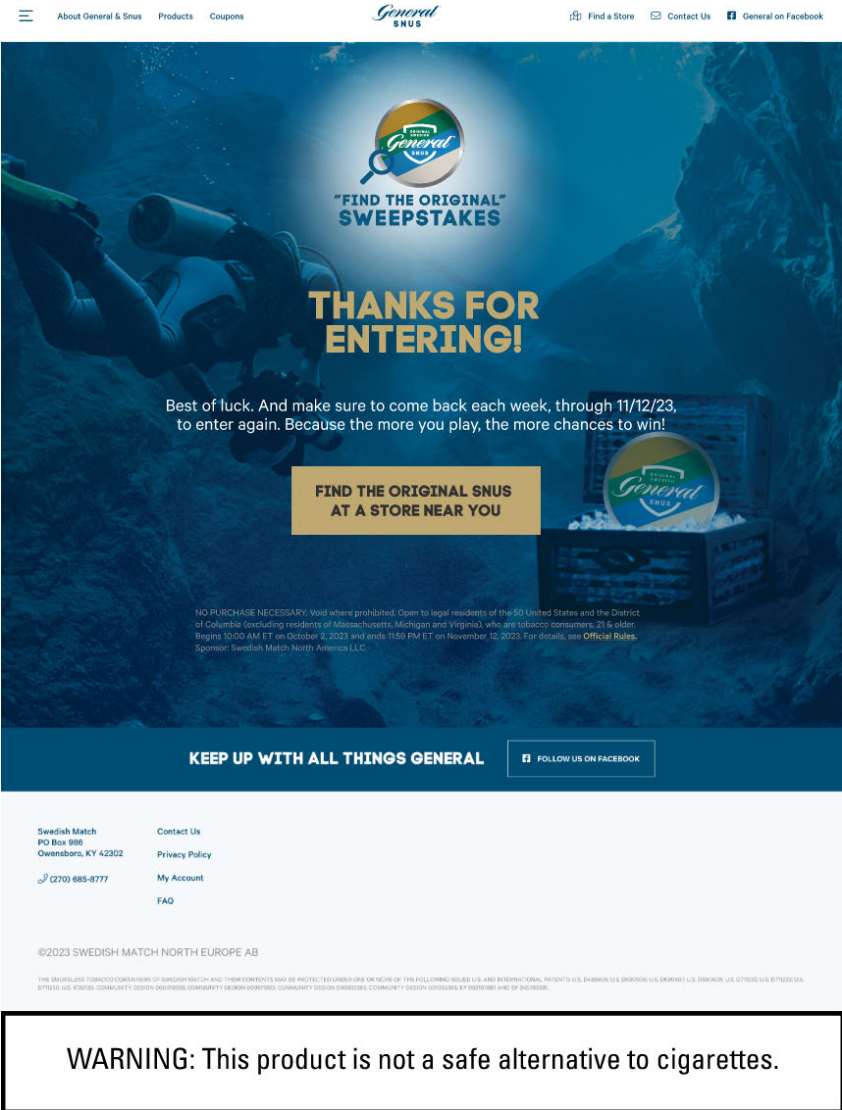
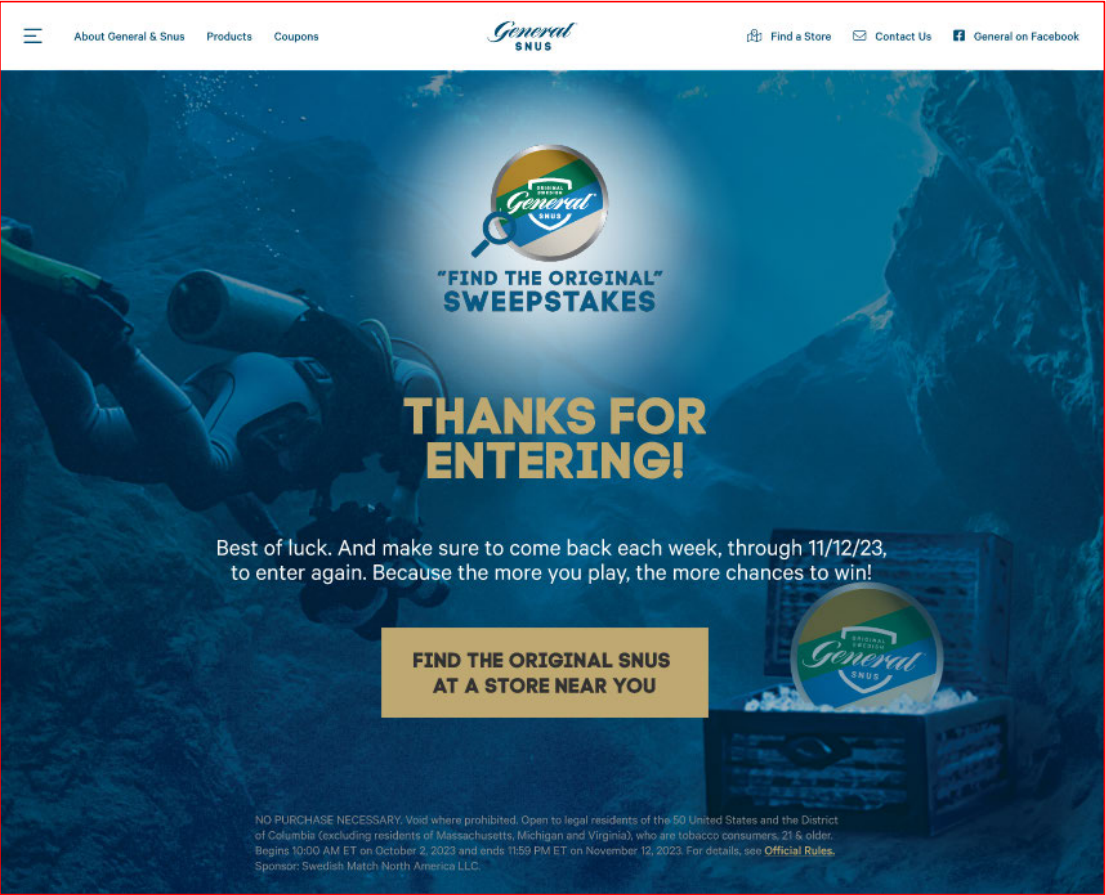
WARNING: This product is not a safe alternative to cigarettes.

10-2-23 – 11-12-23



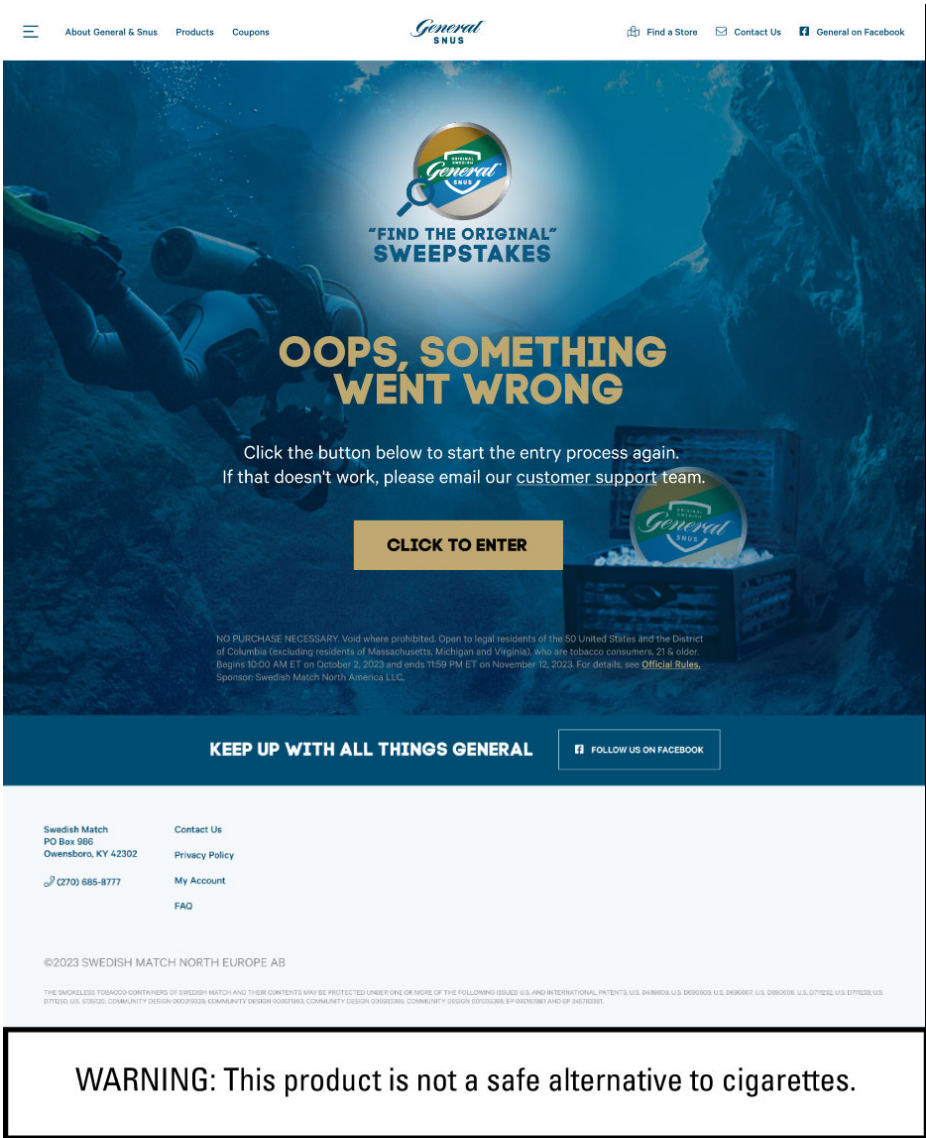
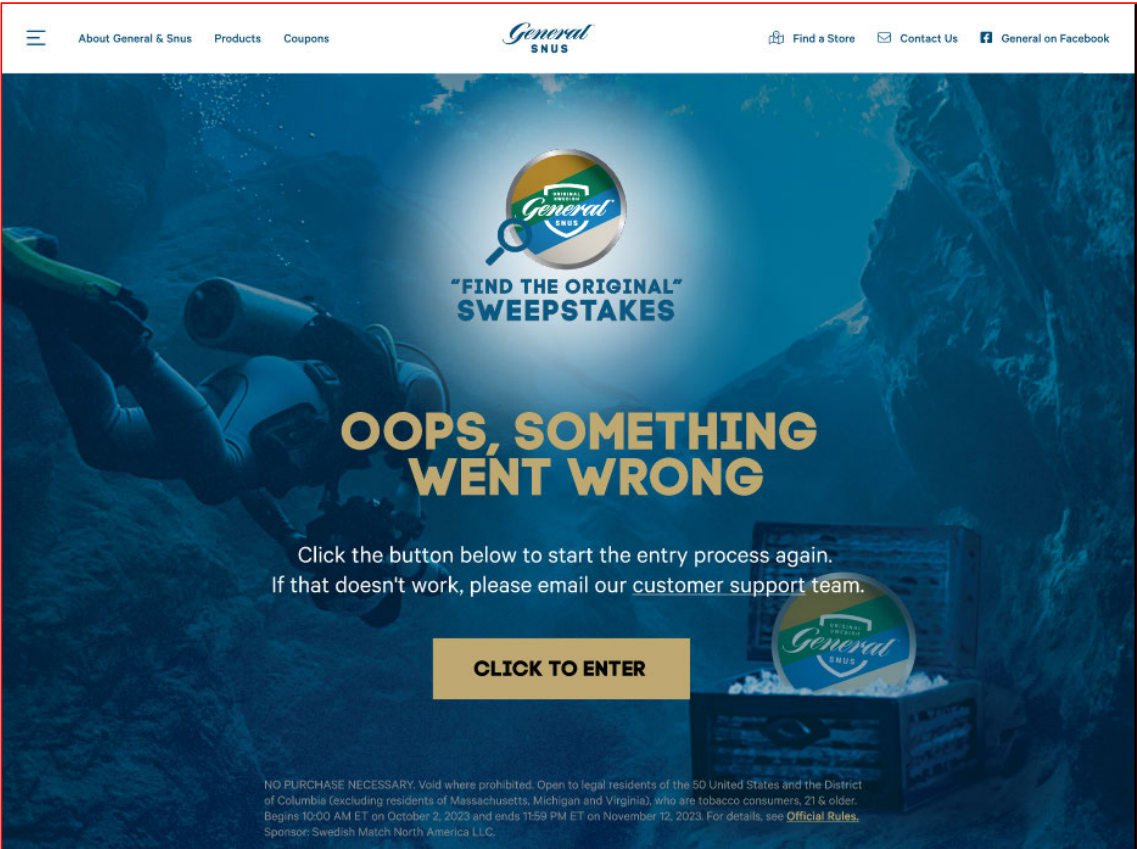
General Snus Find The Original Sweepstakes: Entry Confirmation Page [BEHIND AGE GATE]

10-2-23 – 11-12-23

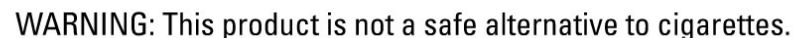


General Snus Find The Original Sweepstakes: Error Page [BEHIND AGE GATE]

10-2-23 – 11-12-23

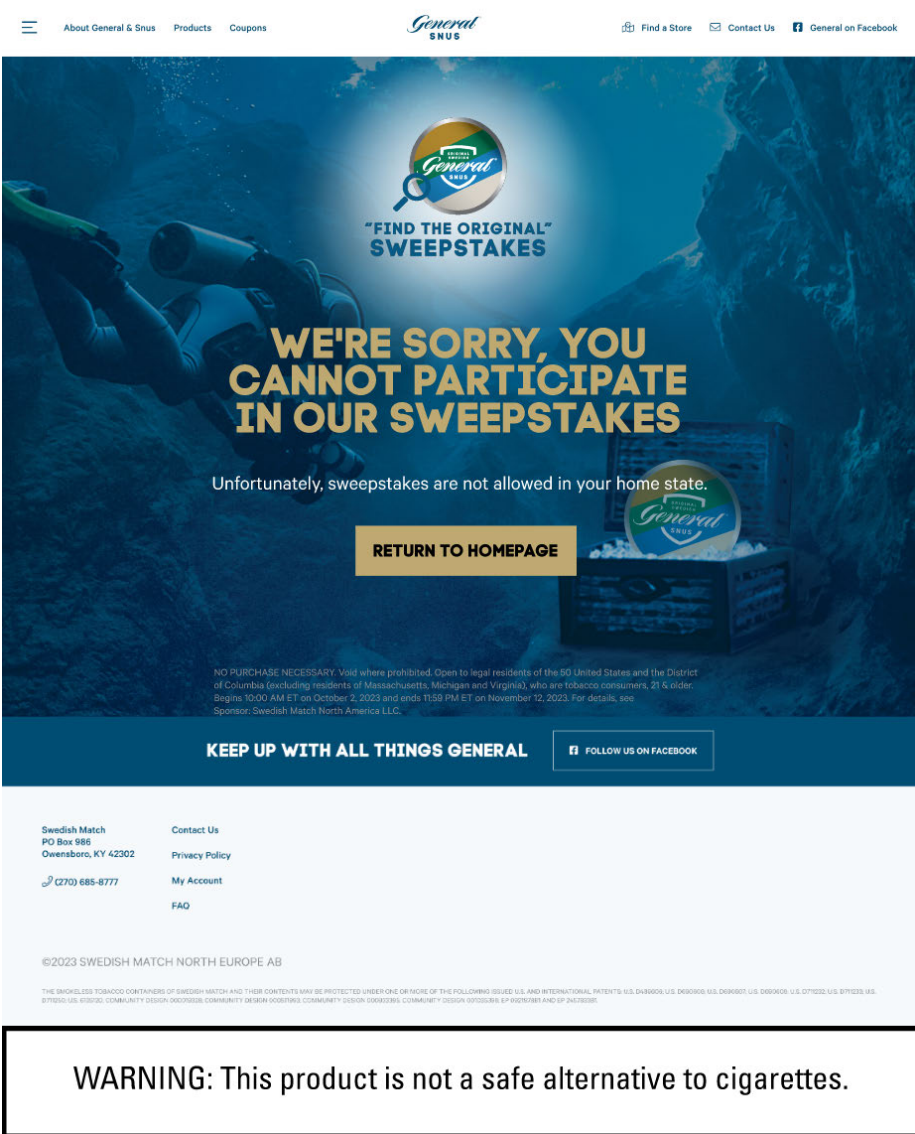
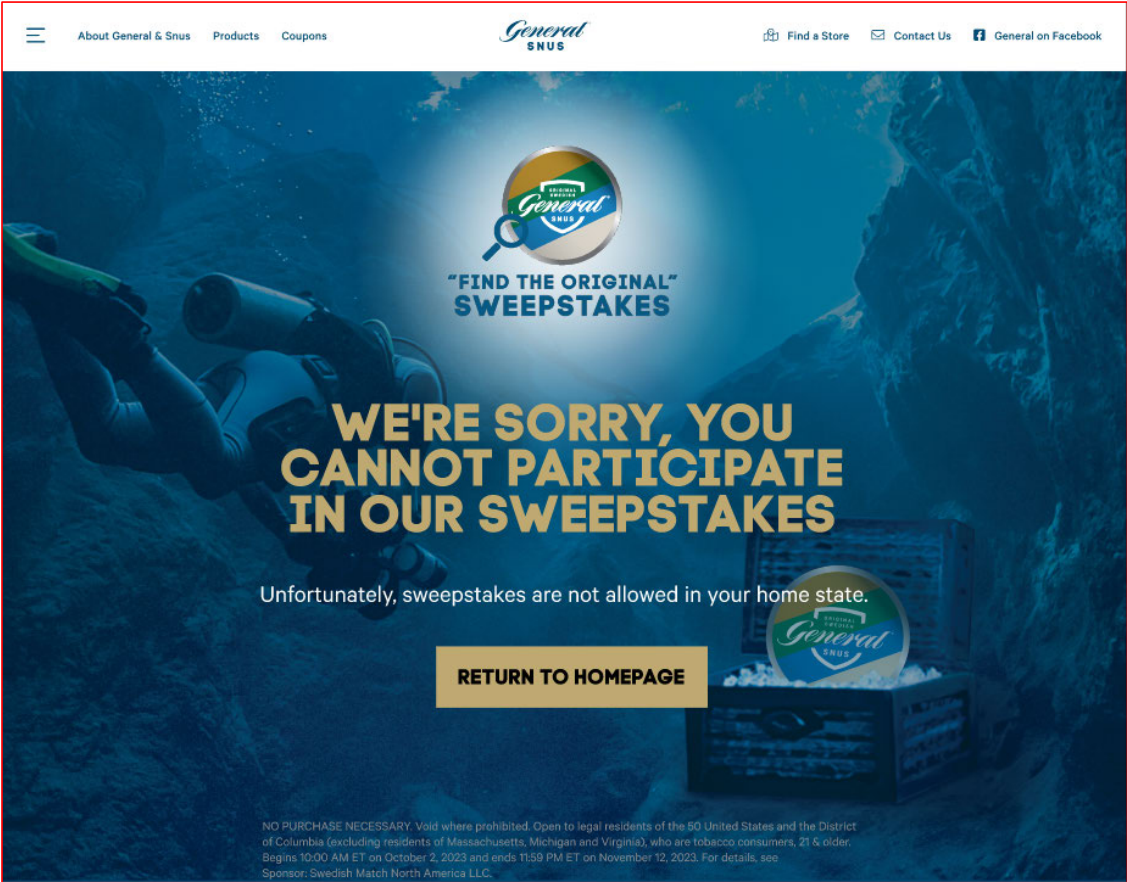


10-2-23 – 11-12-23



General Snus Find The Original Sweepstakes: Cannot Participate Page [BEHIND AGE GATE]

10-2-23 – 11-12-23



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

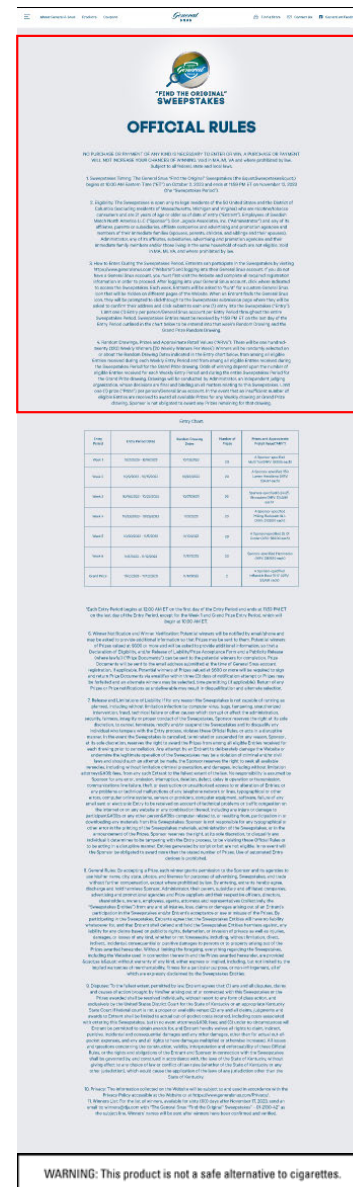
10-2-23 – 11-12-23



1. Sweepstakes Timing: The General Snus "Find the Original" Sweepstakes (the **"Sweepstakes"**) begins at 10:00 AM Eastern Time (**"ET"**) on October 2, 2023 and ends at 11:59 PM ET on November 12, 2023 (the **"Sweepstakes Period"**).

2. **Eligibility:** The Sweepstakes is open only to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia) who are nicotine/tobacco consumers and are 21 years of age or older as of date of entry ("**Entrant**"). Employees of Swedish Match North America LLC ("**Sponsor**"), Don Jagoda Associates, Inc. ("**Administrator**") and any of its affiliates, parents or subsidiaries, affiliate companies and advertising and promotion agencies and members of their immediate families (spouses, parents, children, and siblings and their spouses), Administrator, any of its affiliates, subsidiaries, advertising and promotion agencies and their immediate family members and/or those living in the same household of each are not eligible. Void in MA, MI, VA, and where prohibited by law.

3. **How to Enter:** During the Sweepstakes Period, Entrants can participate in the Sweepstakes by visiting <https://www.generalsnus.com> ("Website") and logging into their General Snus account. If you do not have a General Snus account, you must first visit the Website and complete all required registration information in order to proceed. After logging into your General Snus account, click where indicated to access the Sweepstakes. Each week, Entrants will be asked to "hunt" for a custom General Snus icon that will be hidden on different pages of the Website. When an Entrant finds the General Snus icon, they will be prompted to clickthrough to the Sweepstakes submission page where they will be asked to confirm their address and click submit to earn one (1) entry into the Sweepstakes ("**Entry**"). Limit one (1) Entry per person/General Snus account per Entry Period throughout the entire Sweepstakes Period. Sweepstakes Entries must be received by 11:59 PM ET on the last day of the Entry Period outlined in the chart below to be entered into that week's Random Drawing and the Grand Prize Random Drawing.
4. **Random Drawings, Prizes and Approximate Retail Values ("ARVs"):** There will be one hundred-twenty (120) Weekly Winners [20 Weekly Winners Per Week]: Winners will be randomly selected on or about the Random Drawing Dates indicated in the Entry chart below, from among all eligible Entries received during each Weekly Entry Period and from among all eligible Entries received during the Sweepstakes Period for the Grand Prize drawing. Odds of winning depend upon the number of eligible Entries received for each Weekly Entry Period and during the entire Sweepstakes Period for the Grand Prize drawing. Drawings will be conducted by Administrator, an independent judging organization, whose decisions are final and binding on all matters relating to this Sweepstakes. Limit one (1) prize ("**Prize**") per person/General Snus account. In the event that an insufficient number of eligible Entries are received to award all available Prizes for any Weekly drawing or Grand Prize drawing, Sponsor is not obligated to award any Prizes remaining for that drawing.

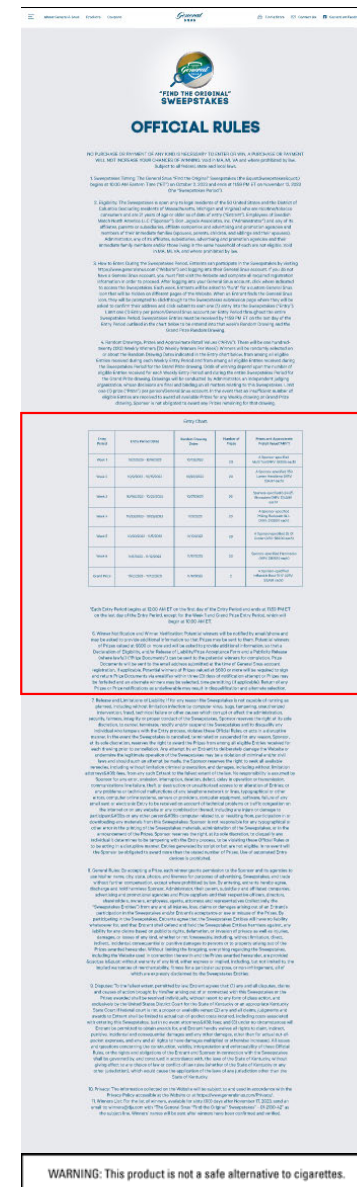


10-2-23 – 11-12-23

Entry Chart:				
Entry Period	Entry Period Dates	Random Drawing Dates	Number of Prizes	Prizes and Approximate Retail Values ("ARV")
Week 1	10/2/2023 - 10/8/2023	10/13/2023	20	A Sponsor-specified Multi Tool (ARV: \$69.95 each)
Week 2	10/9/2023 - 10/15/2023	10/20/2023	20	A Sponsor-specified Trail Running Headlamp (ARV: \$34.97 each)
Week 3	10/16/2023 - 10/22/2023	10/27/2023	20	Sponsor-specified 8-24x25 Binoculars (ARV: \$143.99 each)
Week 4	10/23/2023 - 10/29/2023	11/3/2023	20	A Sponsor-specified Hiking Backpack (ARV: \$109.00 each)
Week 5	10/30/2023 - 11/5/2023	11/10/2023	20	A Sponsor-specified 36-Can Cooler (ARV: \$89.00 each)
Week 6	11/6/2023 - 11/12/2023	11/17/2023	20	Sponsor-specified Hammocks (ARV: \$109.90 each)
Grand Prize	10/2/2023 - 11/12/2023	11/17/2023	2	A Sponsor-specified 15' Inflatable Boat (ARV: \$3,459 each)

*Each Entry Period begins at 12:00 AM ET on the first day of the Entry Period and ends at 11:59 PM ET on the last day of the Entry Period, except for the Week 1 and Grand Prize Entry Period, which will begin at 10:00 AM ET.

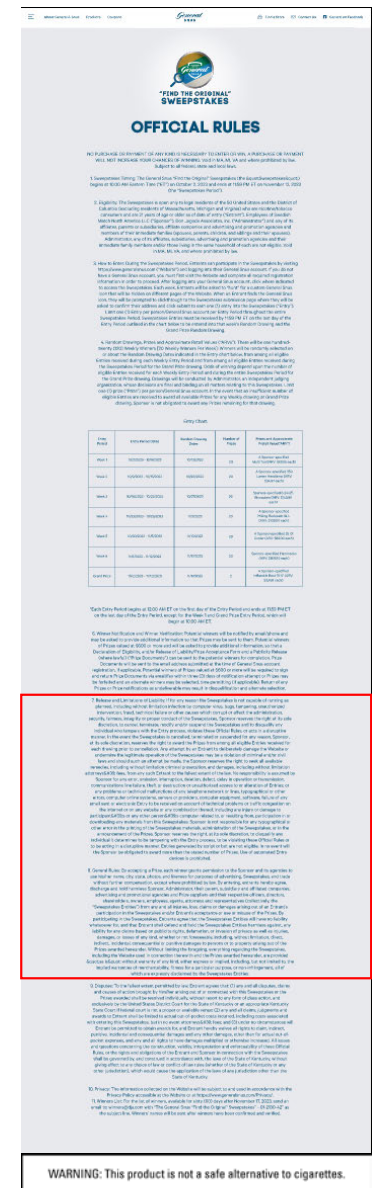
6. **Winner Notification and Winner Verification:** Potential winners will be notified by email/phone and may be asked to provide additional information so that Prizes may be sent to them. Potential winners of Prizes valued at \$600 or more and will be asked to provide additional information, so that a Declaration of Eligibility, and/or Release of Liability/Prize Acceptance Form and a Publicity Release (where lawful) ("**Prize Documents**") can be sent to the potential winners for completion. Prize Documents will be sent to the email address submitted at the time of General Snus account registration, if applicable. Potential winners of Prizes valued at \$600 or more will be required to sign and return Prize Documents via email/fax within three (3) days of notification attempt or Prizes may be forfeited and an alternate winners may be selected, time permitting (if applicable). Return of any Prizes or Prize notifications as undeliverable may result in disqualification and alternate selection.



10-2-23 – 11-12-23

8. **General Rules:** By accepting a Prize, each winner grants permission to the Sponsor and its agencies to use his/her name, city, state, photos, and likeness for purposes of advertising, Sweepstakes, and trade without further compensation, except where prohibited by law. By entering, entrants hereby agree, discharge and hold harmless Sponsor, Administrator, their parent, subsidiary and affiliated companies, advertising and promotional agencies and Prize suppliers and their respective officers, directors, shareholders, owners, employees, agents, attorneys and representatives (collectively, the **"Sweepstakes Entities"**) from any and all injuries, loss, claims or damages arising out of an Entrant's participation in the Sweepstakes and/or Entrant's acceptance or use or misuse of the Prizes. By participating in the Sweepstakes, Entrants agree that the Sweepstakes Entities will have no liability whatsoever for, and that Entrant shall defend and hold the Sweepstakes Entities harmless against, any liability for any claims based on publicity rights, defamation, or invasion of privacy as well as injuries, damages, or losses of any kind, whether or not foreseeable, including, without limitation, direct, indirect, incidental, consequential or punitive damages to persons or to property arising out of the Prizes awarded hereunder. Without limiting the foregoing, everything regarding the Sweepstakes, including the Website used in connection therewith and the Prizes awarded hereunder, are provided "as is" without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, or non-infringement, all of which are expressly disclaimed by the Sweepstakes Entities.

79



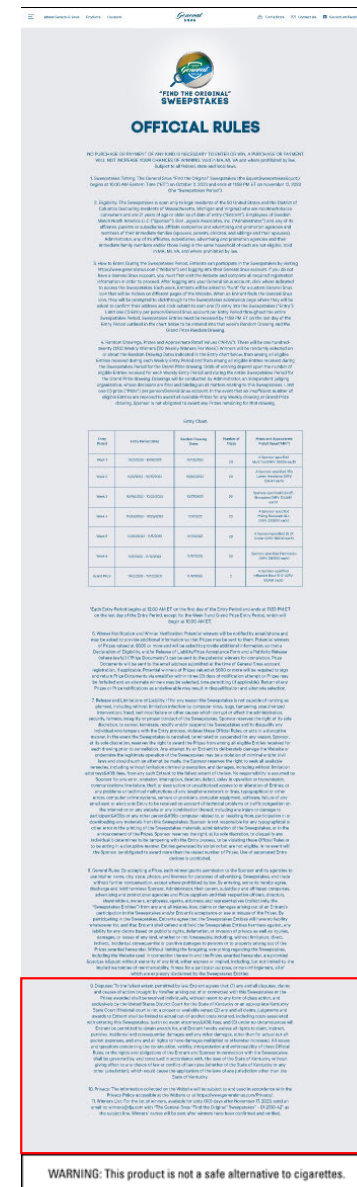
10-2-23 – 11-12-23

10-2-23 – 11-12-23

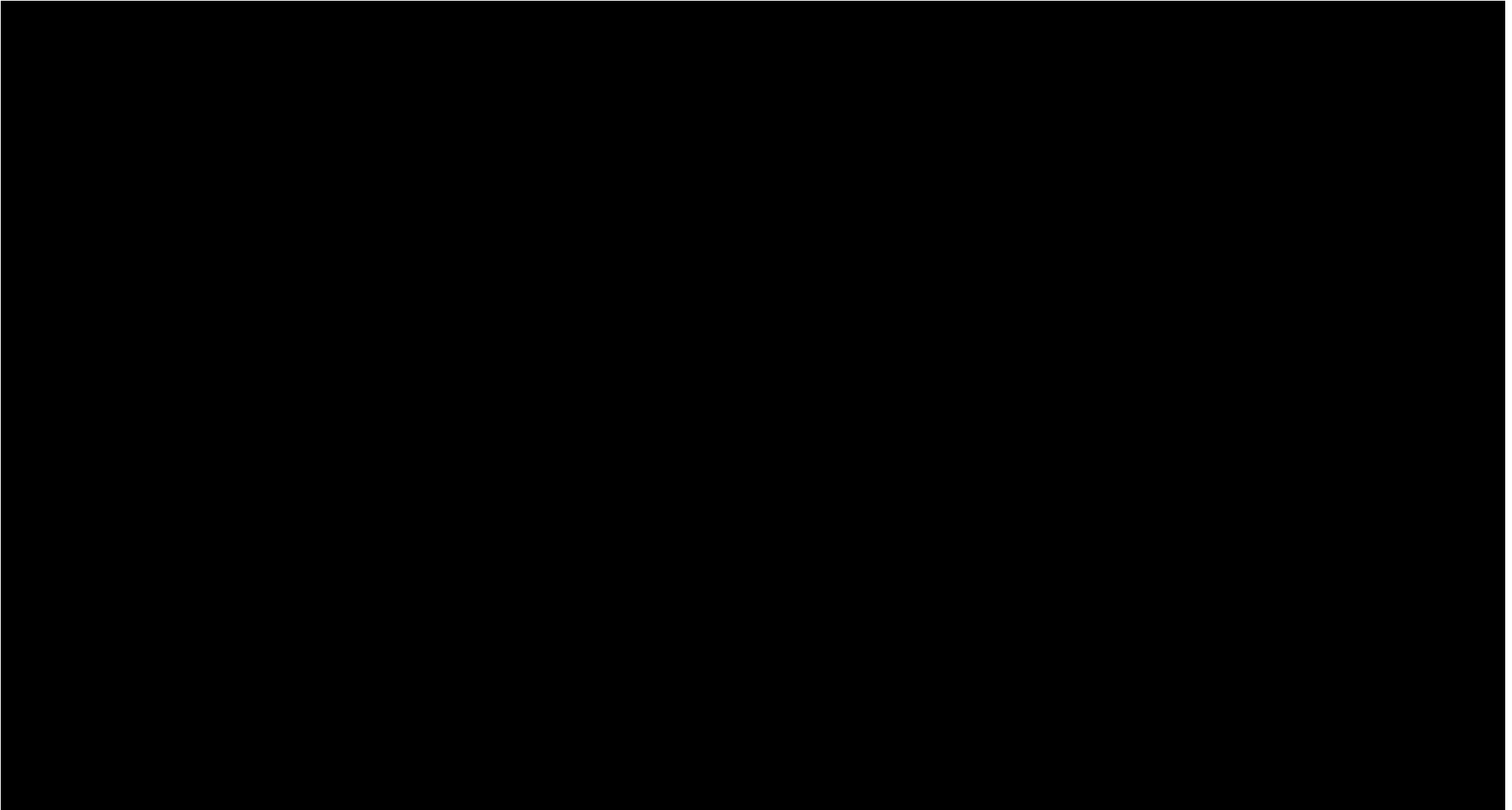
9. **Disputes:** To the fullest extent permitted by law, Entrant agrees that: (1) any and all disputes, claims and causes of action brought by him/her arising out of or connected with this Sweepstakes or the Prizes awarded shall be resolved individually, without resort to any form of class action, and exclusively by the United States District Court for the State of Kentucky or an appropriate Kentucky State Court if federal court is not a proper or available venue; (2) any and all claims, judgments and awards to Entrant shall be limited to actual out-of-pocket costs incurred, including costs associated with entering this Sweepstakes, but in no event attorneys' fees; and (3) under no circumstances will Entrant be permitted to obtain awards for, and Entrant hereby waives all rights to claim, indirect, punitive, incidental and consequential damages and any other damages, other than for actual out-of-pocket expenses, and any and all rights to have damages multiplied or otherwise increased. All issues and questions concerning the construction, validity, interpretation and enforceability of these Official Rules, or the rights and obligations of the Entrant and Sponsor in connection with the Sweepstakes shall be governed by, and construed in accordance with, the laws of the State of Kentucky, without giving effect to any choice of law or conflict of law rules (whether of the State of Kentucky or any other jurisdiction), which would cause the application of the laws of any jurisdiction other than the State of Kentucky.

10. **Privacy:** The information collected on the Website will be subject to and used in accordance with the Privacy Policy accessible at the Website or at <https://www.generalsnus.com/Privacy/>.

11. **Winners List:** For the list of winners, available for sixty (60) days after November 17, 2023, send an email to: winners@dja.com with "The General Snus "Find the Original" Sweepstakes" - 01-2130-42" as the subject line. Winners' names will be sent after winners have been confirmed and verified.



General Snus Digital Website Google Analytics: TTL US Topline



General Snus Digital Website Google Analytics: Demographics

(b) (4)

General Snus Digital Website Google Analytics: by Geography

Nov 1, 2022 - Oct 1, 2023

(b) (4)

General Snus Digital Website Google Analytics: by Web Page

Nov 1, 2022 - Oct 1, 2023

(b) (4)

2023 MRTP Annual Report

CATEGORY: SNUS

BRAND: GENERAL SNUS

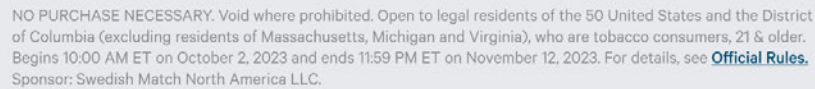
November 2022 – October 2023

Appendix 2A (2)

Website Page with MRTP Content



10-23-23 – 10-29-23

[illegible]

Week 4 Removed [BEHIND AGE GATE]

10-30-23 – current



General Snus Digital Website Google Analytics: MRTP / MODIFIED RISK WEB PAGE

Nov 1, 2022 - Oct 1, 2023

(b) (4)

General Snus Digital Website Google Analytics: MRTP / MODIFIED RISK WEB PAGE

Nov 1, 2021 - Oct 1, 2022

(b) (4)

2023 MRTP Annual Report

CATEGORY: SNUS

BRAND: GENERAL SNUS

November 2022 – October 2023

Appendix 2A (3)

Advertising



CONSUMER ADVERTISING



General Snus Digital Ads: Display, Animated – Multi Frame 300 x 250

June 12, 2023 - current

Re-Targeting

See media file:

1_SWED_GEN_23Q1_Equity1B_300x250_Display_Animated.mp4



See media file:

5_SWED_GEN_23Q1_Equity2B_300x250_Display_Animated.mp4




Swedish Match.

General Snus Digital Ads: Display, Animated – Multi Frame 300 x 250

June 12, 2023 - current


Prospecting

See media file:

 7_SWED_GEN_23Q1_Equity1A_300x250_Display_Animated.mp4



See media file:

 3_SWED_GEN_23Q1_Equity2A_300x250_Display_Animated.mp4



Swedish Match.

General Snus Digital Ads: Display, Animated – Multi Frame 300 x 600

June 12, 2023 - current

Re-Targeting




See media file:

 2_SWED_GEN_23Q1_Equity1B_300x600_Display_Animated.mp4

☆☆☆
Swedish Match.

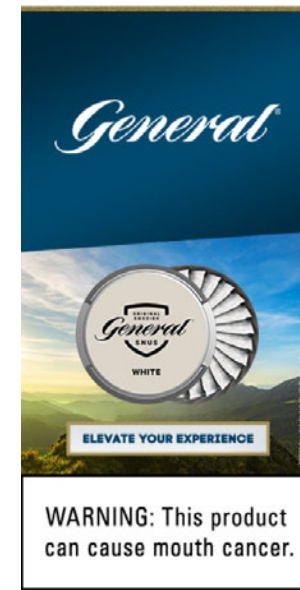
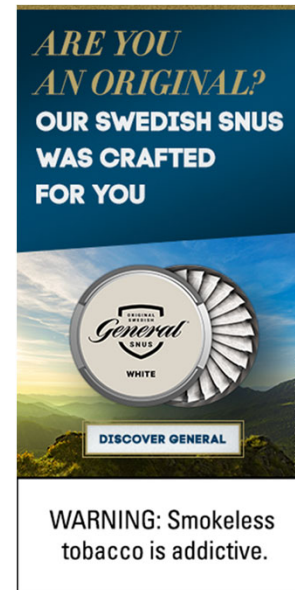
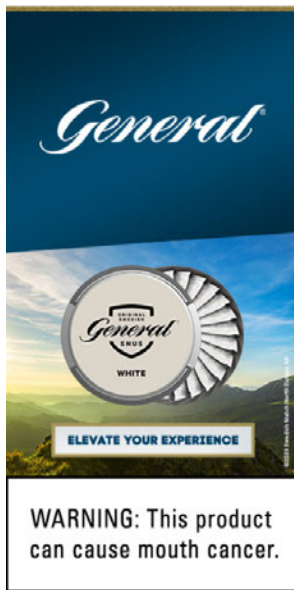
See media file:

 6_SWED_GEN_23Q1_Equity2B_300x600_Display_Animated.mp4

General Snus Digital Ads: Display, Animated – Multi Frame 300 x 600

June 12, 2023 - current

Prospecting



See media file:

8_SWED_GEN_23Q1_Equity1A_300x600_Display_Animated.mp4

Swedish Match.

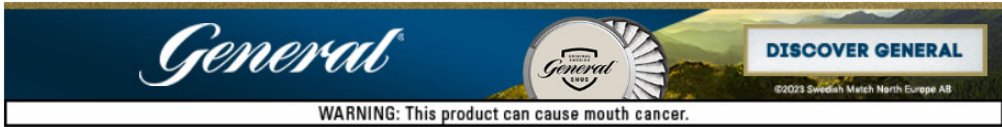
See media file:

4_SWED_GEN_23Q1_Equity2A_300x600_Display_Animated.mp4

General Snus Digital Ads: Display, Animated – Multi Frame 728 x 90

June 12, 2023 - current

Re-Targeting



See media file:

9_SWED_GEN_23Q1_Equity1B_728x90_Display_Animated.mp4



See media file:

10_SWED_GEN_23Q1_Equity2A_728x90_Display_Animated.mp4

General Snus Digital Ads: Display, Animated – Multi Frame 728 x 90

June 12, 2023 - current

Prospecting



See media file:

12_SWED_GEN_23Q1_Equity1A_728x90_Display_Animated.mp4



See media file:

11 SWED_GEN_23Q1_Equity2B_728x90_Display_Animated.mp4

Swedish Match.

General Snus Digital Ads: Display, Static 728 x 90

June 12, 2023 - current

Re-Targeting



Prospecting



General Snus Digital Ads: Display, Static 300 x 250

June 12, 2023 - current

Prospecting



Re-Targeting



General Snus Digital Ads: Display, Static 300 x 600

June 12, 2023 - current

Re-Targeting

**ORIGINAL
SNUS FOR
*ORIGINALS
LIKE YOU***



ELEVATE YOUR EXPERIENCE

WARNING: Smokeless tobacco is addictive.

***STAY ORIGINAL*
WITH THE
ORIGINAL
SWEDISH
SNUS**



FIND GENERAL

WARNING: Smokeless tobacco is addictive.

Prospecting

**AN ELEVATED
TOBACCO
EXPERIENCE
FOR
*ORIGINALS***



DISCOVER GENERAL

WARNING: Smokeless tobacco is addictive.

***ARE YOU
AN ORIGINAL?*
OUR SWEDISH SNUS
WAS CRAFTED
FOR YOU**



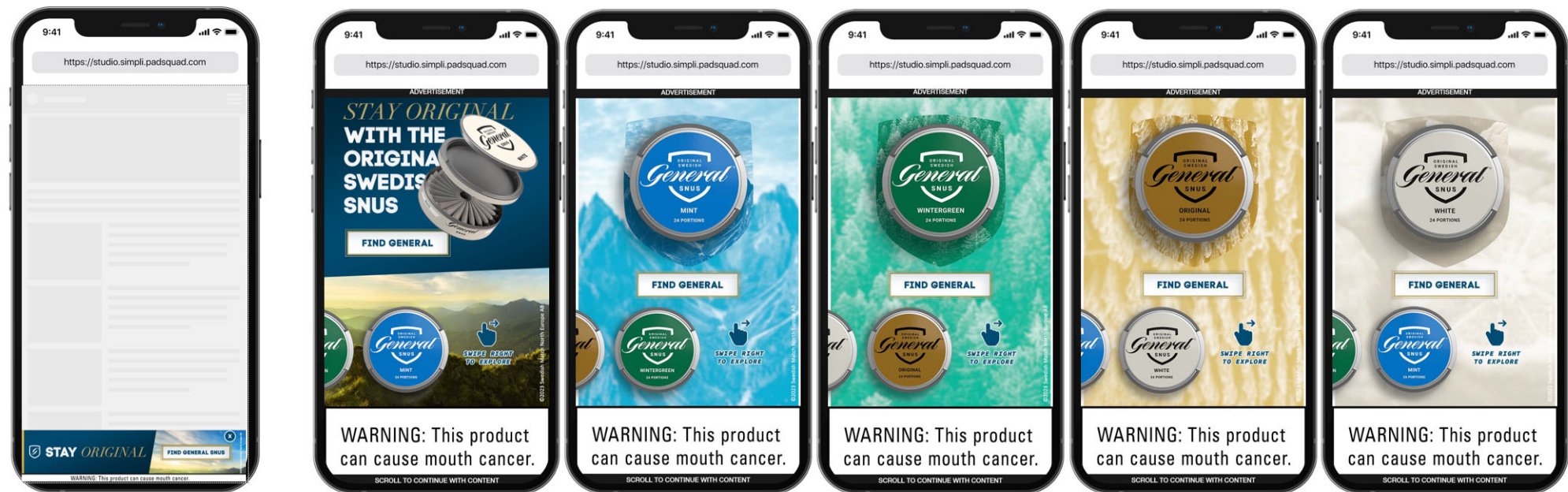
DISCOVER GENERAL

WARNING: Smokeless tobacco is addictive.

General Snus Digital Ads: Product – Reels, Animated

June 12, 2023 - current

PRO version shown for reference

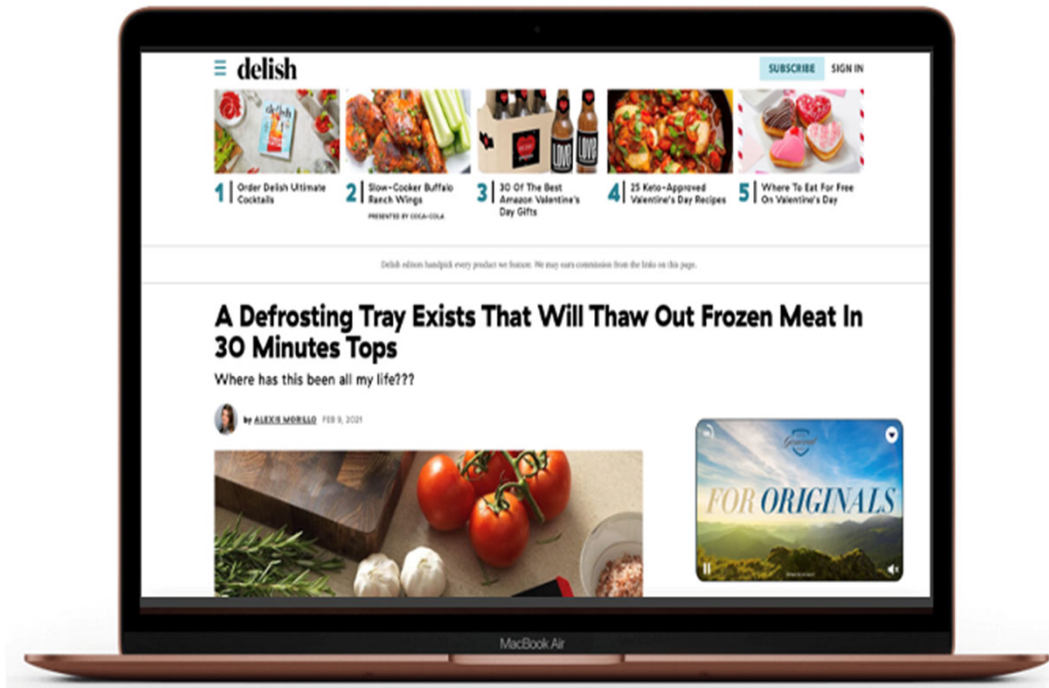
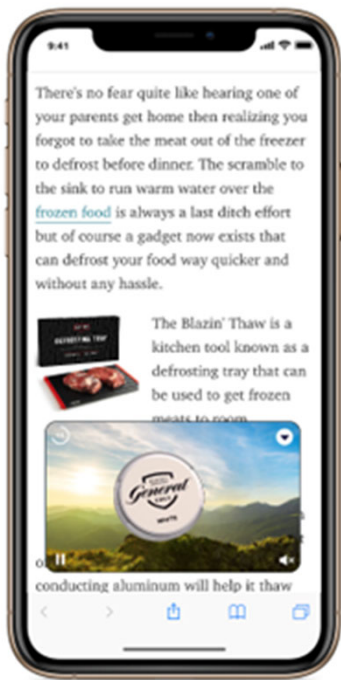


See media file:  11875591_23_Gen_Q1_Media_padsquad.mp4

Swedish Match.

General Snus Digital Ads: Product – OLV VidTile, Animated

June 12, 2023 - current



See media file:

23_GEN_Q1_2023_Media_MessagingA_16x9_15s_OLV.mp4


General Snus Digital Media .mp4 File Guide, Animated Display, 300x250

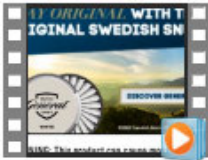
.mp4 Image

.mp4 File Name and Length




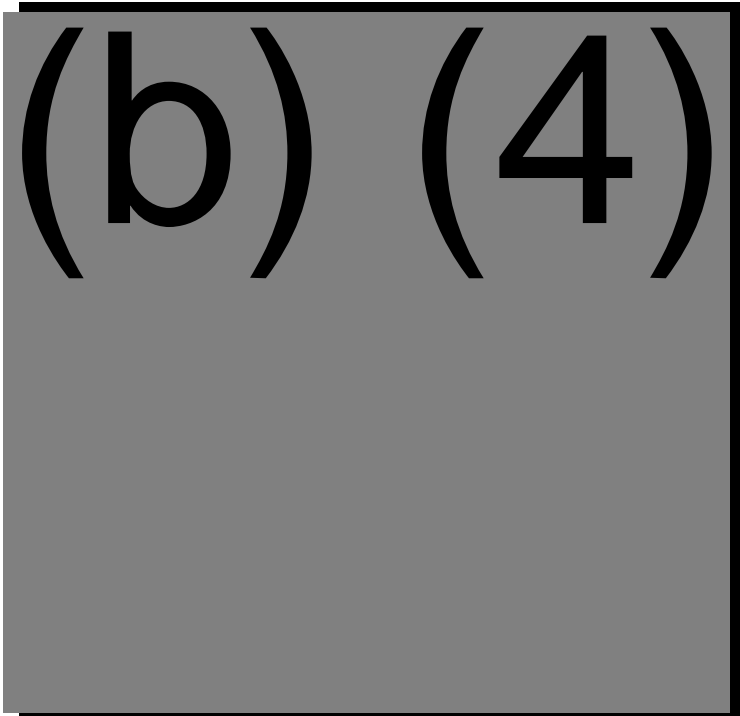
1_SWED_GEN_23
Q1_Equity1B_300
x250_Display_Ani
mated.mp4

 1_SWED_GEN_23Q1_Equity1B_300x250_Display_Animated.mp4
00:00:07



5_
SWED_GEN_23Q
1_Equity2B_300x
250_Display_A...

 5_SWED_GEN_23Q1_Equity2B_300x250_Display_Animated.mp4
00:00:07



General Snus Digital Media .mp4 File Guide, Animated Display, 300x250

.mp4 Image

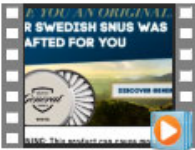
.mp4 File Name and Length



7_SWED_GEN_23
Q1_Equity1A_300
x250_Display_Ani
mated.mp4

7_SWED_GEN_23Q1_Equity1A_300x250_Display_Animated.mp4

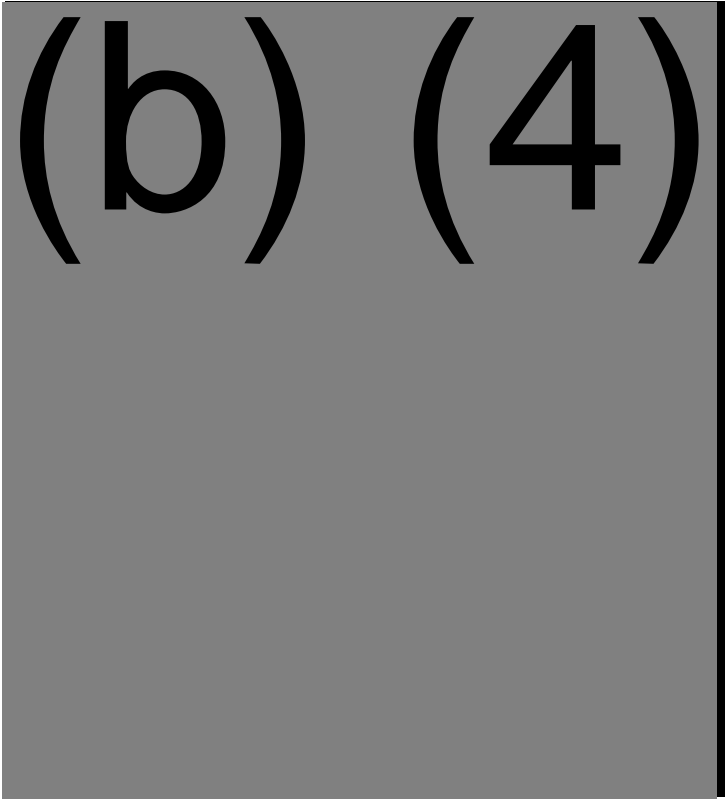
00:00:07







3_SWED_GEN_23
Q1_Equity2A_300
x250_Display_Ani
mated.mp4

3_SWED_GEN_23Q1_Equity2A_300x250_Display_Animated.mp4





00:00:07



General Snus Digital Media .mp4 File Guide, Animated Display

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
 2_ SWED_GEN_23Q 1_Equity1B_300x 600_Display_A...	 2_SWED_GEN_23Q1_Equity1B_300x600_Display_Animated.mp4 00:00:07	(b) (4)
 6_SWED_GEN_23 Q1_Equity2B_300 x600_Display_Ani mated.mp4	 6_SWED_GEN_23Q1_Equity2B_300x600_Display_Animated.mp4 00:00:07	

General Snus Digital Media .mp4 File Guide, Animated Display

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
 <p>8_SWED_GEN_23Q1_Equity1A_300x600_Display_Animated.mp4</p>	 8_SWED_GEN_23Q1_Equity1A_300x600_Display_Animated.mp4 00:00:07	<div>(b) (4)</div>
 <p>4_SWED_GEN_23Q1_Equity2A_300x600_Display_Animated.mp4</p>	 4_SWED_GEN_23Q1_Equity2A_300x600_Display_Animated.mp4 00:00:07	

General Snus Digital Media .mp4 File Guide, Animated Display

.mp4 Image

.mp4 File Name and Length

.mp4 Descripton



9_SWED_GEN_23
Q1_Equity1B_728
x90_
Display_Animat...



9_SWED_GEN_23Q1_Equity1B_728x90_ Display_Animated.mp4

00:00:07



11
SWED_GEN_23Q
1_Equity2B_728x
90_ Display_An...







11 SWED_GEN_23Q1_Equity2B_728x90_ Display_Animated.mp4

00:00:07



(b) (4)



General Snus Digital Media .mp4 File Guide, Animated Display

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Descripton</u>
 12_SWED_GEN_23Q1_Equity1A_728x90_Display_Animat...	 12_SWED_GEN_23Q1_Equity1A_728x90_Display_Animated.mp4 00:00:07	<div>(b) (4)</div>
 10_SWED_GEN_23Q1_Equity2A_728x90_Display_Animat...	 10_SWED_GEN_23Q1_Equity2A_728x90_Display_Animated.mp4 00:00:07	

General Snus Digital Media .mp4 File Guide - OLV


<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Descripton</u>
 <p>23_GEN_Q1_2023 _Media_Messagin gA_16x9_15s_OLV .mp4</p>	 11875591_23_Gen_Q1_Media_16x9_q2_v4a (1).mp4 00:00:15	(b) (4)

General Snus Digital Media .mp4 File Guide – Animated, Reels

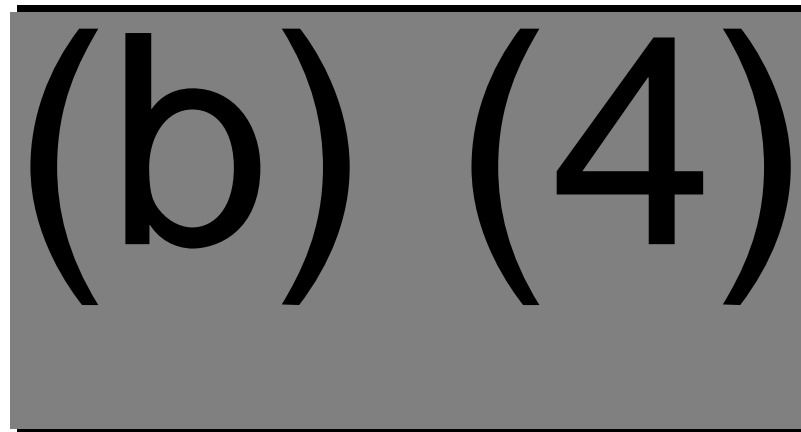
.mp4 Image

.mp4 File Name and Length



 11875591_23_Gen_Q1_Media_padsquad.mp4

00:00:14



General Snus Digital 2023 Media Plan (no digital media in December 2022)

(b) (4)

General Snus Digital 2023 Media Plan

(b) (4)

General Snus Digital 2023 Media Plan con't

(b) (4)

General Snus Digital 2023 Media Plan con't

(b) (4)

General Snus Digital 2023 Media (Havas) Brand Safety Reporting

(b) (4)

General Snus Digital 2022 Media (Havas) Reach by State

(b) (4)

2023 MRTP Annual Report

CATEGORY: SNUS

BRAND: GENERAL SNUS

November 2022 – October 2023

Appendix 2A (4)

Direct Mail / Email / Facebook / POS / Packaging

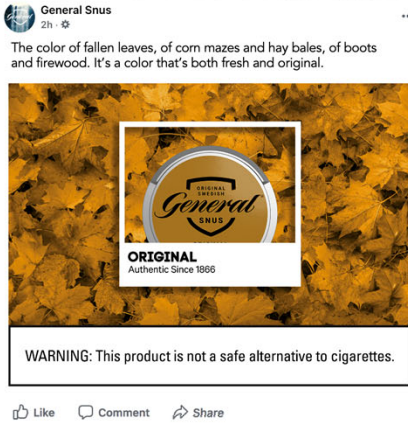


GENERAL SNUS SOCIAL MEDIA

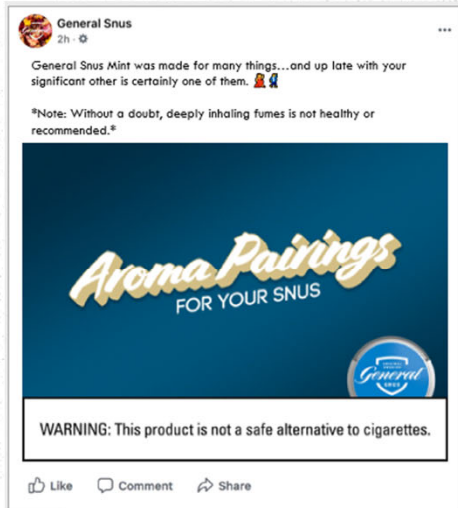


General Snus November 2022 Facebook Posts

11-2-22

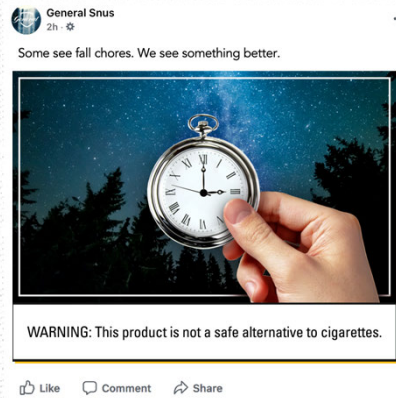


11-11-22




See media file:  11-11-22_GEB FB Mint Aroma Pairing Open Can.mp4

11-4-22



See media file:

 11-4-22_GEN FB_Variety Showcase.mp4

11-15-22



See media file: 11-15-22_GEN FB Snus Starter Pack.mp4

11-6-22



See media file:

11-6-22_GEN FB_Leaves Coupon.mp4

General Snus November 2022 Facebook Posts con't

11-18-22

General Snus

2h · 🌐

What's the most original name you ever gave your fantasy football team?

COMMENT ON THIS POST WITH A TRULY ORIGINAL FANTASY TEAM NAME. 🏈



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

Like

Comment


Share

11-23-22

General Snus

2h · 🌐

Snus the season, everyone.




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

Like

Comment

Share

See media file:


 11-23-22_GEN FB Your Can Follows.mp4

11-24-22

General Snus

2h · 🌐

Wishing you a joyous Thanksgiving. We're thankful for every true original who chooses General Snus.



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

Like

Comment


Share

11-29-22

General Snus

2h · 🌐

The Beautiful Game deserves an elevated tobacco experience.



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

Like

Comment

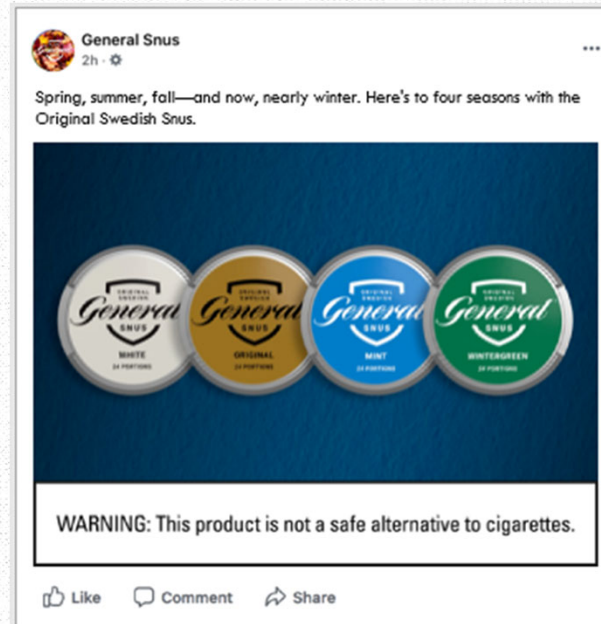
Share

General Snus December 2022 Facebook Posts

12-6-22



12-9-22



12-14-22



See file:

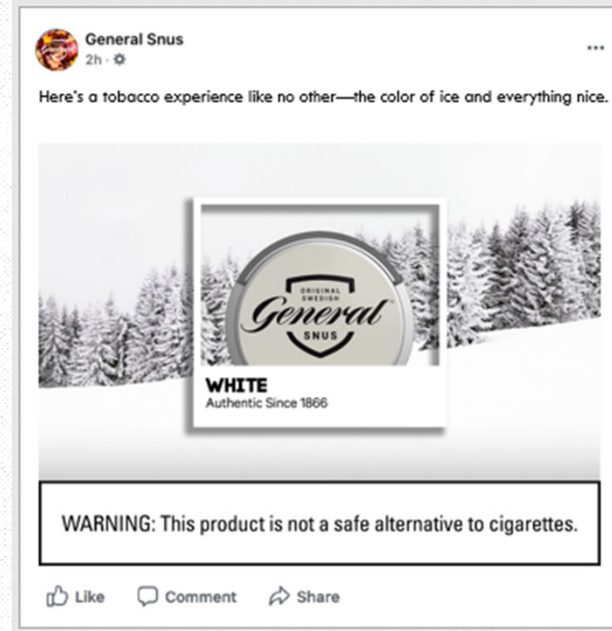
📎 12-9-22 GEN FB_Seasons with the Original.mp4

General Snus December 2022 Facebook Posts con't

12-16-22



12-19-22



12-21-22



See file:

📎 12-16-22 GEN FB_White Aroma Pairings.mp4

General Snus December 2022 Facebook Posts con't

12-24-22

General Snus
2h · 🌐

The gift of the Original Swedish Snus — packed with quality and ready to unwrap.



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

👍 Like

💬 Comment

➦ Share

12-27-22

General Snus
2h · 🌐

Norrskén, pronounced /nor-HWEE-un/, is the Swedish word for aurora borealis or “northern lights”—and Sweden’s far north may be the best place in the world to see them.



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

👍 Like

💬 Comment

➦ Share

See file:

 12-27-22 GEN FB_Norrskén.mp4

12-30-22

General Snus
2h · 🌐

Show your NYE party friends how to toast the new year like Johan.



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

👍 Like

💬 Comment

➦ Share

General Snus January 2023 Facebook Cover Image

1-6-23



General Snus January 2023 Facebook Posts

1-3-23

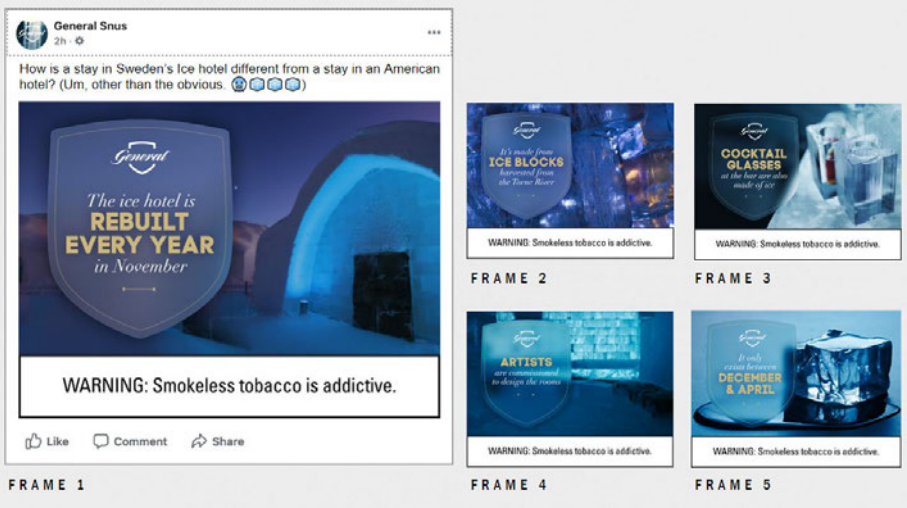


1-7-23



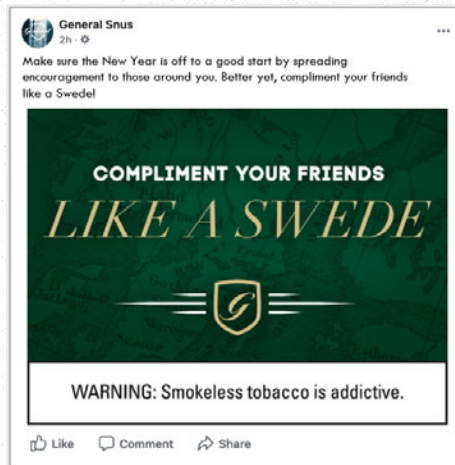
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1-10-23



General Snus January 2023 Facebook Posts con't

1-13-23



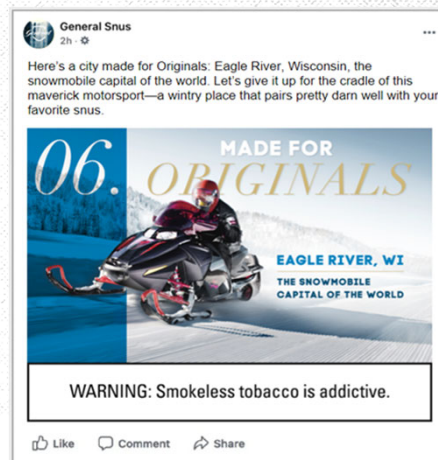
See media file:  1-13-23_FB_POST.mp4

1-17-23



See media file:  1-17-23_FB_POST.mp4

1-24-23



1-26-23



General Snus February 2023 Facebook Posts

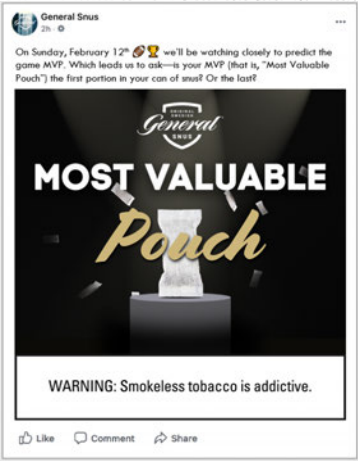
2-1-23



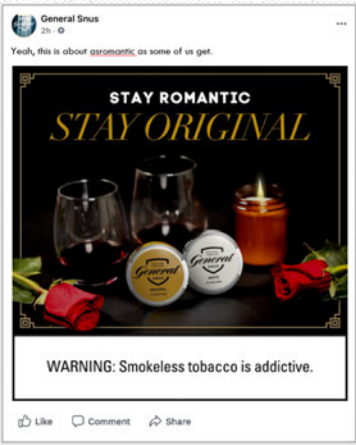
2-8-23



2-10-23



2-14-23

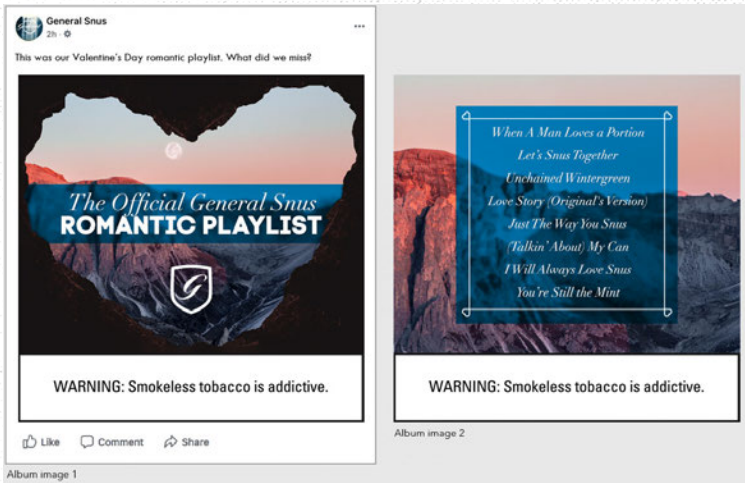


See media file:

2-14-23_FB_POST.mp4

General Snus February 2023 Facebook Posts

2-17-23



2-21-23



2-22-23

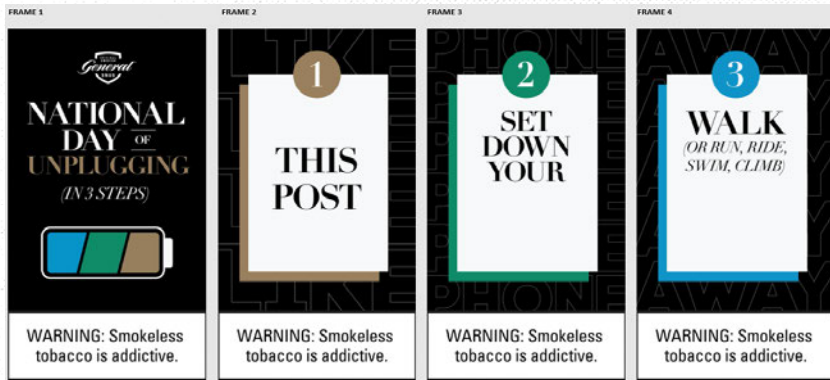


2-24-23



General Snus March 2023 Facebook Posts

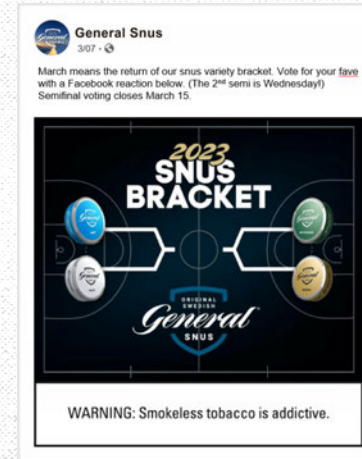
3-3-23



See media file:

- 3-3-23_FB_POST_FRAME1.mp4
- 3-3-23_FB_POST_FRAME2.mp4
- 3-3-23_FB_POST_FRAME3.mp4
- 3-3-23_FB_POST_FRAME4.mp4

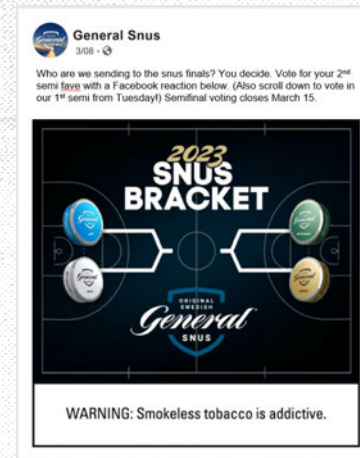
3-7-23



See media file:

- 3-7-23_FB_POST.mp4

3-8-23

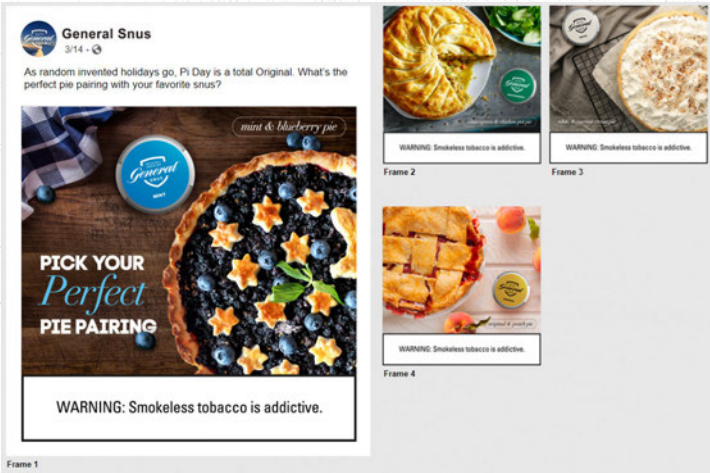


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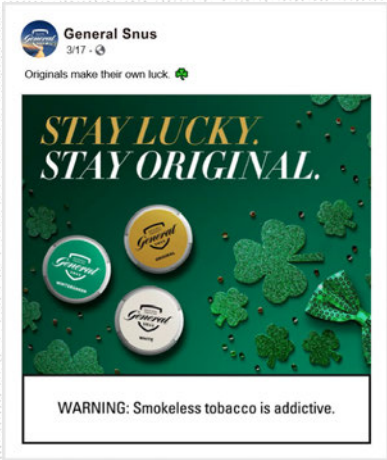
- 3-8-23_FB_POST.mp4

General Snus March 2023 Facebook Posts con't

3-14-23



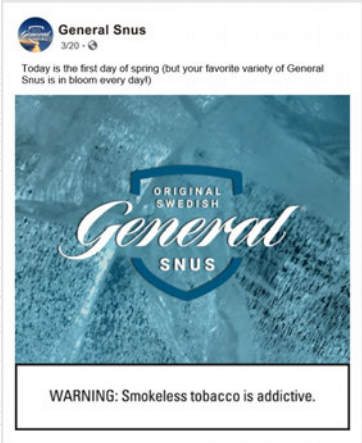
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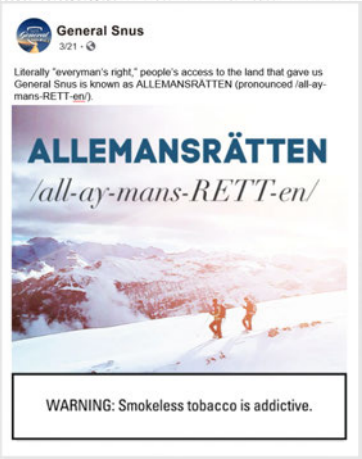
3-20-23



See media file:

3-20-23_FB_POST.mp4

3-21-23




See media file:

3-21-23_FB_POST.mp4

General Snus March 2023 Facebook Posts con't


3-28-23



General Snus

3/28 · 🌐

The only thing more Swedish than the Original Swedish Snus might be Swedish Meatballs! Check out our hearty recipe for Swedish Meatball Soup in the first comment below.



EAT LIKE AN ORIGINAL

SWEDISH MEATBALL SOUP

WARNING: Smokeless tobacco is addictive.

1st comment copy

INGREDIENTS

- 1 large egg
- 2 cups half-and-half, divided
- 1 cup soft breadcrumbs
- 1 small onion, finely chopped
- 1½ tsp salt, divided
- 1½ lbs ground beef
- 1 tbsp butter
- 3 tbsp all-purpose flour
- ¾ tsp beef bouillon granules
- ¼ tsp pepper
- ¼ tsp garlic salt
- 3 cups water
- 1 lb cubed red potatoes, cubed
- 10 oz frozen peas (thawed)

DIRECTIONS

In a large mixing bowl, beat egg, add 1/3 cup cream, breadcrumbs, onion and 1 tsp salt. Crumble beef over mixture and mix lightly but thoroughly. Shape into ½ inch balls.


Using a Dutch oven, brown meatballs in butter in batches. Remove from the pan; set aside. Drain fat.

Add flour, bouillon, pepper, garlic salt and remaining salt to pan; stir until smooth. Gradually stir in water, bring to a boil. Reduce heat; cook and stir for 2 minutes or until thickened. Add potatoes and meatballs.

Reduce heat, cover and simmer for 25 minutes or until potatoes are tender. Stir in peas and remaining cream, heat through. Eat!

After you're full and happy, enjoy with a cocktail or your favorite snus.


3-31-23



General Snus

3/31 · 🌐


What do you say to grabbing your snus and going... heli-skiing? Reply with YOUR hot take on this original, ice-in-your-veins winter sport!



HELI-SKIING

WARNING: Smokeless tobacco is addictive.

See media file:

 3-31-23_FB_POST.mp4

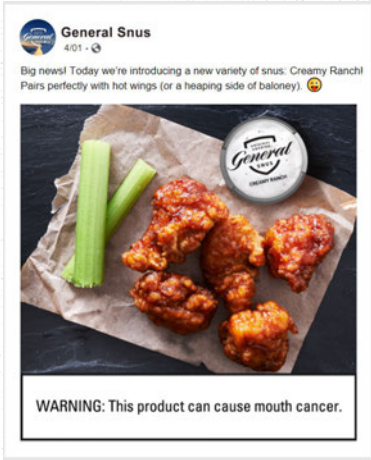
General Snus April 2023 Facebook Cover Image

4-1-23

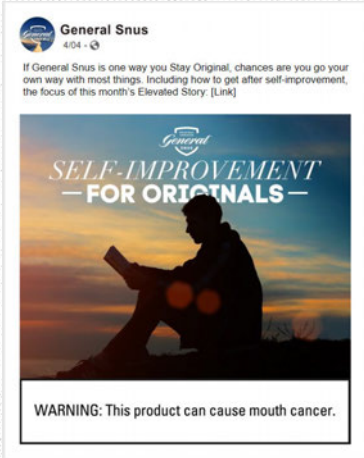


General Snus April 2023 Facebook Posts

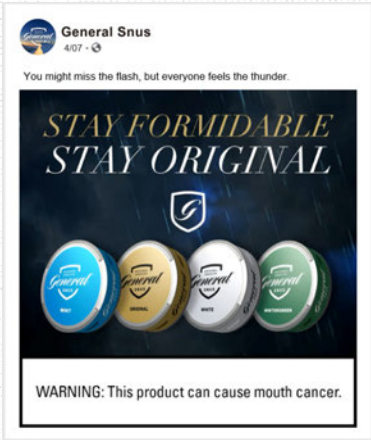
4-1-23



4-4-23



4-7-23

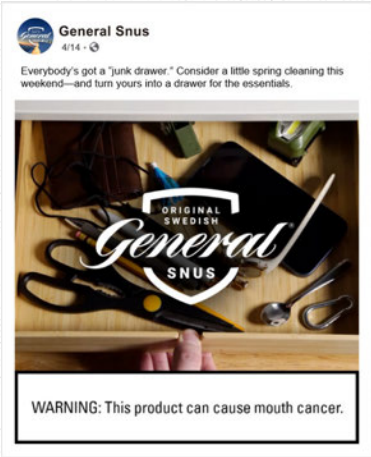


See file:

4-7-23_FB_POST.mp4



4-14-23

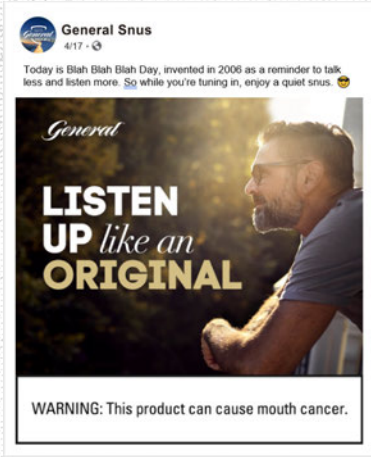


See file:

4-14-23_FB_POST.mp4



4-17-23



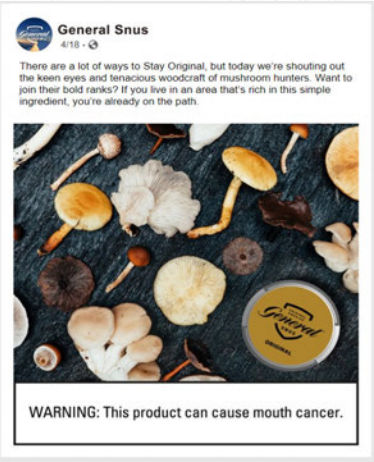
See file:

4-17-23_FB_POST.mp4
Has Sound

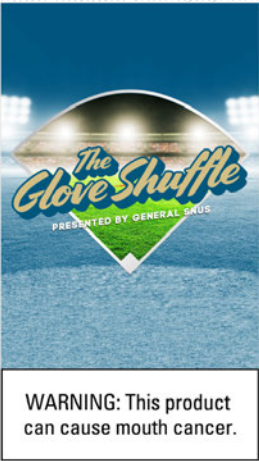


General Snus April 2023 Facebook Posts con't

4-18-23



4-28-22

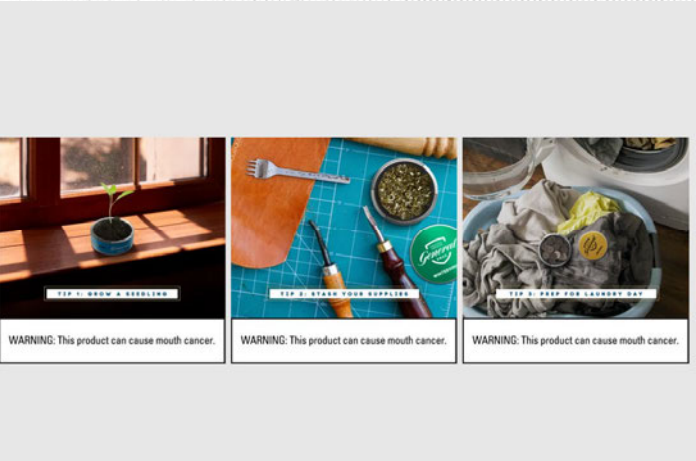
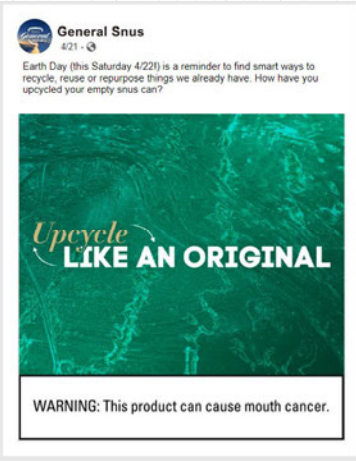


See file:

4-28-23_FB_POST.mp4
Has Sound

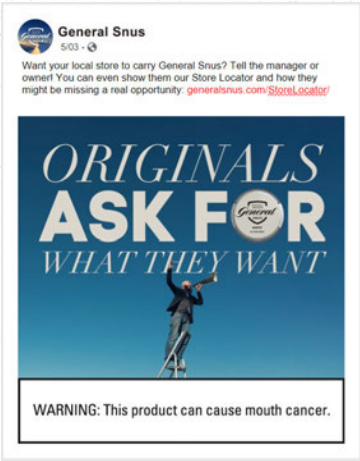


4-21-23

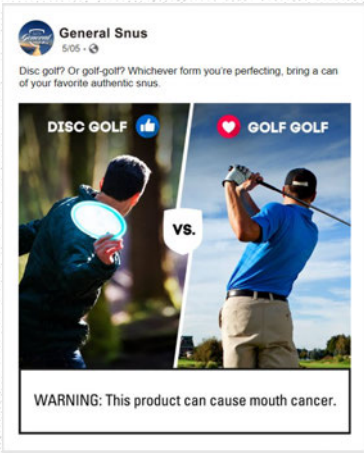


General Snus May 2023 Facebook Posts

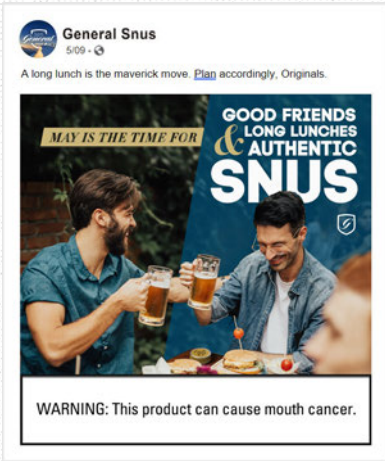
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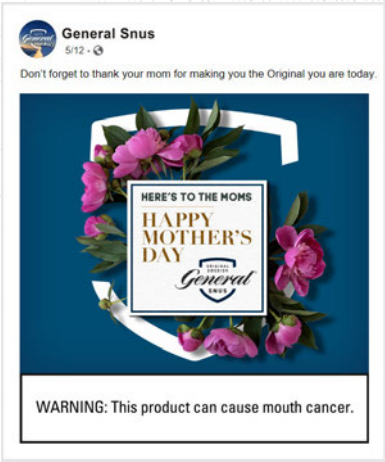
5-5-23



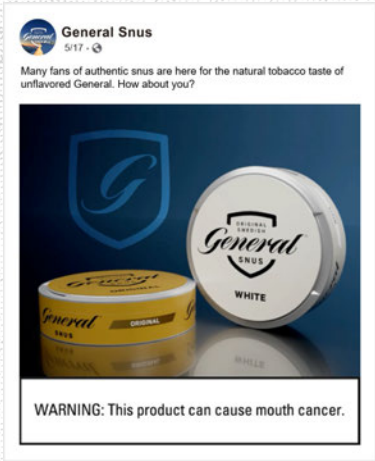
5-9-23



5-12-23



5-17-23



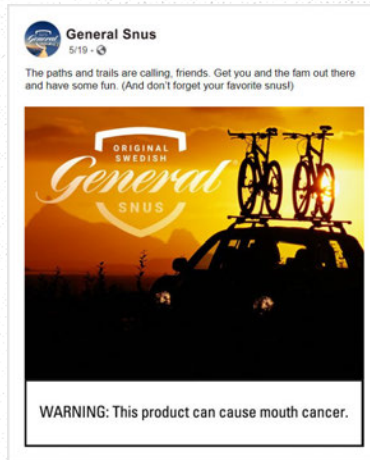
See file:



5-17-23_FB_POST.mp4

General Snus May 2023 Facebook Posts con't

5-19-23



5-23-23




5-24-23



5-28-23



See file:

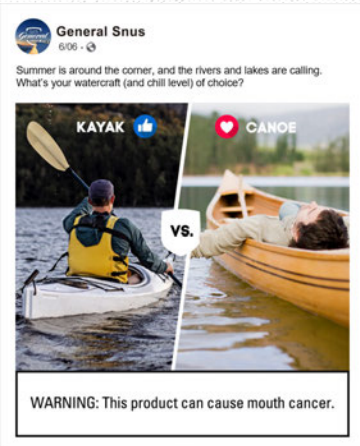
 5-28-23_FB_POST.mp4
Has Sound

General Snus June 2023 Facebook Posts

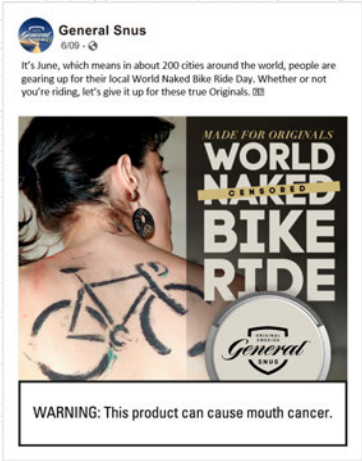
6-2-23



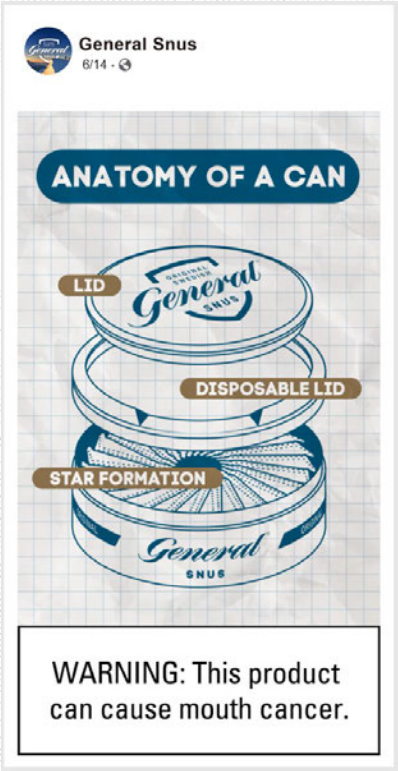
6-6-23



6-9-23



6-14-23

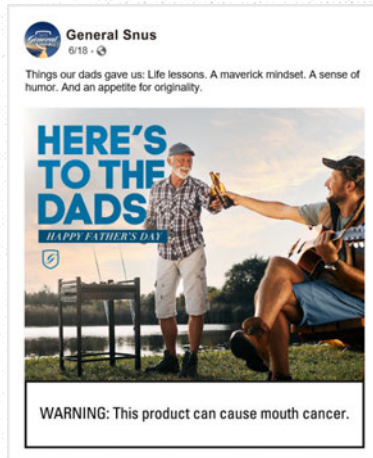


See file:

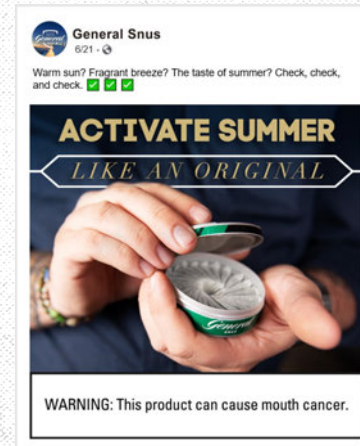
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General Snus June 2023 Facebook Posts con't

6-18-23




6-21-23

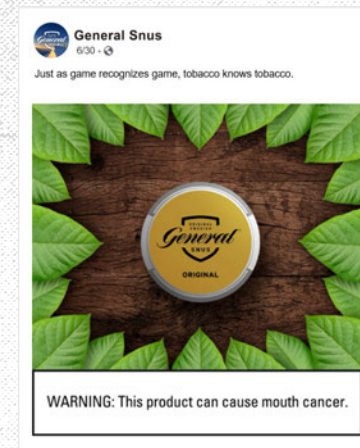



6-23-23



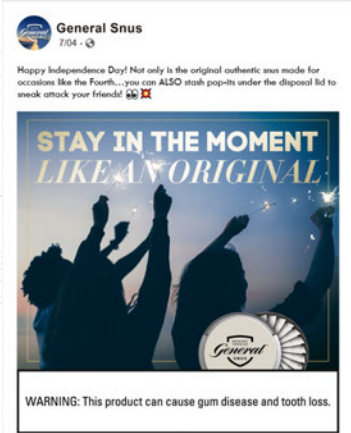
See file:  6-23-23_FB_POST.mp4

6-27-23



See file:  6-27-23_FB_POST.mp4

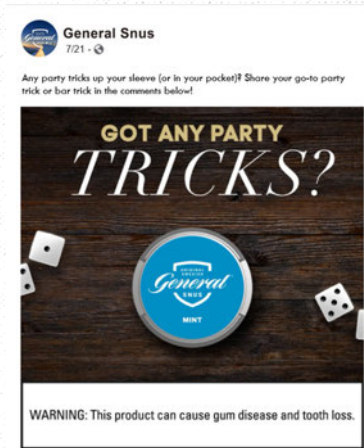
General Snus July 2023 Facebook Posts



See file: 07-05-23_FB_Post.mp4

General Snus July 2023 Facebook Posts con't

7-21-23

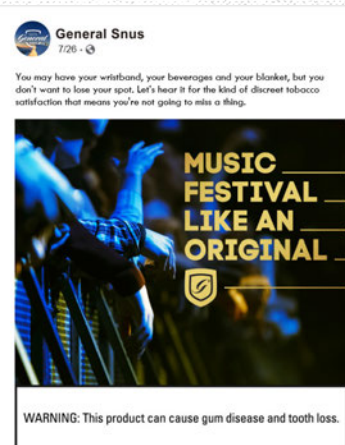


7-25-23

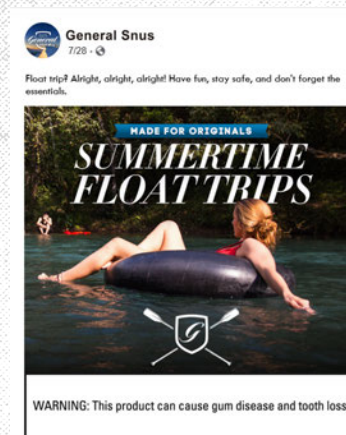


See file: 07-21-23_FB_Post.mp4

7-26-23



7-28-23



General Snus August 2023 Facebook Posts

8-4-23



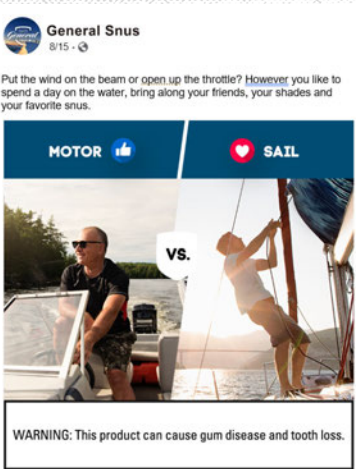
8-8-23



8-11-23



8-15-23



See file: 8-11-23_FB_Post.mp4

General Snus August 2023 Facebook Posts con't

8-22-23



8-25-23



8-29-23



See file: 8-29-23_FB_Post.mp4

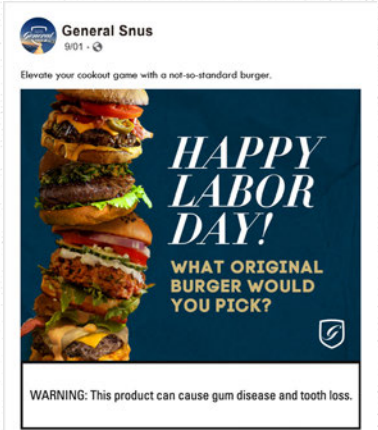
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See file: 8-30-23_FB_Post.mp4

General Snus September 2023 Facebook Posts

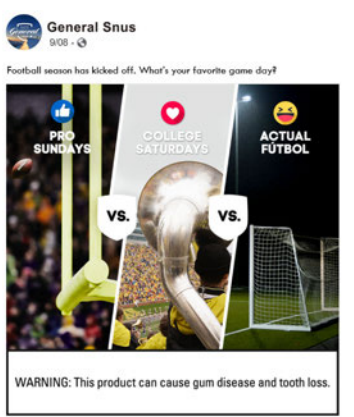
9-01-23



9-06-23



9-08-23



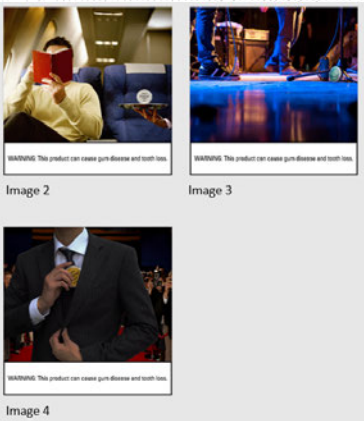
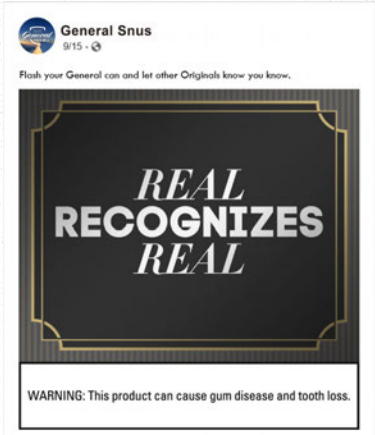
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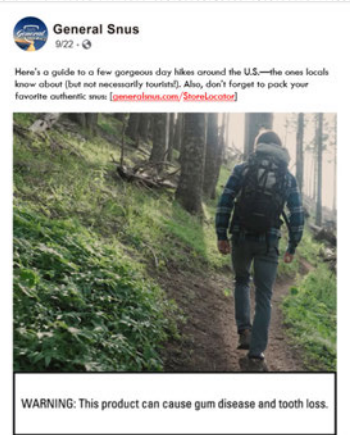
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General Snus September 2023 Facebook Posts con't

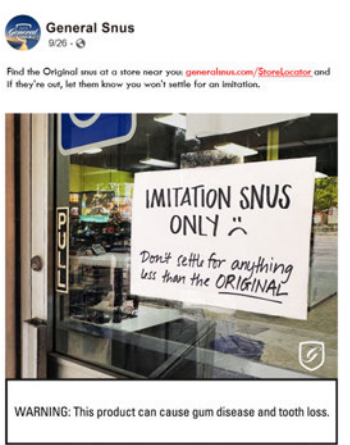
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9-22-23



9-26-23

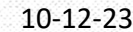
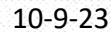
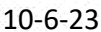
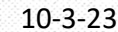
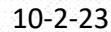


9-29-23



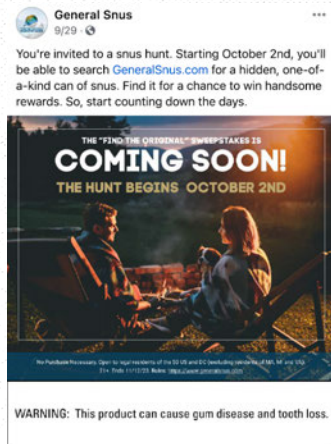
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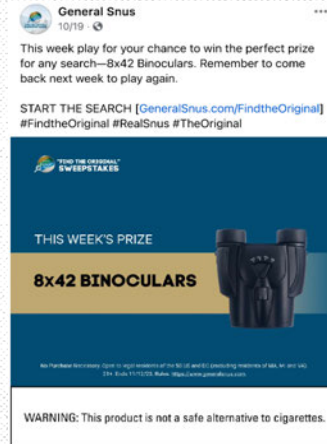


General Snus October 2023 Facebook Posts con't

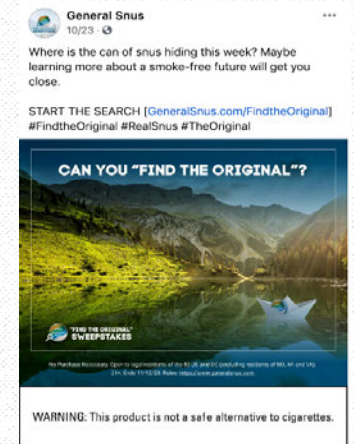
10-16-23



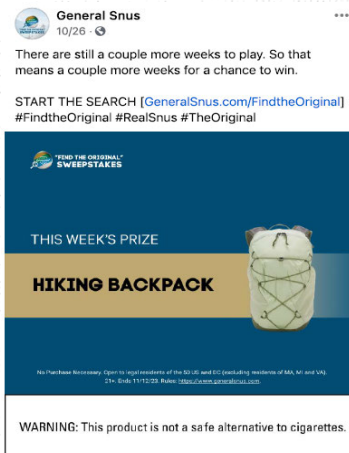
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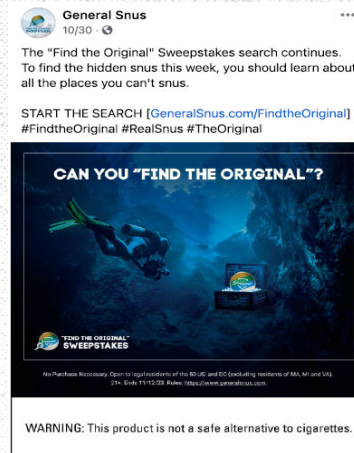
10-23-23



10-26-23



10-30-23



November '22 General Snus Facebook .mp4 File Guide

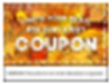
.mp4 Image

.mp4 File Name and Length

.mp4 Description



11-4-22_GEN FB_Variety Showcase.mp4
00:00:07



11-6-22_GEN FB_Leaves Coupon.mp4
00:00:08



11-11-22_GEN FB Mint Aroma Pairing.mp4
00:00:12



11-15-22_GEN FB Snus Starter Pack.mp4
00:00:17




11-23-22_GEN FB Your Can Follows.mp4
00:00:10

(b) (4)

December '22 General Snus Facebook .mp4 File Guide

.mp4 Image .mp4 File Name and Length .mp4 Description



 12-9-22 GEN FB_Seasons with the Original.mp4

00:00:07



 12-16-22 GEN FB_White Aroma Pairings.mp4

00:00:07



 12-27-22 GEN FB_Norrskan.mp4

00:00:12

(b) (4)


January '23 General Snus Facebook .mp4 File Guide

.mp4 Image

.mp4 File Name and Length

.mp4 Description



 1-3-23_FB_POST.mp4


00:00:022



 1-13-23_FB_POST.mp4

00:00:16





 1-17-23_FB_POST.mp4

00:00:19







(b) (4)

February '23 General Snus Facebook .mp4 File Guide











<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Descripton</u>
 <small>WARNING: Smokeless tobacco is addictive.</small>	 2-14-23_FB_POST.mp4 00:00:09	(b) (4)







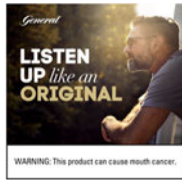




March '23 General Snus Facebook .mp4 File Guide

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
	3-3-23_FB_POST_FRAME1.mp4 00:00:04	(b) (4)
	3-3-23_FB_POST_FRAME2.mp4 00:00:04	
	3-3-23_FB_POST_FRAME3.mp4 00:00:04	
	3-3-23_FB_POST_FRAME4.mp4 00:00:04	
	3-7-23_FB_POST.mp4 00:00:04	
		

March '23 General Snus Facebook .mp4 File Guide con't





<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
	 3-8-23_FB_POST.mp4 00:00:04	(b) (4)
	 3-17-23_FB_POST.mp4 00:00:06	
	 3-20-23_FB_POST.mp4 00:00:07	
	 3-21-23_FB_POST.mp4 00:00:14	
	 3-31-23_FB_POST.mp4 00:00:05	

April '23 General Snus Facebook .mp4 File Guide



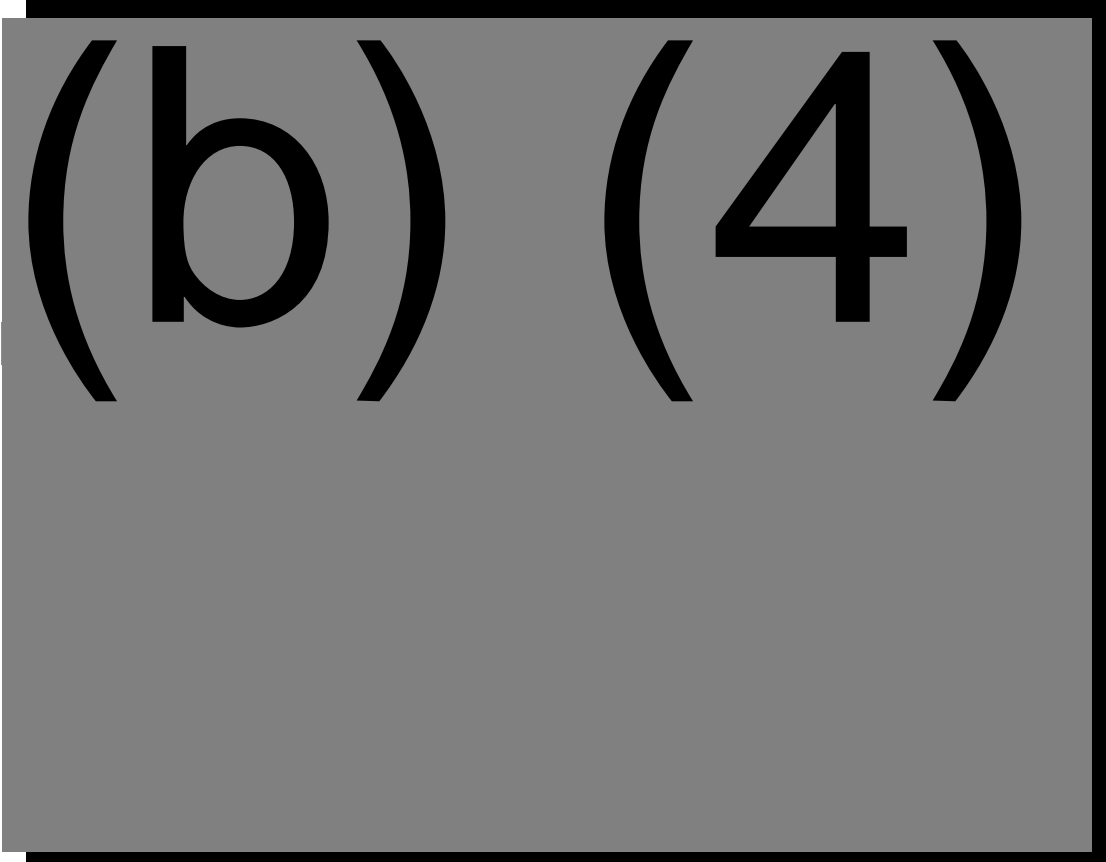




<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Descripton</u>
	 4-7-23_FB_POST.mp4 00:00:06	
	 4-14-23_FB_POST.mp4 00:00:10	
	 4-17-23_FB_POST.mp4 00:00:19	
	 4-28-23_FB_POST.mp4 00:00:22	
		

(b) (4)

May '23 General Snus Facebook .mp4 File Guide

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	 5-17-23_FB_POST.mp4 00:00:07	(b) (4)
	 5-28-23_FB_POST.mp4 00:00:07	

June '23 General Snus Facebook .mp4 File Guide

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
	 6-14-23_FB_POST.mp4 00:00:07	
	 6-23-23_FB_POST.mp4 00:00:03	
	 6-27-23_FB_POST.mp4 00:00:08	




July '23 General Snus Facebook .mp4 File Guide


.mp4 Image



.mp4 File Name and Length

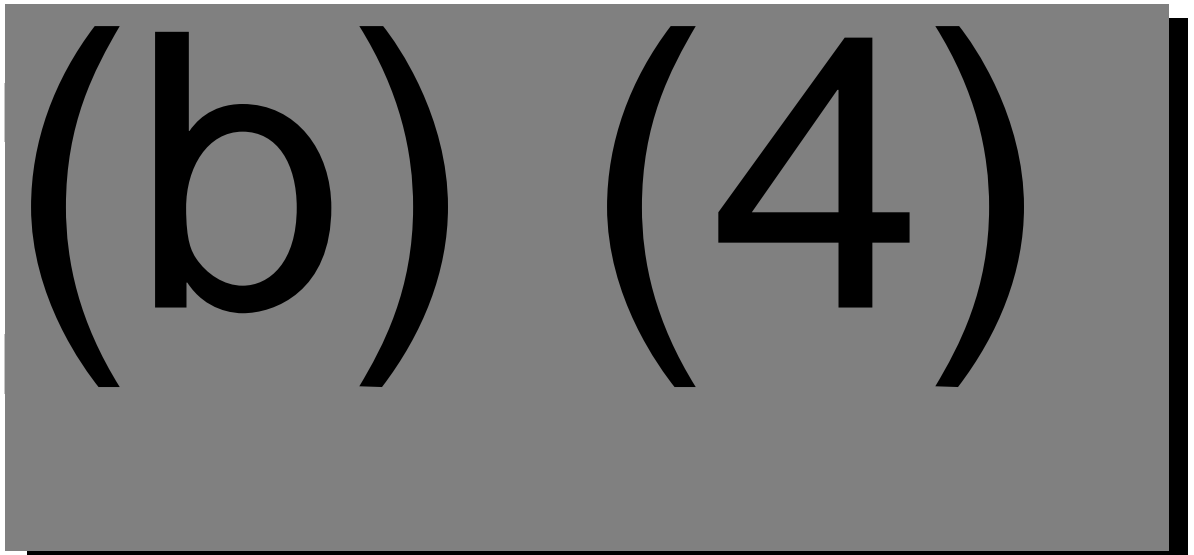
 07-05-23_FB_Post.mp4

00:00:06







 07-21-23_FB_Post.mp4

00:00:10

.mp4 Description







August '23 General Snus Facebook .mp4 File Guide

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	 8-11-23_FB_Post.mp4 00:00:05	<div>(b) (4)</div>
	 8-29-23_FB_Post.mp4 00:00:10	
	 8-30-23_FB_Post.mp4 00:00:06	



September '23 General Snus Facebook .mp4 File Guide

<u>.mp4 Image</u>	<u>.mp4 File Name and Length</u>	<u>.mp4 Description</u>
	 9-12-23_FB_Post.mp4 00:00:12	(b) (4)
	 9-29-23_FB_Post.mp4 00:00:05	

General Snus Facebook Analytics: Nov. 1, 2022 – Oct. 1, 2023

(b) (4)

General Snus Facebook Analytics: Nov. 1, 2022 – Oct. 1, 2023

(b) (4)

General Snus Facebook Analytics: Nov. 1, 2022 – Oct. 1, 2023


(b) (4)

GENERAL SNUS EMAILS



General Snus November EM1

See media file:

 Nov 2022 EM1_Leaves.mp4



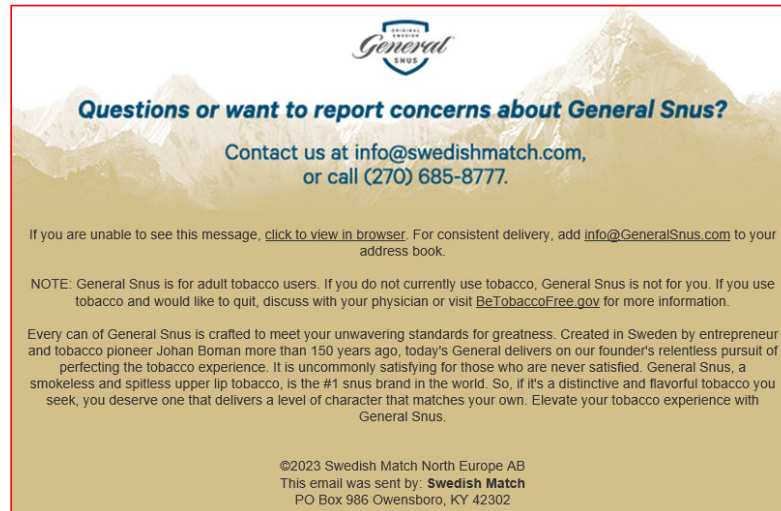
General Snus logo

SAVE UP TO \$8 ON GENERAL

ENJOY AUTUMN SAVINGS

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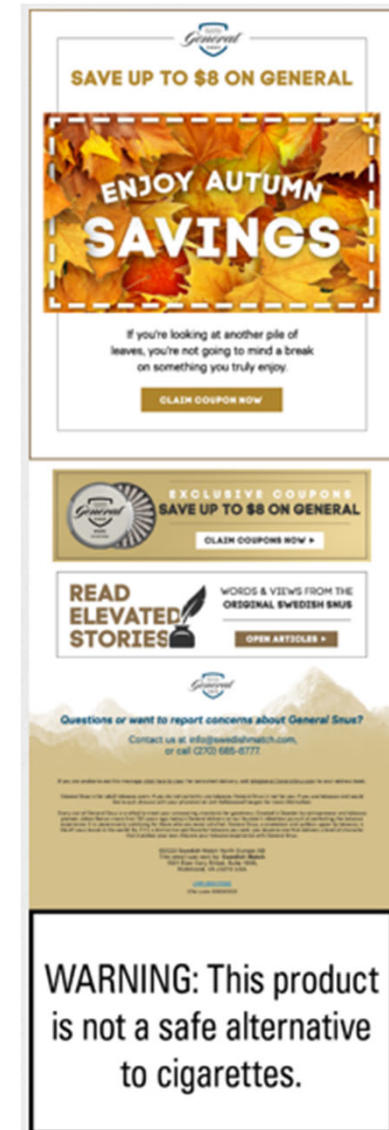
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General Snus November EM2




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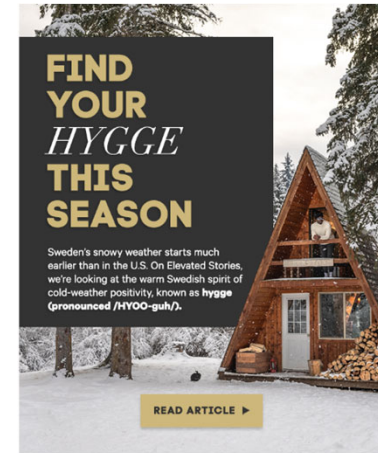
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General Snus December EM1

HOW TO ENTERTAIN *WHILE WAITING* TO ENTERTAIN



Not quite ready but the guests are here?
We've been there and we've got you covered.
Here are three activities for different wait times to keep
the party going while you finish up.

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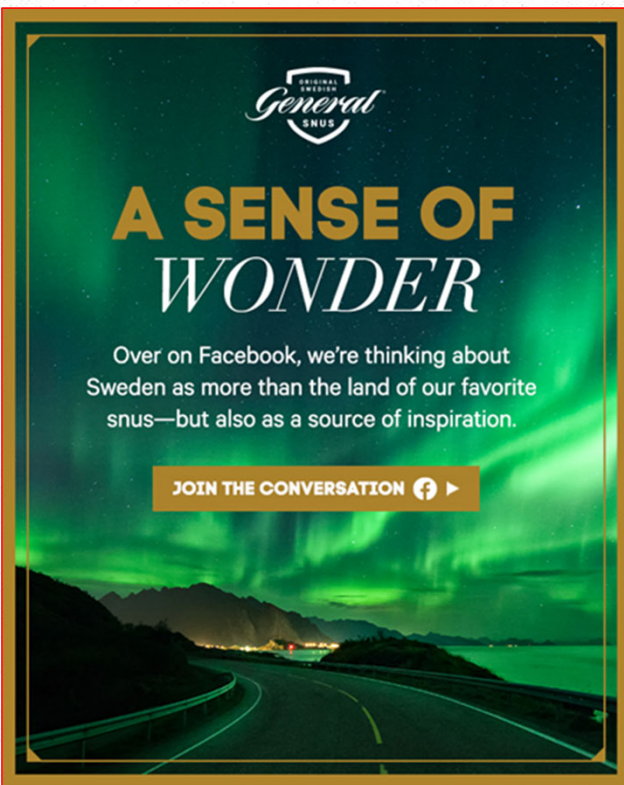
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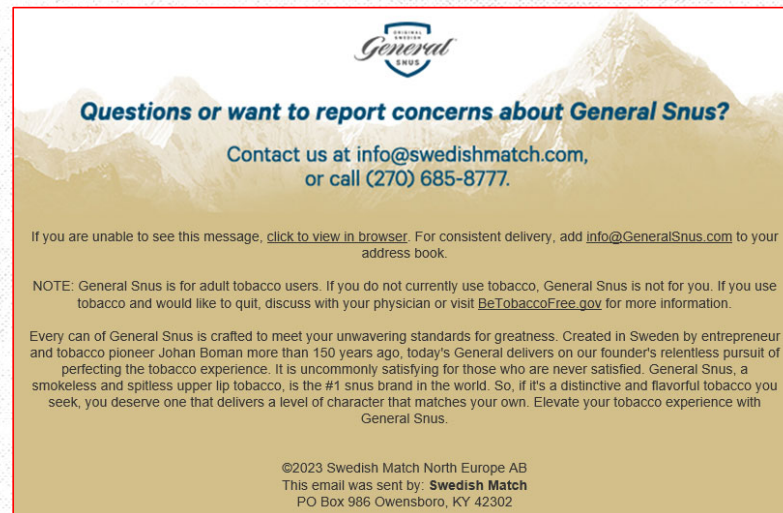


ORIGINAL SWEDISH
General
SNUS

A SENSE OF WONDER

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General
SNUS

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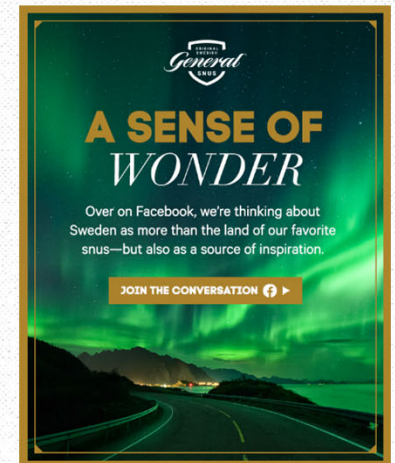
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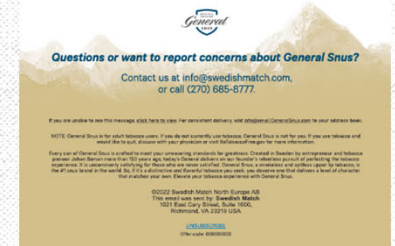
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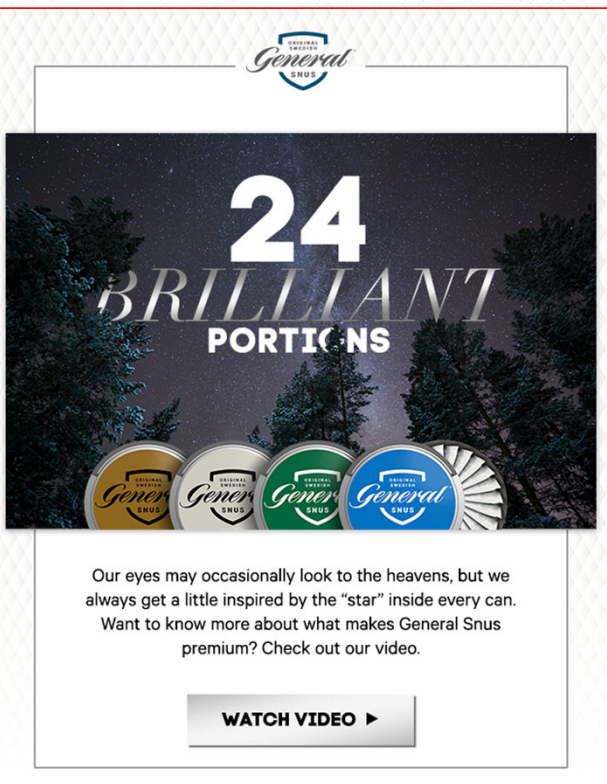
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General Snus January EM1

1-10-23




General Snus

24 BRILLIANT PORTIONS



Our eyes may occasionally look to the heavens, but we always get a little inspired by the "star" inside every can. Want to know more about what makes General Snus premium? Check out our video.

WATCH VIDEO ►

See file:  General Snus Brand Original Website Video_2022.mp4
Has Sound



General Snus

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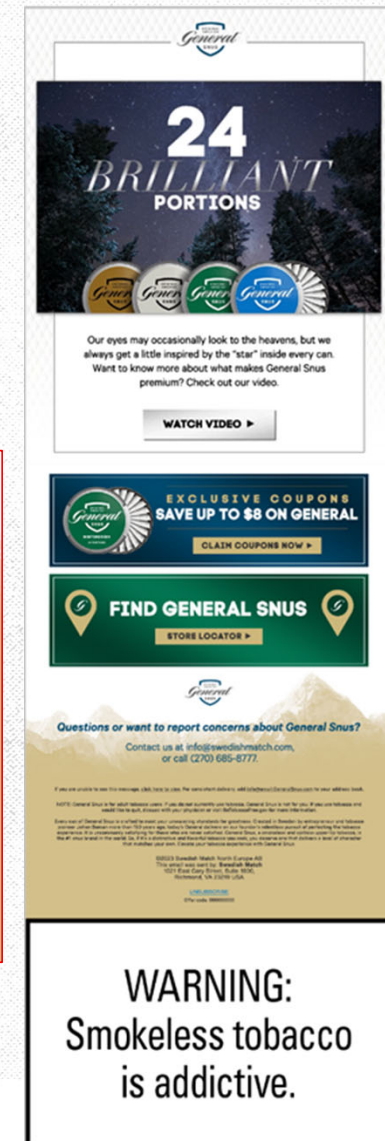
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General Snus

24 BRILLIANT PORTIONS



Our eyes may occasionally look to the heavens, but we always get a little inspired by the "star" inside every can. Want to know more about what makes General Snus premium? Check out our video.

WATCH VIDEO ►

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SAVE UP TO \$8 ON GENERAL**

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General Snus January EM2

1-24-23

REALISTIC RESOLUTIONS

The pressure to make and stick to New Year's resolutions can be more overwhelming than the resolutions themselves. In **Elevated Stories** we created some achievable goals so you don't feel anxious in the New Year.

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General Snus February EM1

2-14-23


HOW ORIGINALS LOVE





February's **Elevated Story** is all about the gear Originals love and how they love it. From those serious about upkeep, to those who wear until it's destroyed, to those who fully customize.

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General Snus February EM2


2-28-23



GOOD THINGS COME IN *small* CONTAINERS

February is the shortest month of the year and yet somehow contains a lot of great stuff. What other good thing comes in small containers? **Your favorite snus, of course.**

DISCOVER GENERAL ►



General Snus

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GOOD THINGS COME IN *small* CONTAINERS

Even at a short twenty-eight days, February still contains a lot of enjoyment—a quality it shares with your favorite can of snus.

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NEW MOBILE COUPONS IN YOUR AREA

READ ELEVATED STORIES WORDS & VIEWS FROM THE ORIGINAL SWEDISH SNUS **OPEN ARTICLES ►**

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General Snus March EM1

3-3-23

NATIONAL DAY OF UNPLUGGING

1

SET
DOWN
YOUR
PHONE



2

GRAB
YOUR
FAVORITE
SNUS



3

GET
OUT
THERE



Did you know letting your phone battery run down to 0% is good for it? Set down your phone, grab your favorite can of snus and get out there!

DISCOVER GENERAL ➔



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General Snus March EM2

3-21-23



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ALLEMANSRÄTTEN

/all-ay-mans-RETT-en/ Sweden's Freedom to Roam

This month in Elevated Stories, we're appreciating this important custom from the land of the Original Swedish Snus.

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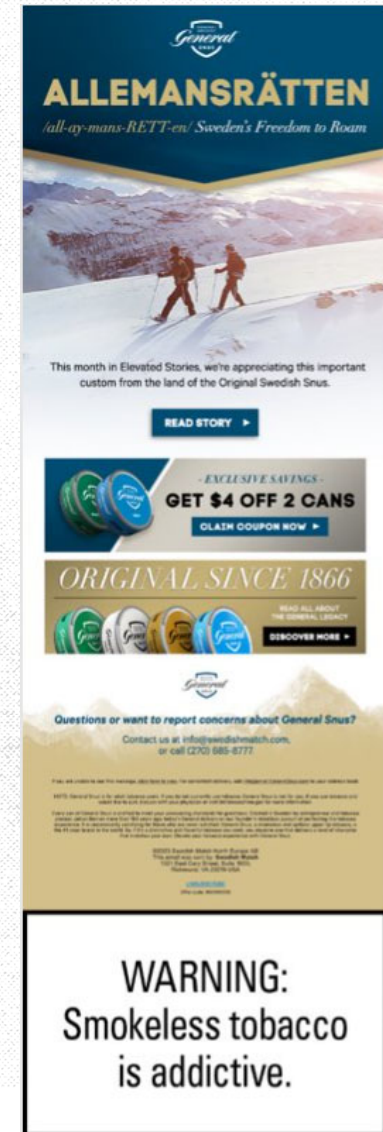
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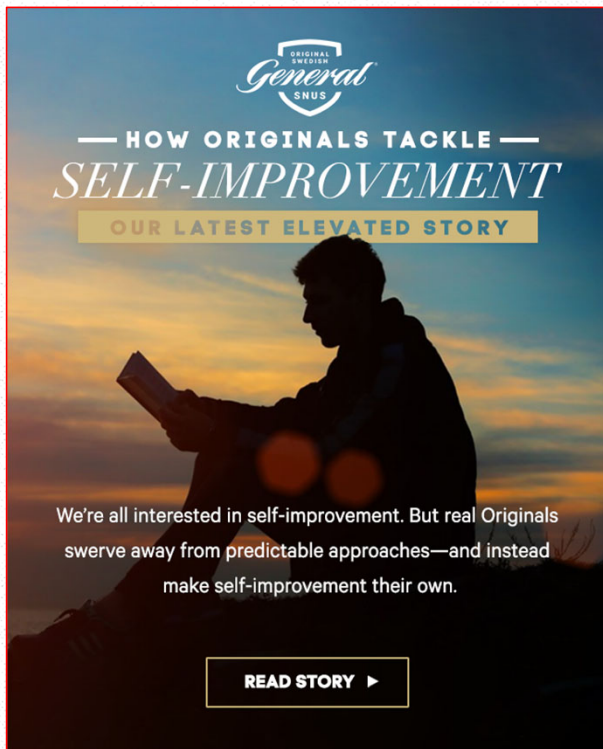
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General Snus April EM1

4-4-23



ORIGINAL SWEDISH
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— HOW ORIGINALS TACKLE —
SELF-IMPROVEMENT
OUR LATEST ELEVATED STORY

We're all interested in self-improvement. But real Originals swerve away from predictable approaches—and instead make self-improvement their own.

READ STORY ►



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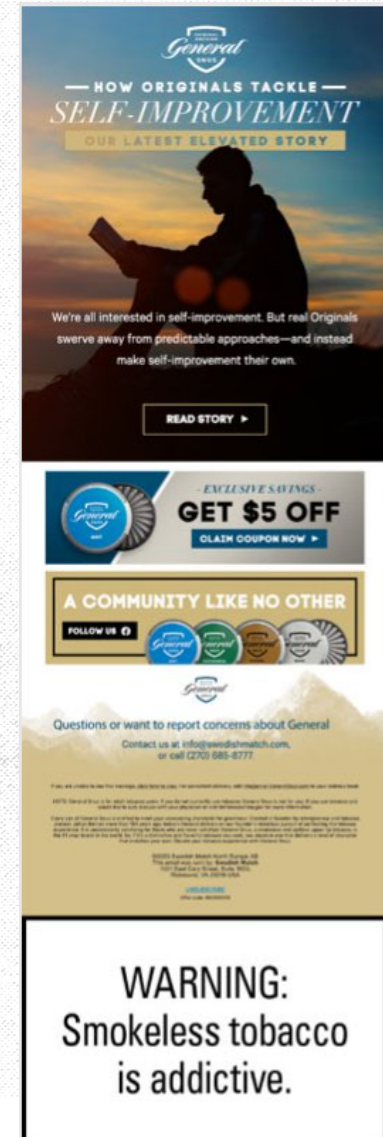
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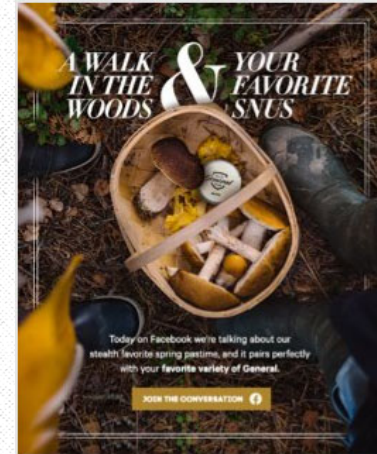
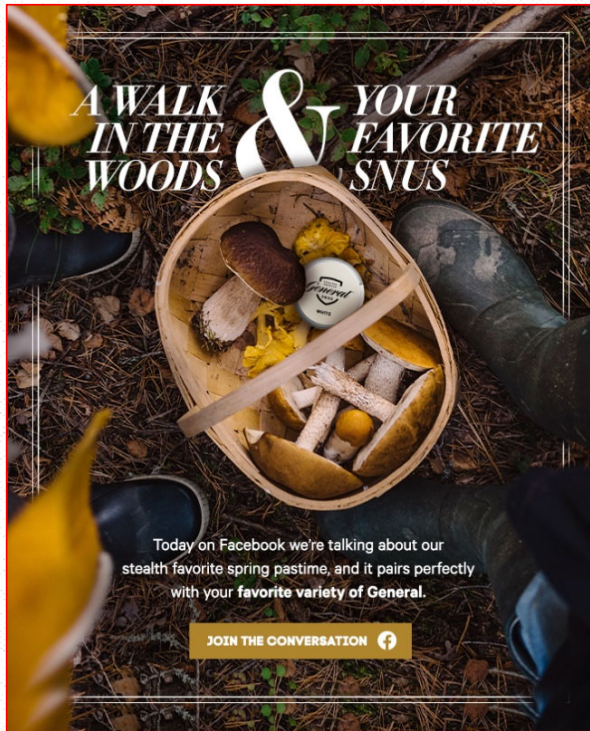
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General Snus April EM2

4-18-23



WARNING: This product can cause mouth cancer.

General Snus May EM1


5-9-23



GARDEN LIKE AN ORIGINAL
Our latest Elevated Story

May is when gardeners do much of the work that transforms their patch of soil into real abundance. Here are a few tips for a garden that pays off year-round.

[READ STORY ►](#)



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General Snus May EM2


5-23-23



THE DEFINITIVE TOBACCO EXPERIENCE

For some, the taste of real tobacco is the whole point. Give it up for White and Original—our unflavored varieties. And let's hear it for the true tobacco fans who make them their own.

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General Snus June EM1

6-6-23




**GEAR UP FOR
CAMPING
SEASON**

Our Latest Elevated Story

The last week of June is National Camping Week, and we've got some tips to help you prepare.

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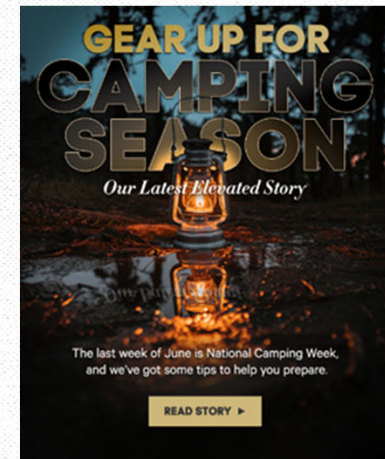
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General Snus June EM2

6-18-23

HAPPY FATHER'S DAY

Whether you're thinking of your own father or trying to be the best parent you can be—here's to the dads. And all the qualities that set them apart.

EXPERIENCE ORIGINALITY ►



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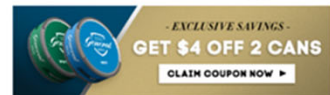
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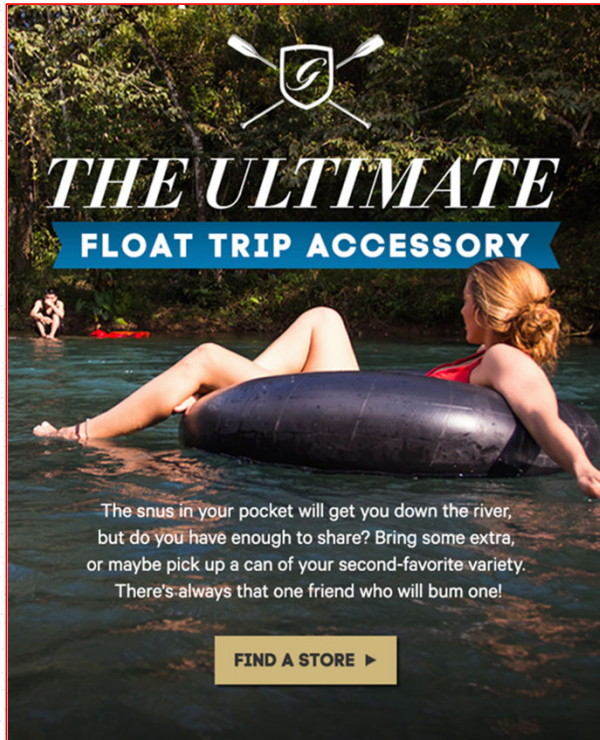
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SWEDISH MATCH
100% TOBACCO

WARNING: This product can cause mouth cancer.

General Snus July EM1


7-11-23



THE ULTIMATE
FLOAT TRIP ACCESSORY

The snus in your pocket will get you down the river, but do you have enough to share? Bring some extra, or maybe pick up a can of your second-favorite variety. There's always that one friend who will bum one!

FIND A STORE ►



Questions or want to report concerns about General Snus?

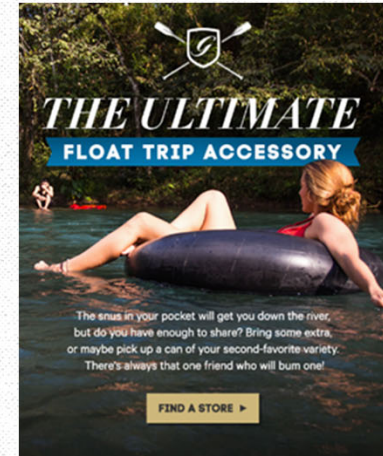
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SAVINGS & SATISFACTION
GET \$5 OFF
CLAIM COUPON NOW ►

LIVE LIFE ELEVATED
Embrace the Original Lifestyle
with our Elevated Stories
READ BLOG ►

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**WARNING: This product
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General Snus July EM2

7-25-23




ORIGINAL SWEDISH
General
SNUS

ULTRAMARATHONERS

Our Latest Elevated Story

Even if we can't all keep up with these truly amazing Originals, we definitely appreciate them.

READ STORY ▶



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ORIGINAL SWEDISH
General
SNUS

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EXCLUSIVE SAVINGS
GET \$4 OFF 2 CANS
CLAIM COUPON NOW ▶

ORIGINAL SINCE 1866
READ ALL ABOUT THE ORIGINAL LEGACY
DISCOVER MORE ▶

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Please see inside for more information. ©2023 Swedish Match North Europe AB. This email was sent by: Swedish Match. PO Box 986 Owensboro, KY 42302.

WARNING:
Smokeless tobacco
is addictive.

General Snus August EM1


8-8-23

THE LOST ART OF CRASHING A PARTY



You can find a lively gathering most weekends in any public space. Do you have the moxie to smile big, make a friend, score a burger, and maybe share your favorite snus?

FIND A STORE ►



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FIND A STORE ►

STOCK UP & SAVE
GET \$4 OFF 2 CANS

CLAIM COUPON NOW ►



**GOT QUESTIONS?
WE'VE GOT ANSWERS.**

READ FAQ ►

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General Snus August EM2

8-22-23





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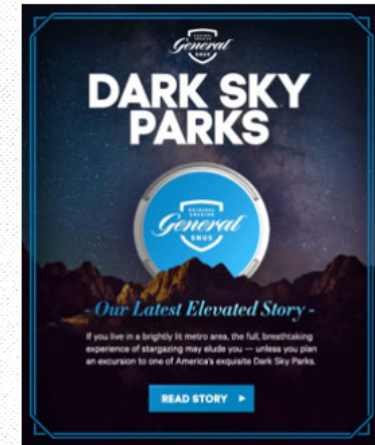
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General Snus September EM1

9-12-23

CELEBRATE
POSITIVE ORIGINALITY

The true mavericks don't gatekeep originality. They live their life authentically, set high standards and invite others to do the same. And while originality isn't exclusive, it is unique. Just like your favorite snus. Stay Original.

FIND A STORE

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FIND A STORE

FOR ORIGINALS ONLY
BUY 3 CANS, SAVE \$6

CLAIM COUPON NOW

READ ELEVATED STORIES

WORDS & VIEWS FROM THE ORIGINAL SWEDISH SNUS

OPEN ARTICLES

General

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General Snus September EM2

8-22-23





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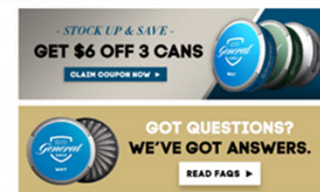
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**WARNING: This product
can cause gum disease
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General Snus Sweepstakes EM1

9-27-23



"FIND THE ORIGINAL" SWEEPSTAKES

You're invited to a snus hunt. Starting October 2nd, you'll be able to search GeneralSnus.com for a hidden, one-of-a-kind can of snus. Find it for a chance to win handsome rewards. So, start counting down the days.

THE HUNT BEGINS OCTOBER 2ND



WEEKLY PRIZES

Find the Original and you could walk away with one of these weekly prizes, or even the Grand Prize. Make sure to come back every week for another chance to play and another chance to win.

- WEEK 1** Multi-tool
- WEEK 2** Trail-Running Headlamp
- WEEK 3** 8x42 Binoculars
- WEEK 4** Hiking Backpack
- WEEK 5** 36-Can Cooler
- WEEK 6** Hammock



GRAND PRIZE

15' INFLATABLE BOAT

The more you play the better your chances of winning the Grand Prize.

As you wait for the hunt to begin, grab a can of General Snus at your local store then scout out our website to better know your hunting grounds.

FIND GENERAL SNUS NEAR YOU

NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For details, see Official Rules. Sponsor: Swedish Match North America LLC.

General SNUS

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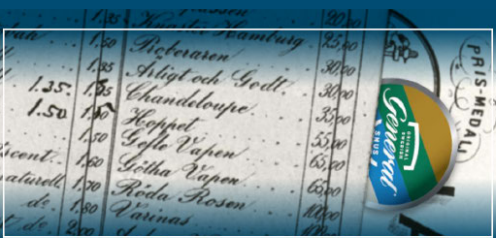
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General Snus Sweepstakes EM2

10-2-23



THE "FIND THE ORIGINAL" SWEEPSTAKES BEGINS TODAY!



Somewhere hidden on the pages of GeneralSnus.com is a one-of-a-kind can of snus. Track it down then enter to win the weekly prize.

Ready to start the search? There's a little hint below to get you pointed in the right direction.


THIS WEEK'S HINT:

Learn how we made history...literally.

START THE SEARCH ►

During each week of the Sweepstakes, we're giving away amazing gear, gadgets, and gizmos. All you have to do is find the special can (like in the image above) then enter to earn a chance to win prizes like the one you see below.

THIS WEEK'S PRIZE STAINLESS STEEL MULTI-TOOL

START THE SEARCH ►


GRAND PRIZE 15' INFLATABLE BOAT

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Find the Original snus and win!
Let the snus hunt begin. Earn a chance to win Big PRIZES!

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General Snus Sweepstakes EM3

10-9-23



"FIND THE ORIGINAL" SWEEPSTAKES



The special can of snus is hiding once again on GeneralSnus.com. Can you find it and earn a chance to win this week's prize?

THIS WEEK'S HINT:


Made in the shade.

START THE SEARCH ►

THIS WEEK'S PRIZE

TRAIL-RUNNING HEADLAMP


START THE SEARCH ►



GRAND PRIZE

15' INFLATABLE BOAT

After this week there are still 4 weeks (and prizes) left. Make sure to come back and play again to increase your chances of winning the Grand Prize.



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The best for the Original is just getting going. Could it be your week to win?



"FIND THE ORIGINAL" SWEEPSTAKES



The special can of snus is hiding once again on GeneralSnus.com. Can you find it and earn a chance to win this week's prize?

THIS WEEK'S HINT:


Made in the shade.

START THE SEARCH ►

THIS WEEK'S PRIZE

TRAIL-RUNNING HEADLAMP


START THE SEARCH ►




GRAND PRIZE

15' INFLATABLE BOAT

After this week there are still 4 weeks (and prizes) left. Make sure to come back and play again to increase your chances of winning the Grand Prize.



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Questions or want to report concerns about General Snus?

Contact us at info@swedishmatch.com, or call (270) 685-8777.

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NOTE: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.


Every can of General Snus is crafted to meet your unwavering standards for greatness. Created in Sweden by entrepreneur and tobacco pioneer Johan Boman more than 150 years ago, today's General delivers on our founder's relentless pursuit of perfecting the tobacco experience. It is uncommonly satisfying for those who are never satisfied. General Snus, a smokeless and spitless upper lip tobacco, is the #1 snus brand in the world. So, if it's a distinctive and flavorful tobacco you seek, you deserve one that delivers a level of character that matches your own. Elevate your tobacco experience with General Snus.

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General Snus Sweepstakes EM4

10-16-23



"FIND THE ORIGINAL" SWEEPSTAKES



This week you're playing for a chance to win these high-power binoculars, the perfect prize for any search.

THIS WEEK'S HINT:


Higher standards.

START THE SEARCH ►

THIS WEEK'S PRIZE

8X42 BINOCULARS


START THE SEARCH ►



GRAND PRIZE

15' INFLATABLE BOAT

And remember to come back every week to play again. The more you play the more you increase your chances of winning the Grand Prize.



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Another week. Another hunt. Another chance to win.
Find the Original for a chance to win this week's prize.



"FIND THE ORIGINAL" SWEEPSTAKES



This week you're playing for a chance to win these high-power binoculars, the perfect prize for any search.

THIS WEEK'S HINT:


Higher standards.

START THE SEARCH ►

THIS WEEK'S PRIZE

8X42 BINOCULARS


START THE SEARCH ►




GRAND PRIZE

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General Snus Sweepstakes EM5

10-23-23



"FIND THE ORIGINAL" SWEEPSTAKES



There's another hidden can of General Snus to find. So start searching for your chance to win this week's prize.

THIS WEEK'S HINT:

A smoke-free future.

START THE SEARCH ►

THIS WEEK'S PRIZE

HIKING BACKPACK

START THE SEARCH ►



GRAND PRIZE

15' INFLATABLE BOAT

We're more than halfway through the "Find the Original" Sweepstakes. That means you still have a couple more weeks to play. The more you play, the more chances you have to win the Grand Prize.



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The best for the Original (and incredible prize) continues. Find the Original for a chance to win this week's prize.



"FIND THE ORIGINAL" SWEEPSTAKES



There's another hidden can of General Snus to find. So start searching for your chance to win this week's prize.

THIS WEEK'S HINT:


A smoke-free future.

START THE SEARCH ►

THIS WEEK'S PRIZE

HIKING BACKPACK


START THE SEARCH ►




GRAND PRIZE

15' INFLATABLE BOAT

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General Snus Sweepstakes EM6

10-30-23



"FIND THE ORIGINAL" SWEEPSTAKES



Where is the can of snus hiding this week?
Find it for a chance to win our coolest prize yet!


THIS WEEK'S HINT:

Where can't you snus?

START THE SEARCH ►

THIS WEEK'S PRIZE

36-CAN COOLER




START THE SEARCH ►

GRAND PRIZE

15' INFLATABLE BOAT

The "Find the Original" Sweepstakes is ending in just two weeks. So make sure to come back again for one last chance to win the Grand Prize.



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Track down the Original snus to win the coolest prize yet.
Join the hunt again for another chance to win!



"FIND THE ORIGINAL" SWEEPSTAKES



Where is the can of snus hiding this week?
Find it for a chance to win our coolest prize yet!


THIS WEEK'S HINT:

Where can't you snus?

START THE SEARCH ►

THIS WEEK'S PRIZE

36-CAN COOLER




START THE SEARCH ►


GRAND PRIZE

15' INFLATABLE BOAT

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General Snus Sweepstakes EM7

11-6-23



"FIND THE ORIGINAL" SWEEPSTAKES



All good things must come to an end. So good luck in your search for the final hidden can—and one last chance to win a weekly prize.

THIS WEEK'S HINT:


Everyone needs a little originality.

START THE SEARCH ►

THIS WEEK'S PRIZE

HAMMOCK


START THE SEARCH ►



GRAND PRIZE

15' INFLATABLE BOAT

Make this your best hunt yet! Earn one more chance to enter to win the weekly and Grand Prize!



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Last chance to hunt. Last chance to win.
Join the hunt one last time to seek away a winner.



"FIND THE ORIGINAL" SWEEPSTAKES



All good things must come to an end. So good luck in your search for the final hidden can—and one last chance to win a weekly prize.

THIS WEEK'S HINT:


Everyone needs a little originality.

START THE SEARCH ►

THIS WEEK'S PRIZE

HAMMOCK


START THE SEARCH ►




GRAND PRIZE

15' INFLATABLE BOAT

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General Snus Sweepstakes EM8

11-6-23



"FIND THE ORIGINAL" SWEEPSTAKES



All good things must come to an end. So good luck in your search for the final hidden can—and one last chance to win a weekly prize.

THIS WEEK'S HINT:


Everyone needs a little originality.

START THE SEARCH ►

THIS WEEK'S PRIZE

HAMMOCK

START THE SEARCH ►



GRAND PRIZE

15' INFLATABLE BOAT

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Last chance to hunt. Last chance to win.
Join the hunt one last time to sweep away a winner.



"FIND THE ORIGINAL" SWEEPSTAKES



All good things must come to an end. So good luck in your search for the final hidden can—and one last chance to win a weekly prize.

THIS WEEK'S HINT:


Everyone needs a little originality.

START THE SEARCH ►

THIS WEEK'S PRIZE

HAMMOCK


START THE SEARCH ►




GRAND PRIZE

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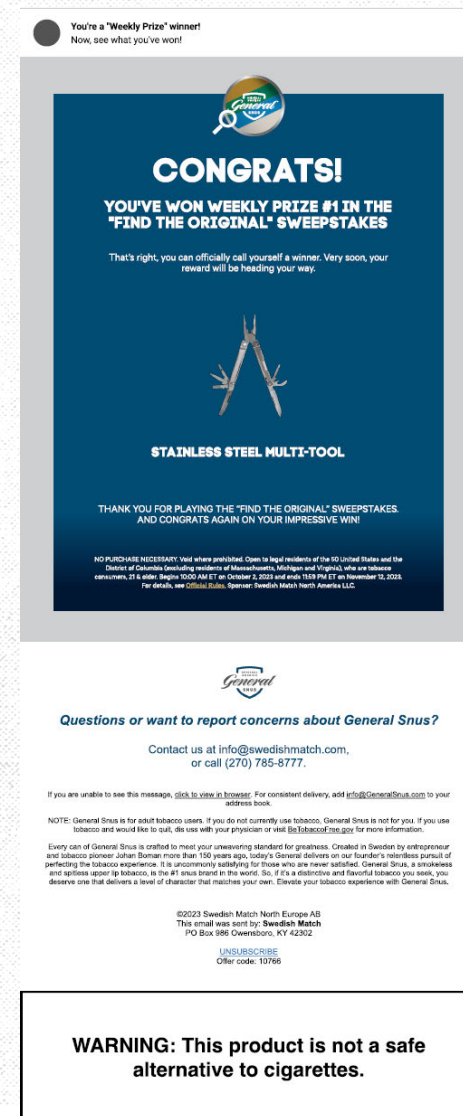
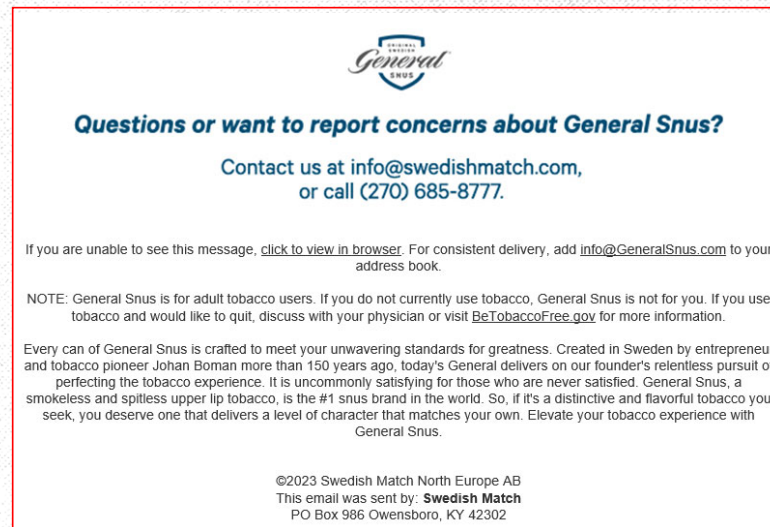
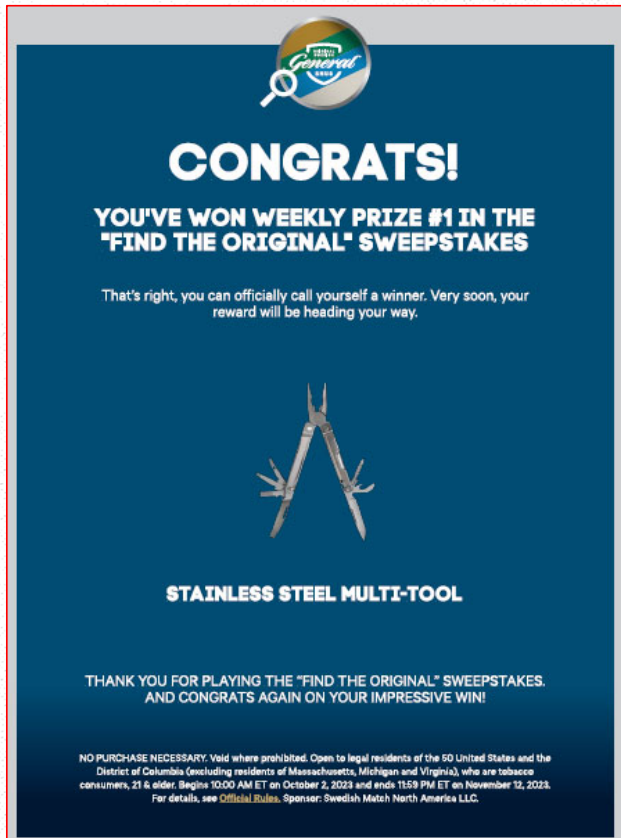
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General Snus Sweepstakes Winner EM1


10-13-23



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General Snus Sweepstakes Winner EM2


10-20-23



CONGRATS!

YOU'VE WON WEEKLY PRIZE #2 IN THE "FIND THE ORIGINAL" SWEEPSTAKES


That's right, you can officially call yourself a winner. Very soon, your reward will be heading your way.



TRAIL-RUNNING HEADLAMP

THANK YOU FOR PLAYING THE "FIND THE ORIGINAL" SWEEPSTAKES. AND CONGRATS AGAIN ON YOUR IMPRESSIVE WIN!

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You're a "Weekly Prize" winner!
Now, see what you've won!



CONGRATS!

YOU'VE WON WEEKLY PRIZE #2 IN THE "FIND THE ORIGINAL" SWEEPSTAKES


That's right, you can officially call yourself a winner. Very soon, your reward will be heading your way.



TRAIL-RUNNING HEADLAMP

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General Snus Sweepstakes Winner EM3


10-27-23



CONGRATS!

**YOU'VE WON WEEKLY PRIZE #3 IN THE
'FIND THE ORIGINAL' SWEEPSTAKES**


That's right, you can officially call yourself a winner. Very soon, your reward will be heading your way.



8X42 BINOCULARS

THANK YOU FOR PLAYING THE "FIND THE ORIGINAL" SWEEPSTAKES.
AND CONGRATS AGAIN ON YOUR IMPRESSIVE WIN!

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CONGRATS!

**YOU'VE WON WEEKLY PRIZE #3 IN THE
'FIND THE ORIGINAL' SWEEPSTAKES**


That's right, you can officially call yourself a winner. Very soon, your reward will be heading your way.



8X42 BINOCULARS

THANK YOU FOR PLAYING THE "FIND THE ORIGINAL" SWEEPSTAKES.
AND CONGRATS AGAIN ON YOUR IMPRESSIVE WIN!

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or call (270) 785-8777.

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NOTE: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

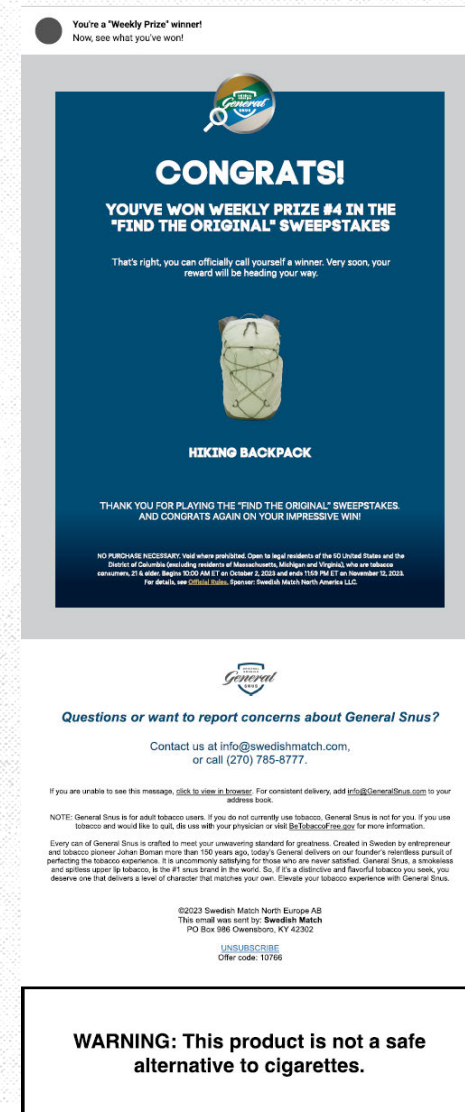
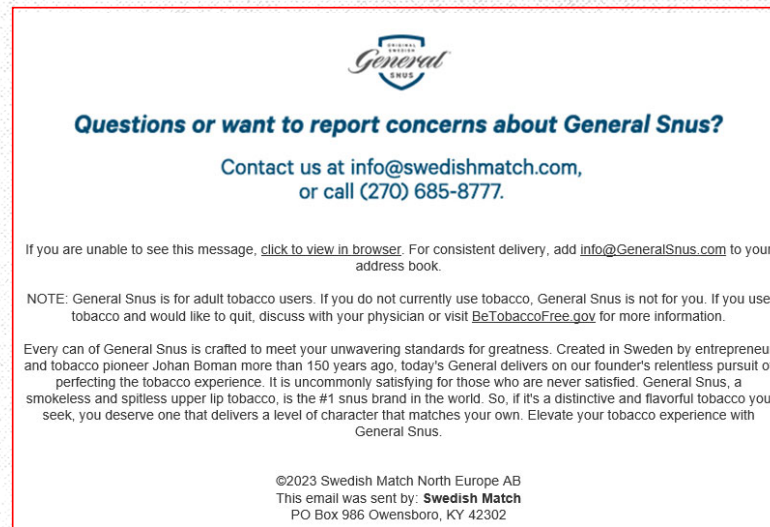
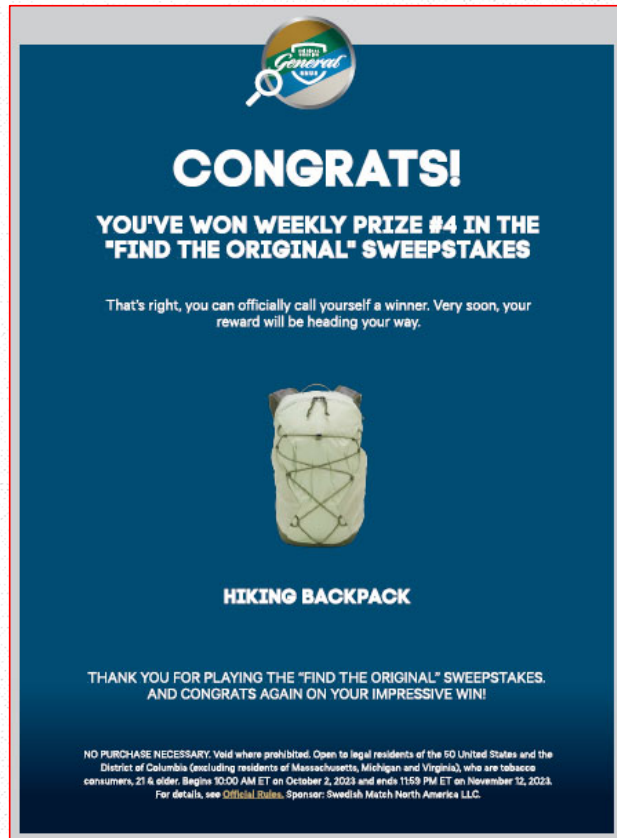
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Offer code: 10796

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alternative to cigarettes.**


General Snus Sweepstakes Winner EM4

11-3-23



General Snus Sweepstakes Winner EM5


11-10-23



CONGRATS!

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36-CAN COOLER

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Now, see what you've won!



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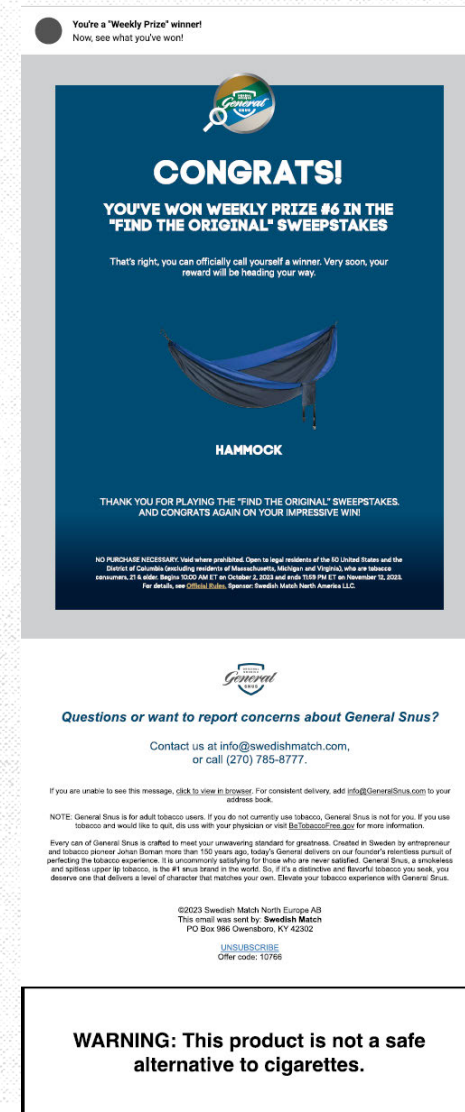
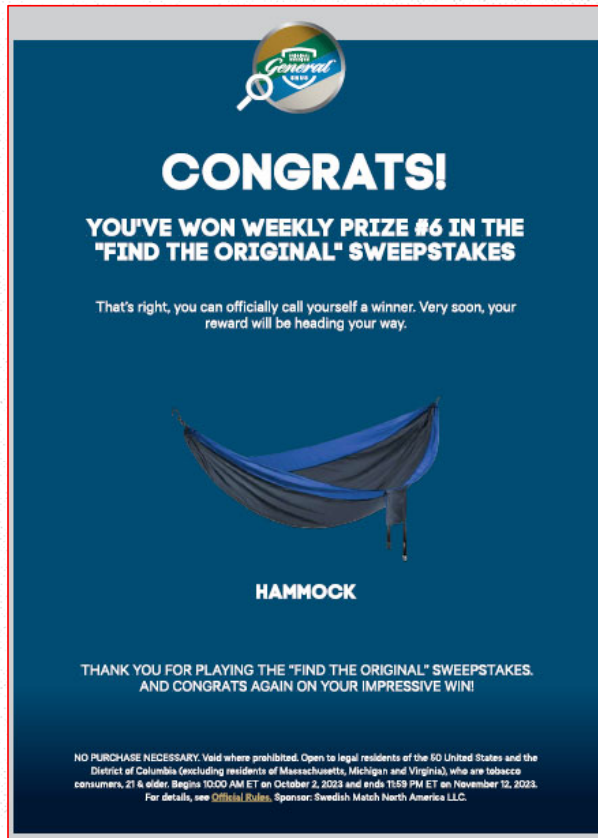
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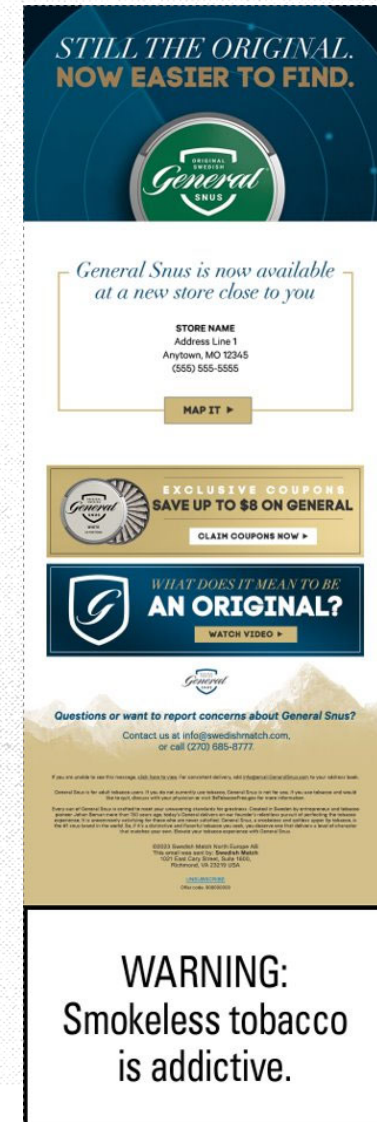
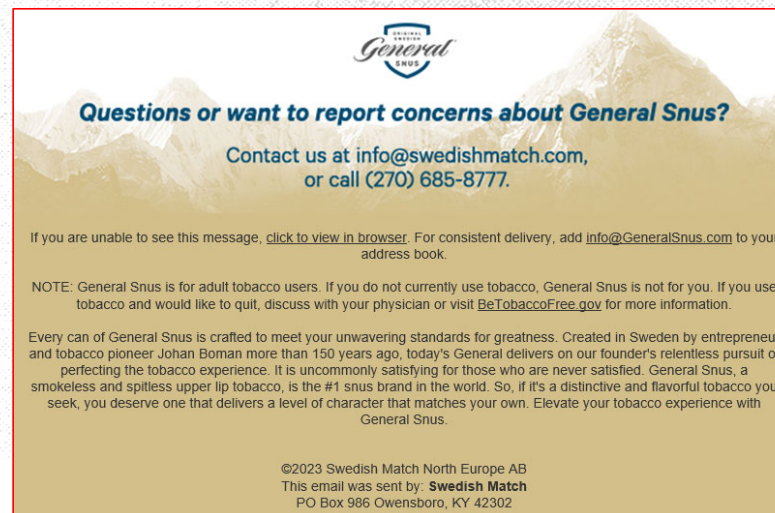
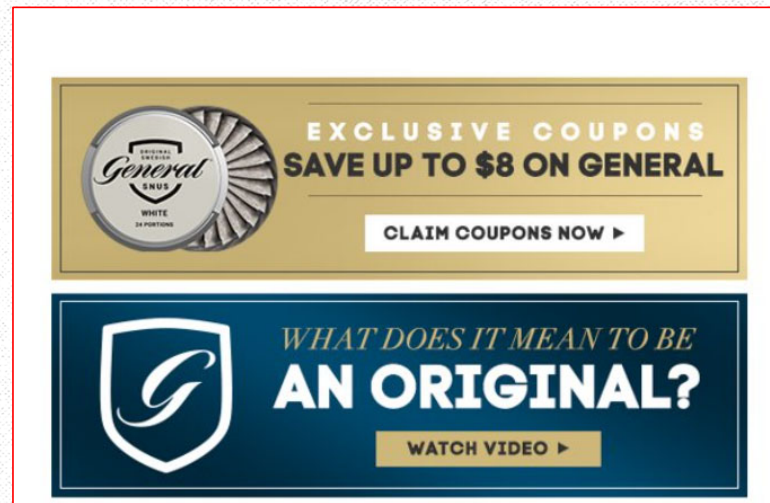
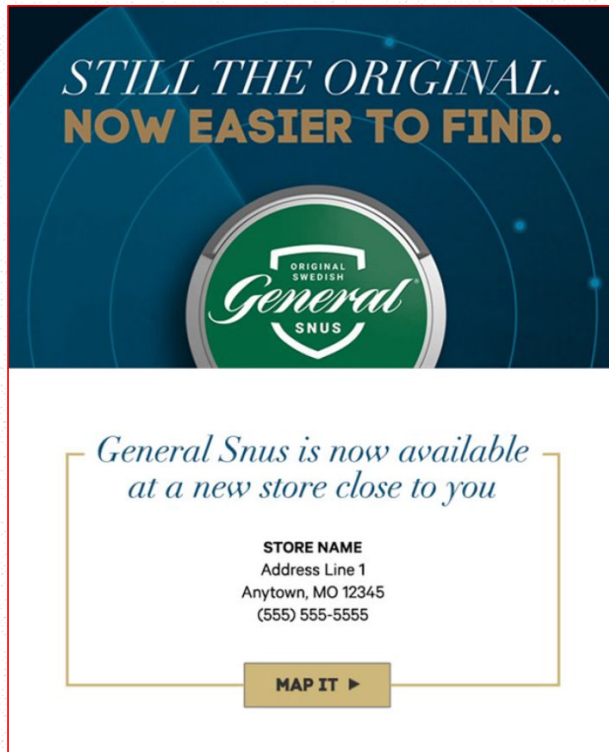
General Snus Sweepstakes Winner EM6

11-17-23



Ongoing Email: Anniversary

1-2-23 - current



Ongoing Email: Welcome (Coupon)

5-12-23 - current

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The world's #1 selling snus
Discreet no-spit upper lip pouches
Made with four simple ingredients

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General Snus adheres to strict Swedish food-grade quality standards from seed to can.

To get exclusive monthly savings, make sure you're signed up to receive mail from us. It's just our way of saying thanks from General Snus.

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An original since 1866

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

Ongoing Email: Welcome (No Coupon)

5-12-23 - current

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Discreet no-spit upper lip pouches
Made with four simple ingredients

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You're now a part of something very special. We can't wait for you to come explore with us.





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OUR PATH TO PERFECTION

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WARNING: This product can cause mouth cancer.

Ongoing Email: Anniversary

5-12-23 - current



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ORIGINALS
STICK TOGETHER

General SNUS

We're celebrating another year of your loyalty to General Snus. Because with fans like you, the maverick pulse of the Original Swedish Snus still beats on. That's why we promise to always hold our tobacco to a higher standard — all the way from Sweden to you.

**WE'LL STICK BY YOU.
JUST LIKE YOU STICK BY US.**

Your friends at General Snus

General SNUS

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General Snus Email .mp4 File Guide

.mp4 Image

.mp4 File Name and Length

.mp4 Descripton



Nov 2022 EM1_Leaves.mp4

00:00:08



General Snus Brand Original Website Video_2022.mp4

00:00:50

(b) (4)



General Snus EMail Reporting – By Email – Nov. '22 – Oct. '23

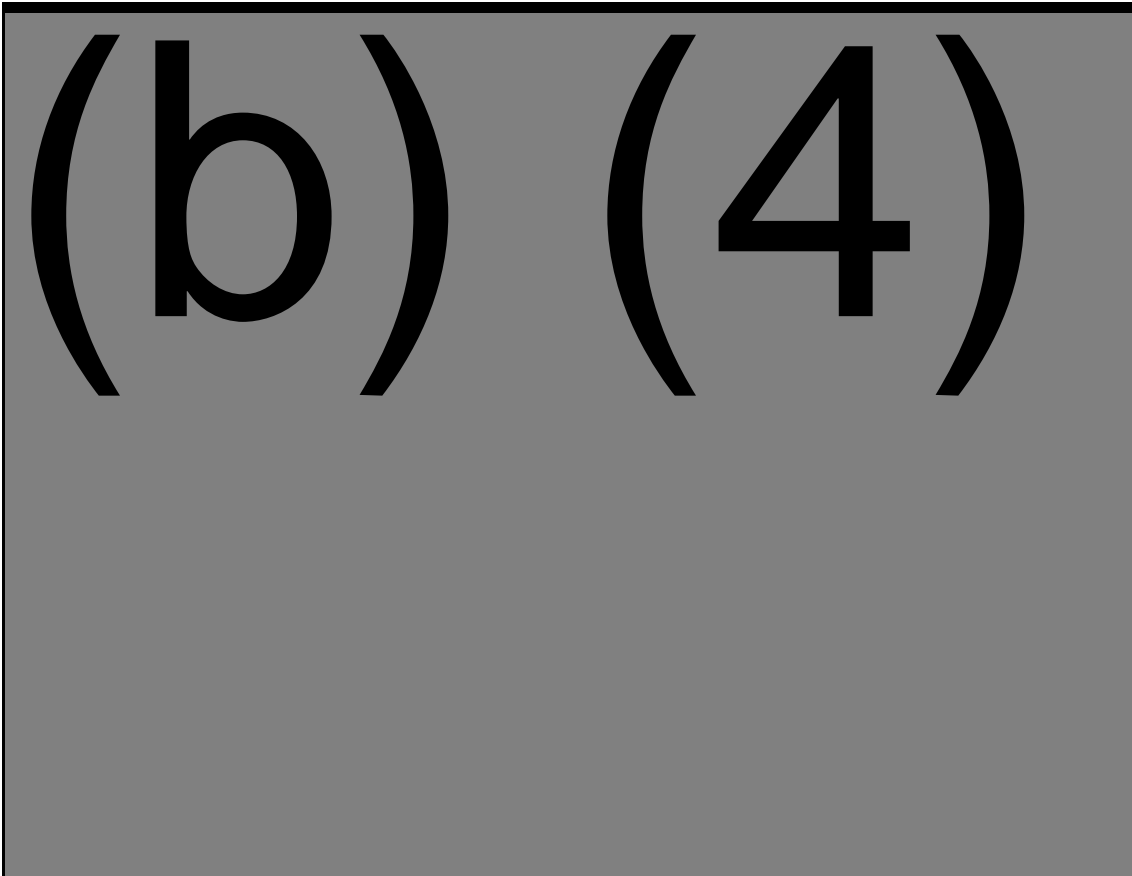
(b) (4)

General Snus EMail Reporting – By State – Nov. '22 – Oct. '23

(b) (4)

Swedish Match

General Snus EMail Reporting – By Age – Nov. '22 – Oct. '23



GENERAL SNUS DIRECT MAIL



General Snus Conversion Direct Mailer

3-27-23 - current

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Take the quiz to find your path.

On or off the beaten path?

- Off
 - Music or podcast?
 - Music
 - How's your legacy?
 - Secured
 - Get exclusive savings
 - In progress
 - Enjoy original content
 - Podcast
 - Stay up to date
 - Way, way off
 - Windows up or down?
 - Up
 - Are you bold?
 - 100%
 - Always be the first to know
 - Of course
 - Stay up to date
 - Down
 - Stay up to date

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General Snus Conversion Direct Mailer con't

3-27-23 - current

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0609249-877112

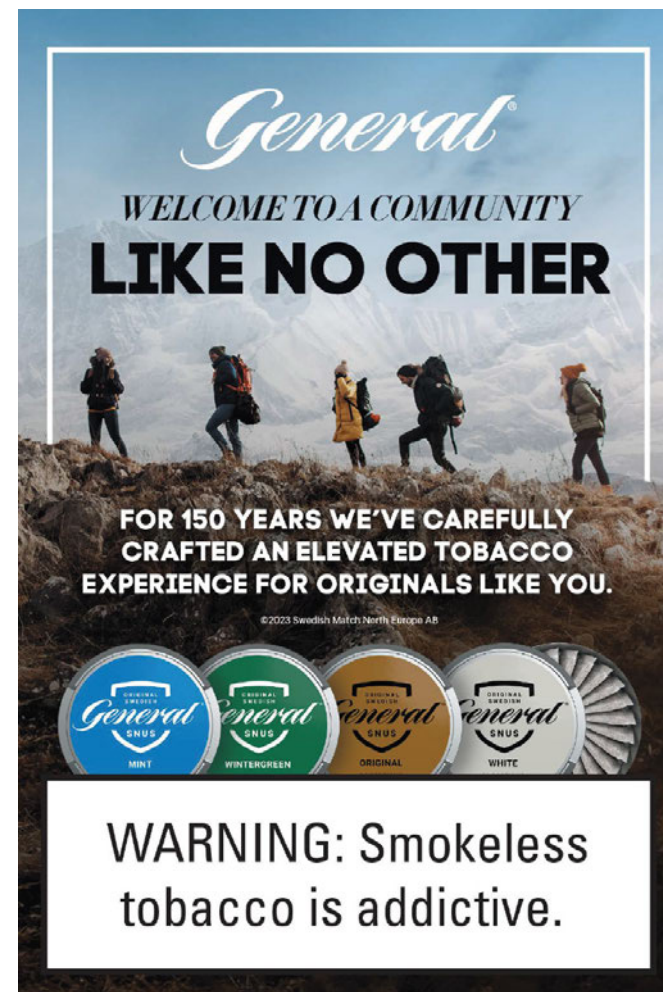
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General Snus Welcome Direct Mailer

3-27-23 - current



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3-27-23 - current

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General Snus
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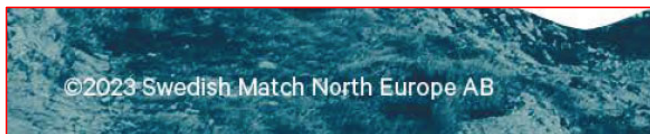
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General Snus Birthday Direct Mailer

3-27-23 - current

INSIDE

The main graphic for the birthday mailer. It features a large white 'G' logo superimposed over a photograph of a person standing on a rocky outcrop, looking out over a body of water. The background is a mix of blue and white, suggesting a sky or water. The text "©2023 Swedish Match North Europe AB" is visible in small print at the bottom left of the image.

HERE'S TO ANOTHER YEAR

Dear Matthew.

Happy birthday! Enjoy this exclusive coupon and here's to staying original for another year!

Your friends at **General**

WARNING: Smokeless tobacco is addictive.

Swedish Match.

General Snus Birthday Direct Mailer con't

3-27-23 - current

OUTSIDE

Pinkerton Tobacco Co. LP
PO Box 22915
Owensboro, KY 42304-9701

Return Service Requested

©2023 Swedish Match North Europe AB
GNA29003

*Enjoy exclusive birthday
savings on your special day.*



Pinkerton Tobacco Co. LP
PO Box 22915
Owensboro, KY 42304-9701

Return Service Requested

©2023 Swedish Match North Europe AB
GNA29003

*Enjoy exclusive birthday
savings on your special day.*

QUESTIONS OR WANT TO REPORT CONCERNS ABOUT GENERAL SNUS? CONTACT US AT

info@swedishmatch.com | (270) 685-8777
You can also learn more at GeneralSnus.com

To opt out of future promotional mailings and be removed from our mailing list, please contact Consumer Care at (270) 685-8777.

NOTE: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

MANUFACTURER'S COUPON EXPIRES 03/31/24

RETAILER: Subtract \$1.00 from your normal retail price including applicable sales tax. Write that amount (your price minus \$1) in the space provided.

RETAILER: Swedish Match North America LLC, will pay you the face value of this coupon plus \$.08 handling provided you accept the coupon from a consumer in exchange for specified package purchase. Retailer must submit on request invoices proving purchases of sufficient stock within normal redemption cycle to cover the coupons presented for redemption. This coupon is non-transferable. Void where prohibited, taxed or otherwise restricted. Cash redemption value 1/20 of \$01. LIMIT ONE COUPON PER PURCHASE. ANY USE NOT CONSISTENT WITH THESE TERMS CONSTITUTES FRAUD. For coupon inquiries, call the Retailer Hotline: 1-800-285-7602. EXPIRATION DATE: 3/31/24. **CONSUMER:** By submitting this coupon, I hereby certify that I am 21 years of age or older as may be specified by state law, and am a current consumer of tobacco products. Distribution of product prohibited to persons under 21. THIS COUPON CANNOT BE COMBINED WITH ANY OTHER OFFERS OR COUPONS. Mail to: Inmar Brand Solutions Dept. 70195 Mfr Rev Office 801 UNION PACIFIC BLVD STE 5 LAREDO TX 78045-9475

QUESTIONS OR WANT TO REPORT CONCERNS ABOUT GENERAL SNUS? CONTACT US AT

info@swedishmatch.com | (270) 685-8777
You can also learn more at GeneralSnus.com

To opt out of future promotional mailings and be removed from our mailing list, please contact Consumer Care at (270) 685-8777.

NOTE: General Snus is for adult tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit BeTobaccoFree.gov for more information.

Swedish Match.

General Snus Specialty Mailer

10-2-23

VISIT [GENERALSNU.COM](https://generalsnus.com) EVERY WEEK FOR A CHANCE TO WIN!

While there are many imitations, knockoffs, and version 2.0s, **THERE'S ONLY ONE ORIGINAL LIKE GENERAL SNUS.** And there's only one special (and hidden) General Snus can. Find it and the riches could be yours.

THE HUNT BEGINS OCTOBER 2ND


STEP 1: FIND THE SPECIAL CAN

Somewhere hidden on the pages of GeneralSnus.com is a one-of-a-kind can of Snus. Track it down, and you could walk away with way more than a sense of accomplishment.



SHARE THE THRILL OF THE HUNT

DON'T KEEP ALL THE FUN TO YOURSELF. INVITE A FRIEND TO JOIN THE HUNT USING THIS QR CODE.



NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For Official Rules, visit <https://www.generalsnus.com>. Sponsor: Swedish Match North America LLC.

Inside

VISIT [GENERALSNU.COM](https://generalsnus.com) EVERY WEEK FOR A CHANCE TO WIN!

While there are many imitations, knockoffs, and version 2.0s, **THERE'S ONLY ONE ORIGINAL LIKE GENERAL SNUS.** And there's only one special (and hidden) General Snus can. Find it and the riches could be yours.


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SHARE THE THRILL OF THE HUNT

DON'T KEEP ALL THE FUN TO YOURSELF. INVITE A FRIEND TO JOIN THE HUNT USING THE QR CODE.



NO PURCHASE NECESSARY. Void where prohibited. Open to legal residents of the 50 United States and the District of Columbia (excluding residents of Massachusetts, Michigan and Virginia), who are tobacco consumers, 21 & older. Begins 10:00 AM ET on October 2, 2023 and ends 11:59 PM ET on November 12, 2023. For Official Rules, visit <https://www.generalsnus.com>. Sponsor: Swedish Match North America LLC.

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


Swedish Match.

General Snus Specialty Mailer

10-2-23

STEP 2:
ENTER TO WIN

CLICK ON THE TREASURE TO ENTER.



STEP 3:
REPEAT EACH WEEK

Visit the site every week to "Find the Original" can. And each week you'll have more chances to enter — and that means more chances to walk away with great prizes.

You've found the special can. Click on it to enter the "Find the Original" Sweepstakes. You'll have a chance to win prizes from brands that are also true originals like General Snus.

PRIZES AWARDED WEEKLY

WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	GRAND PRIZE
Multi-tool	Trail-Running Headlamp	8x42 Binoculars	Hiking Backpack	36-Can Cooler	Hammock	15' Inflatable Boat

PINKERTON TOBACCO CO. LP
PO BOX 22915
OWENSBORO, KY 42304-9701

To opt out of future promotional mailings and be removed from our mailing list, please contact the Consumer Call Center at (270) 685-8777.

READY TO SEEK THE TREASURE? START YOUR HUNT TODAY.

Outside

STEP 2:
ENTER TO WIN

CLICK ON THE TREASURE TO ENTER.



STEP 3:
REPEAT EACH WEEK

Visit the site every week to "Find the Original" can. And each week you'll have more chances to enter — and that means more chances to walk away with great prizes.


You've found the special can. Click on it to enter the "Find the Original" Sweepstakes. You'll have a chance to win prizes from brands that are also true originals like General Snus.

PRIZES AWARDED WEEKLY

WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	GRAND PRIZE
Multi-tool	Trail-Running Headlamp	8x42 Binoculars	Hiking Backpack	36-Can Cooler	Hammock	15' Inflatable Boat

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

"FIND THE ORIGINAL" SWEEPSTAKES



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

FIND THE ORIGINAL SNUS AND WIN.

READY TO SEEK THE TREASURE? START YOUR HUNT TODAY.

To opt out of future promotional mailings and be removed from our mailing list, please contact the Consumer Call Center at (270) 685-8777.

PINKERTON TOBACCO CO. LP
PO BOX 22915
OWENSBORO, KY 42304-9701

Swedish Match.

General Snus Direct Mail Reporting – By Direct Mailer – Nov. '22 – Oct. '23

(b) (4)

Swedish Match

General Snus Direct Mail Reporting – By State – Nov. '22 – Oct. '23

(b) (4)

General Snus Direct Mail Reporting – By Age – Nov. ‘22 – Oct. ‘23

(b) (4)



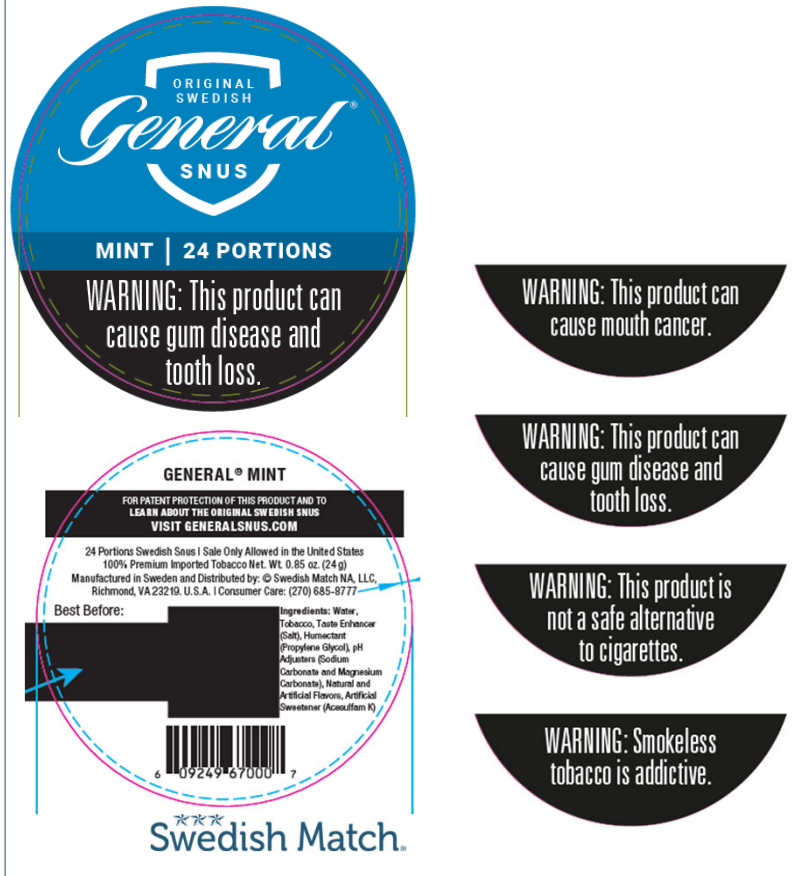
GENERAL SNUS PACKAGING



General Packaging – Mint – In stores Dec. 2022

(Removed URL from side label & Implemented Track & Trace Bottom Label)

NO CHANGES MADE TO TOP LABEL



Updated Side Labels

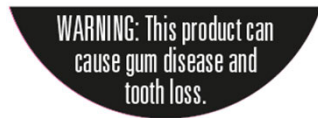


104

General Packaging – Wintergreen – In stores Dec. 2022

(Removed URL from side label & Implemented Track & Trace Bottom Label)

NO CHANGES MADE TO TOP LABELS



Swedish Match.

105

Updated Side Labels



General Packaging – White – In stores Dec. 2022

(Removed URL from side label & Implemented Track & Trace Bottom Label)

NO CHANGES MADE TO TOP LABEL



WARNING: This product can cause mouth cancer.

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

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

WARNING: Smokeless tobacco is addictive.

Updated Side Labels

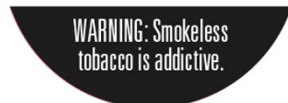
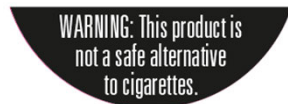
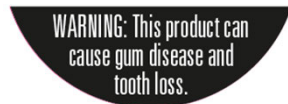


106

General Packaging – Original – In stores Dec. 2022

(Removed URL from side label - Track & Trace Bottom Label not implemented until 2023)

NO CHANGES MADE TO TOP LABEL



Swedish Match.

Updated Side Labels



General Bottom Label Packaging Detail In Stores Dec. 2022

GENERAL® MINT

FOR PATENT PROTECTION OF THIS PRODUCT AND TO
LEARN ABOUT THE ORIGINAL SWEDISH SNUS
VISIT [GENERALSNU.S.COM](https://www.generalsnus.com)

24 Portions Swedish Snus | Sale Only Allowed in the United States
100% Premium Imported Tobacco Net. Wt. 0.85 oz. (24 g)
Manufactured in Sweden and Distributed by: © Swedish Match NA, LLC,
Richmond, VA 23219. U.S.A. | Consumer Care: (270) 685-8777

Ingredients: Water,
Tobacco, Taste Enhancer
(Salt), Humectant
(Propylene Glycol), pH
Adjusters (Sodium
Carbonate and Magnesium
Carbonate), Natural and
Artificial Flavors, Artificial
Sweetener (Acesulfam K)

GENERAL® WINTERGREEN

FOR PATENT PROTECTION OF THIS PRODUCT AND TO
LEARN ABOUT THE ORIGINAL SWEDISH SNUS
VISIT [GENERALSNU.S.COM](https://www.generalsnus.com)

24 Portions Swedish Snus | Sale Only Allowed in the United States
100% Premium Imported Tobacco Net. Wt. 0.85 oz. (24 g)
Manufactured in Sweden and Distributed by: © Swedish Match NA, LLC,
Richmond, VA 23219. U.S.A. | Consumer Care: (270) 685-8777

Ingredients: Water,
Tobacco, Taste Enhancer
(Salt), Humectant
(Propylene Glycol), pH
Adjusters (Sodium
Carbonate and Magnesium
Carbonate), Natural and
Artificial Flavors, Artificial
Sweetener (Acesulfam K)

GENERAL® WHITE

FOR PATENT PROTECTION OF THIS PRODUCT AND TO
LEARN ABOUT THE ORIGINAL SWEDISH SNUS
VISIT [GENERALSNU.S.COM](https://www.generalsnus.com)

24 Portions Swedish Snus | Sale Only Allowed in the United States
100% Premium Imported Tobacco Net. Wt. 0.85 oz. (24 g)
Manufactured in Sweden and Distributed by: © Swedish Match NA, LLC,
Richmond, VA 23219. U.S.A. | Consumer Care: (270) 685-8777

Ingredients: Water,
Tobacco, Taste Enhancer
(Salt), Humectant
(Propylene Glycol), pH
Adjusters (Sodium
Carbonate and Magnesium
Carbonate), Natural and
Artificial Flavors, Artificial
Sweetener (Acesulfam K)

GENERAL® ORIGINAL

24 Portions Swedish Snus
Sale Only Allowed in the United States
100% Premium Imported Tobacco | Net. Wt. 0.85 oz. (24 g)
For patent protection of this product, see [GeneralSnus.com](https://www.generalsnus.com)
Manufactured in Sweden and Distributed by:
© Swedish Match NA, LLC, Richmond, VA 23219. U.S.A.
Consumer Care: (270) 685-8777
For more info visit [GeneralSnus.com](https://www.generalsnus.com)

Ingredients: Water, Tobacco, Humectant
(Propylene Glycol), Taste Enhancer (Salt), pH Adjuster
(Sodium Carbonate), Natural and Artificial
Flavors including Artificial Smoke Flavor

General Shipper Packaging Change – In-market Dec. 2022



Listikant



General Shipper Packaging Change – In-market Dec. 2022



General Shipper Packaging Change – In-market Dec. 2022



General Shipper Packaging Change – In-market Dec. 2022



General Roll Label Packaging Change – In-market Dec. 2022



GENERAL SNUS POS



General Roll Header: In-market Dec. 2022



©2022 Swedish Match North Europe AB POS# 894538



©2022 Swedish Match North Europe AB POS# 894538 UNFLAVORED

General Roll 2-Sided Counter Mat: In-market Dec. 2022



©2022 Swedish Match North Europe AB POS# 894538



©2022 Swedish Match North Europe AB POS# 894538 UNFLAVORED

General Roll Horizontal Door Spanners: In-market Dec. 2022



POS# 894537 ©2022 Swedish Match North Europe AB



UNFLAVORED POS# 894544 ©2022 Swedish Match North Europe AB

General Roll Door Decals: In-market Dec. 2022



©2022 Swedish Match North Europe AB POS# 894536



UNFLAVORED ©2022 Swedish Match North Europe AB POS# 894536



General Roll 2-sided Shelf Talker: In-market Dec. 2022



UNFLAVORED

POS #894543 ©2022 Swedish Match North Europe AB



General Roll H4 Chiller Door Sign: In-market Dec. 2022



POS #894539 ©2022 Swedish Match North Europe AB



POS #894540 ©2022 Swedish Match North Europe AB

UNFLAVORED

General Roll V4 Chiller Door Sign: In-market Dec. 2022



POS #894541 ©2022 Swedish Match North Europe AB



UNFLAVORED

POS #894542 ©2022 Swedish Match North Europe AB

General Roll V4 Pedestal: In-market Dec. 2022



POS #894393
©2022 Swedish Match North Europe AB

Swedish Match®



POS #894393 ©2022 Swedish Match North Europe AB

General Roll LED: In-market Dec. 2022



General Roll 2-Sided Menu Board: In-market Dec. 2022



POS# 894085
©2022 Swedish Match North Europe AB



POS# 894085
©2022 Swedish Match North Europe AB

Swedish Match®

General Roll 2-Sided Header: In-market Dec. 2022



©2022 Swedish Match North Europe AB POS# 894540

☆☆☆
Swedish Match®

General Roll CTA-50 Chiller Decal: In-market Dec. 2022



©2022 Swedish Match North Europe AB POS# 894541

GENERAL SNUS MERCHANDISING



General Snus Merchandiser Graphics

Dec. 2022 – current

4-Wide Side Graphic



4-Wide Back Graphic



4-wide Header

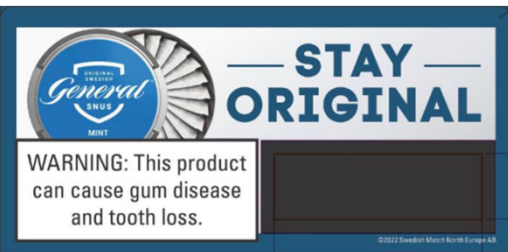


2-Wide Back Graphic



©2022 Swedish Match North Europe AB

2-wide Header



4 x 2 Back Graphic



4 x 2 Side Graphic



©2022 Swedish Match North Europe AB

General Snus Merchandiser Graphics [Unflavored]

Dec. 2022 – current

4-Wide Side Graphic



4-Wide Back Graphic



4-wide Header



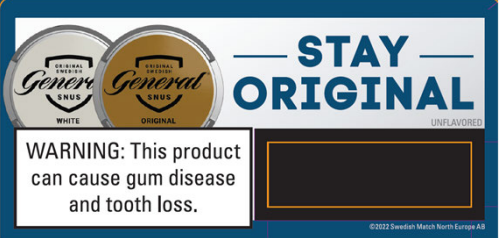
UNFLAVORED

2-Wide Back Graphic



©2022 Swedish Match North Europe AB

2-wide Header



4 x 2 Back Graphic



4 x 2 Side Graphic



©2022 Swedish Match North Europe AB

2023 MRTP Annual Report

CATEGORY: SNUS

BRAND: GENERAL SNUS

November 2022 – October 2023

Appendix 2A (7)

Trade Advertising



General Print Trade Ad: In-market Feb 2023-Apr 2023

GROW PROFITS
with
THE ORIGINAL

STAY ORIGINAL
AUTHENTIC TASTE ONLY
WARNING: This product can cause gum disease and tooth loss.

ORIGINAL SNUS

ORIGINAL SWEDISH
General
SNUS
MINT
24 PORTIONS

#1 Selling Snus Worldwide

For trade purposes only. ©2023 Swedish Match North America, Inc.

Swedish Match. **CALL 800-774-7754** or contact your Swedish Match representative for more information.

General Print Trade Ad: In-market May 2023 – Jul 2023, Nov 2023



**IF YOU STOCK IT,
THEY WILL COME**

ORIGINAL
SWEDISH
General
SNUS
WHITE


**THIS IS THE PREMIUM PRODUCT THAT CREATES LOYAL
CUSTOMERS. LOYAL CUSTOMERS WHO DRIVE PROFITS.**

#1 in penny profit in snus
The World's #1 Selling Snus
First to Receive a Modified Risk
Tobacco Product Order

RECEIVED A MODIFIED RISK
2019
TOBACCO PRODUCT ORDER

For tobacco products only. ©2023 Swedish Match North America, Inc.


General Print Trade Ad: In-market Aug 2023 – Oct 2023

A cylindrical tin of General Snus White. The lid is silver with a white center. The center features the text "ORIGINAL SWEDISH" in a small font, "General" in a large, elegant script font, "SNUS" in a bold sans-serif font, and "WHITE" in a bold sans-serif font at the bottom. The tin is shown at an angle, revealing the white snus pouches inside.

THE WORLD'S #1 SELLING SNUS

The #1 penny profit snus in U.S. stores

Many tobacco users are already looking for alternatives. They want real tobacco satisfaction from a premium product. General Snus delivers on all of the above—and it's the first to receive a Modified Risk Tobacco Product Order.

A circular gold seal with a dark border. Inside the border, the text "RECEIVED A MODIFIED RISK" is at the top, "2019" is in the center, and "TOBACCO PRODUCT ORDER" is at the bottom.

For trade purposes only. ©2023 Swedish Match North America AB

General NACS Show Banner: In-market Q2 2023



© 2023 Swedish Match North Europe AB

General NACS Show Banner: In-market Q3 2023

FOR TRADE PURPOSES ONLY
©2023 Swedish Match North Europe AB

**GIVE YOUR
SALES THE
LOYAL
TREATMENT**

Make our loyal customers, your loyal customers
by carrying the premium Snus they're looking for.

#1 IN PENNY PROFIT IN SNUS
THE WORLD'S #1 SELLING SNUS



ORIGINAL
SWEDISH
General
SNUS
WHITE
24 PORTIONS

2019
AWARD
WINNER

FOR TRADE PURPOSES ONLY
©2023 Swedish Match North Europe AB

2023 General Print Trade Ad Plan

(b) (4)



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

JUN 1 - 2018

RECEIVED
LEGAL OPS

June 01, 2018

GENERAL CORRESPONDENCE

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

FDA Submission Tracking Numbers (STN(s)): MULTIPLE STNs, See Below

Dear Mr. Roerty:

Please refer to your Postmarket Periodic reports for the Premarket Tobacco Applications (PMTAs) received on October 27, 2017 and November 22, 2017, submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco products:

<u>Periodic Report STN</u>	<u>STN</u>	<u>TOBACCO PRODUCT NAME</u>
TC0003310	PM0000010	General Loose
TC0003024	PM0000017	General Wintergreen Portion White Large
TC0003025	PM0000011	General Dry Mint Portion Original Mini
TC0003026	PM0000012	General Portion Original Large
TC0003028	PM0000014	General Mint Portion White Large
TC0003030	PM0000016	General Portion White Large

Based on our review of your 2017 Periodic reports, we have identified the following issues for which we believe additional information or clarification will be helpful to FDA in performing a complete substantive review of **subsequent** Periodic Reports.

(b) (4)

(b) (4)

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter or mailed to :

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Shireen Ahmad, MS, Regulatory Health Project Manager, at (240) 402 – 0435 or at Shireen.Ahmad@fda.hhs.gov.

Sincerely,

Ilun C. Murphy -S

2018.06.01 13:12:30 -04'00'

Ilun Murphy, M.D.
Director, Division of Individual Health Science
Office of Science
Center for Tobacco Products

GENERAL SNUS EXPLORATORY QUALITATIVE OMNIBUS

April 2022



(b) (4)

MRTP DESIGNATION: REACTIONS + PERCEPTIONS

(b) (4)

(b) (4)

(b) (4)

(b) (4)



(b) (4)

BRAND USAGE CRITERIA + PERCEPTIONS

(b) (4)

(b) (4)

(b) (4)

(b) (4)

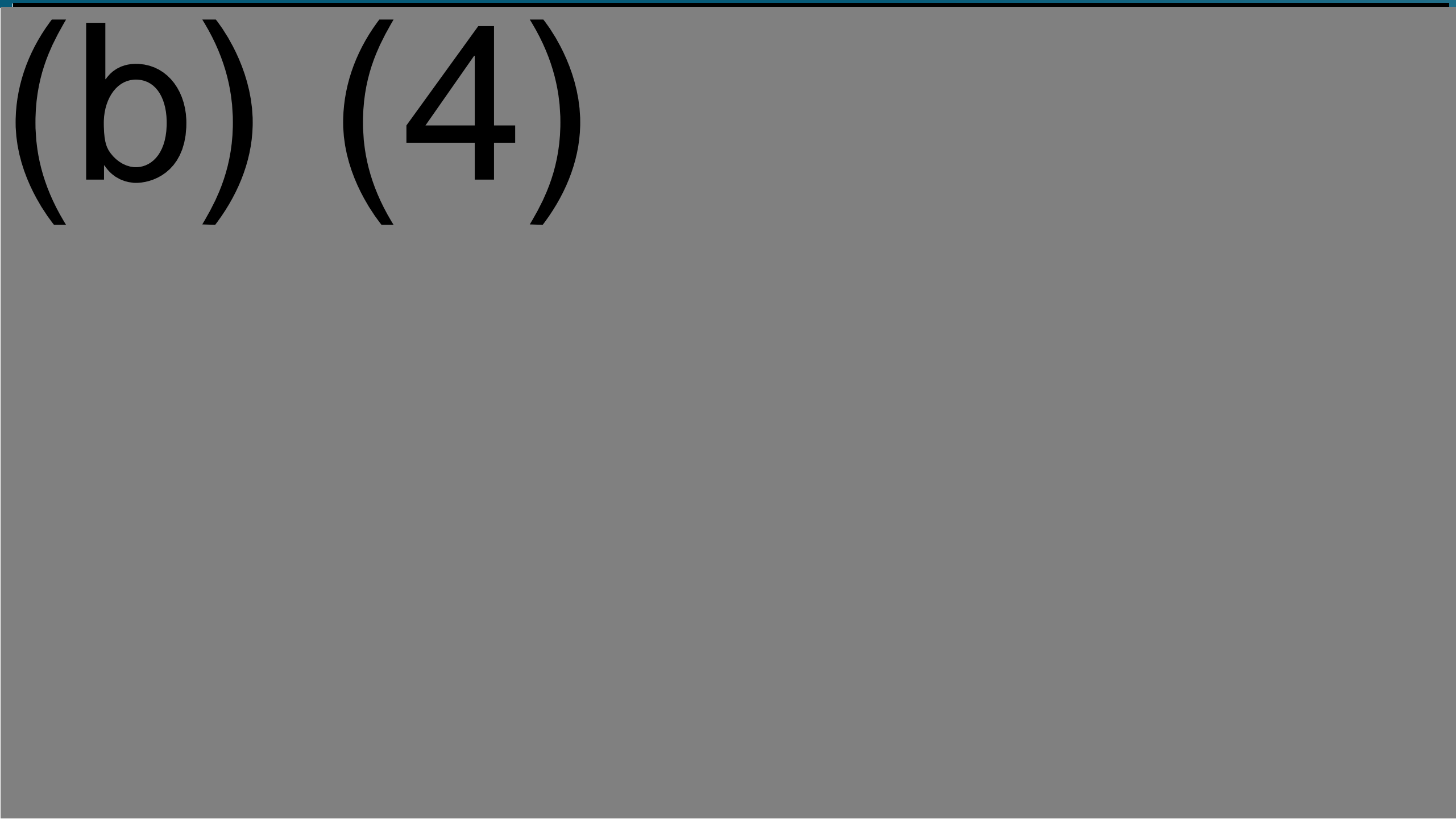
(b) (4)

(b) (4)

(b) (4)

RESPONDENT PROFILE AND PRODUCT USAGE

(b) (4)



(b) (4)

(b) (4)

(b) (4)

QUESTIONS OR COMMENTS?

(b) (4)

Original Paper

Perceptions and Discussions of Snus on Twitter: Observational Study

Jiarui Chen¹; Siyu Xue¹, BSc; Zidian Xie², PhD; Dongmei Li², PhD

¹Goergen Institute for Data Science, University of Rochester, Rochester, NY, United States

²Department of Clinical & Translational Research, University of Rochester Medical Center, Rochester, NY, United States

Corresponding Author:

Dongmei Li, PhD

Department of Clinical & Translational Research

University of Rochester Medical Center

265 Crittenden Boulevard CU 420708

Rochester, NY, 14642-0708

United States

Phone: 1 585 276 7285

Email: Dongmei_Li@urmc.rochester.edu

Abstract

Background: With the increasing popularity of snus, it is essential to understand the public perception of this oral tobacco product. Twitter—a popular social media platform that is being used to share personal experiences and opinions—provides an ideal data source for studying the public perception of snus.

Objective: This study aims to examine public perceptions and discussions of snus on Twitter.

Methods: Twitter posts (tweets) about snus were collected through the Twitter streaming application programming interface from March 11, 2021, to February 26, 2022. A temporal analysis was conducted to examine the change in number of snus-related tweets over time. A sentiment analysis was conducted to examine the sentiments of snus-related tweets. Topic modeling was applied to tweets to determine popular topics. Finally, a keyword search and hand-coding were used to understand the health symptoms mentioned in snus-related tweets.

Results: The sentiment analysis showed that the proportion of snus-related tweets with a positive sentiment was significantly higher than the proportion of negative sentiment tweets (4341/11,631, 37.32% vs 3094/11,631, 26.60%; $P < .001$). The topic modeling analysis revealed that positive tweets focused on snus's harm reduction and snus use being an alternative to smoking, while negative tweets focused on health concerns related to snus. Mouth and respiratory symptoms were the most mentioned health symptoms in snus-related tweets.

Conclusions: This study examined the public perception of snus and popular snus-related topics discussed on Twitter, thus providing a guide for policy makers with regard to the future formulation and adjustment of tobacco regulation policies.

(*JMIR Med Inform* 2022;10(8):e38174) doi: [10.2196/38174](https://doi.org/10.2196/38174)

KEYWORDS

snus; Twitter; sentiment; topic modeling; smokeless tobacco products

Introduction

Smokeless tobacco is a type of tobacco that is neither smoked nor burnt during consumption. Examples of smokeless tobacco products include chewing tobacco, dissolvable tobacco, and oral nicotine pouches. According to the Centers for Disease Control and Prevention (CDC), in 2020, there were 5.7 million adult users of smokeless tobacco nationwide in the United States [1]. Among the smokeless tobacco products, snus is a smokeless and sometimes flavored tobacco product for oral consumption

that originated from Sweden. It is usually in the following two forms: loose ground powder and sachets. When snus is consumed, it is held behind the upper lip [2]. Although this tobacco product was banned in the member countries of the European Union, with a few exceptions such as Sweden [3], its use in the rest of the world is prevalent. By 2013 for example, 18% of adolescents had tried snus in Finland [4]. In the United States, a study conducted in 2021 by the CDC suggested that 1.2% of US high school students are current users of smokeless products, including snus [1].

Studies have found that snus use may result in oral cancer, cardiovascular diseases, respiratory diseases, diabetes, and other illnesses [5]. A cohort study on 135,036 male, Swedish construction industry employees found that the age-adjusted relative risk of dying from cardiovascular disease for smokeless tobacco users was 40% higher than that for nonusers [6]. Despite these concerns, previous studies indicated that snus use has a considerably lower health risk than cigarette smoking [2,7]. According to a review on multiple health symptoms, including oral health and cardiovascular diseases, among others, the health risk of snus is significantly lower than that of cigarettes [2].

Similar to other tobacco products, snus use results in nicotine dependence, and the perceptions toward the relationship between snus consumption and other types of nicotine consumption have been controversial [5]. The gateway hypothesis states that the use of snus may lead to more addictive smoking behaviors. On the contrary, the pathway hypothesis claims that snus use helps to prevent people from smoking [5]. Previous studies on this topic reported different conclusions. A previous study tracked 496 pairs of users and nonusers of smokeless tobacco products and concluded that there was insufficient evidence to conclude that using smokeless tobacco products leads to a higher chance of smoking [8]. Another research study on smokers in Sweden found that 76.3% of the male smokers and 71.6% of the female smokers included in the study quit smoking after they started consuming snus [9]. However, a focus group study that was performed on 66 participants in 2010 concluded that the participants believed that snus use could potentially lead to smoking [10].

With the controversial gateway and pathway hypotheses and the potential health impact of snus products, disagreements on the perception of snus product may exist among the public. As snus is becoming increasingly popular, governmental regulation plays an essential role in the relationship between snus consumption and public health. For example, the US Food and Drug Administration stipulates that for smokeless tobacco products, including snus, special warnings such as “WARNING: Smokeless tobacco is addictive” should be attached to the packages [11]. For governors and regulators to better manage the relationship between snus and public health and be more informed in policy making, it is beneficial to understand how the public truly perceives snus.

Twitter, as a popular social media platform, has been used to examine smoking behaviors and perceptions of tobacco products, such as e-cigarettes [12,13]. Although perceptions of snus have been investigated by using focus groups, the sample sizes of such focus groups are very limited [10,14]. Research that uses social media data to study the public perceptions of snus is scarce.

Our study aimed to examine the public perceptions of and popular topics regarding snus on Twitter. Our study consisted of 3 specific goals. First, we aimed to determine the sentiments of snus-related tweets via a sentiment analysis. Second, we attempted to explore specific topics related to snus. Finally, we tried to examine potential health risks that were mentioned in snus-related tweets. Through a comprehensive examination of the public perceptions and the top topics discussed about snus,

we hope to provide some insights to policy makers on regulating snus for public health protection.

Methods

Ethics Approval

We only used publicly available tweets for this study, and there was no identifying information on Twitter users in this study. In addition, this study was reviewed and approved by the Office for Human Subject Protection Research Subjects Review at the University of Rochester (study ID: STUDY00006570).

Data Collection and Preprocessing

We collected Twitter posts (tweets) related to snus from March 11, 2021, to February 26, 2022, through the Twitter streaming application programming interface by using the keyword *snus*, and we obtained a data set with 28,427 tweets. We then preprocessed the data to enhance their quality. First, all the tweets were lowercased. Afterward, by using the Regular Expression Operations Package (Python Software Foundation) [15], we removed the parts of tweets that did not contribute to the tweets' actual contents, including email addresses, new-line characters, single quotation marks, URLs, and “@” signs (used to mention other users). Next, we applied 2 sets of promotion filters to eliminate tweets that were related to the commercial promotion of snus [13]. The first filter targeted the usernames, using keywords such as *snus*, *smokeless*, *dealer*, *supply*, *nicotine*, *cigarette*, and *store*. Tweets posted by users with usernames containing any of these words were not included in this study because they might have been posted by commercial accounts. The second layer of the filter aimed to remove potentially commercial tweet content, and the keywords included *order*, *new*, *offer*, *discount*, and *free shipping*. Tweets that contained these words were highly likely to be promotional tweets. Finally, we eliminated the repetitive tweets. After preprocessing, the final data set contained 11,631 tweets.

Sentiment Analysis

Sentiment analysis is a computational method of learning the attitudes in text, and the Valence Aware Dictionary and Sentiment Reasoner (VADER) is a sentiment analysis package that is specialized for social media data [16]. By applying the VADER on each tweet, we assigned each tweet a sentiment score of between -1.0 and 1.0. To better define the sentiments, we grouped the tweets into 3 categories based on the corresponding sentiment scores; tweets with a sentiment score of ≥ 0.05 were labeled as “positive,” and tweets with a score of ≤ -0.05 were labeled as “negative.” The remaining tweets were labeled as “neutral.” The proportions of positive, neutral, and negative tweets were then calculated. The daily proportion of positive tweets was then calculated.

We performed the chi-square goodness-of-fit test by using statistical analysis software (R version 4.0.2; R Foundation for Statistical Computing) to examine the frequency distribution of different attitudes [17]. A significance level of .05 was used to determine whether the proportion of positive tweets was statistically significantly higher than the proportion of the negative tweets.

Topic Modeling

Topic modeling is a computational method of identifying major topics in text. The model we chose for our study was the latent Dirichlet allocation model, which was applied to positive tweets, neutral tweets, and negative tweets to observe the main topics that Twitter users had been discussing.

By using the *gensim* package in Python [18], we built a bigram and trigram based on our data set. Bigrams and trigrams are sequences of 2 words and 3 words, respectively. With the bigram and the trigram, we treated some of the most frequently mentioned phrases as a whole instead of 2 or 3 separate words. For example, *harm reduction* was a frequently mentioned phrase among the tweets, and we considered *harm reduction* as a single token that contributed to a topic instead of preserving *harm* and *reduction* separately.

We applied the Natural Language Toolkit to remove the stop words in the tweets [19]. Stop words include but are not limited to commonly used articles, pronouns, and propositions, which undermine the quality of topic modeling results if kept. In addition, we used spaCy (Explore) to lemmatize the words in tweets into their dictionary forms without changing their meaning [20]. For example, *smoked* became *smoke* after lemmatization. After conversion, words like *smoked* were left unused for topic modeling, and only their dictionary forms were included. Both coherence scores and intertopic distance maps were used to determine the optimal number of topics discussed in the tweets, using the *pyLDAvis* package in Python [21].

To better interpret the results from the model, we inferred the topics based on the keyword outputs and example tweets. Two authors reviewed the tweets from each category and summarized the topics independently. The results from the two authors were

compared and discussed. Any discrepancy was resolved by a group of 4 members.

Health-Related Discussion

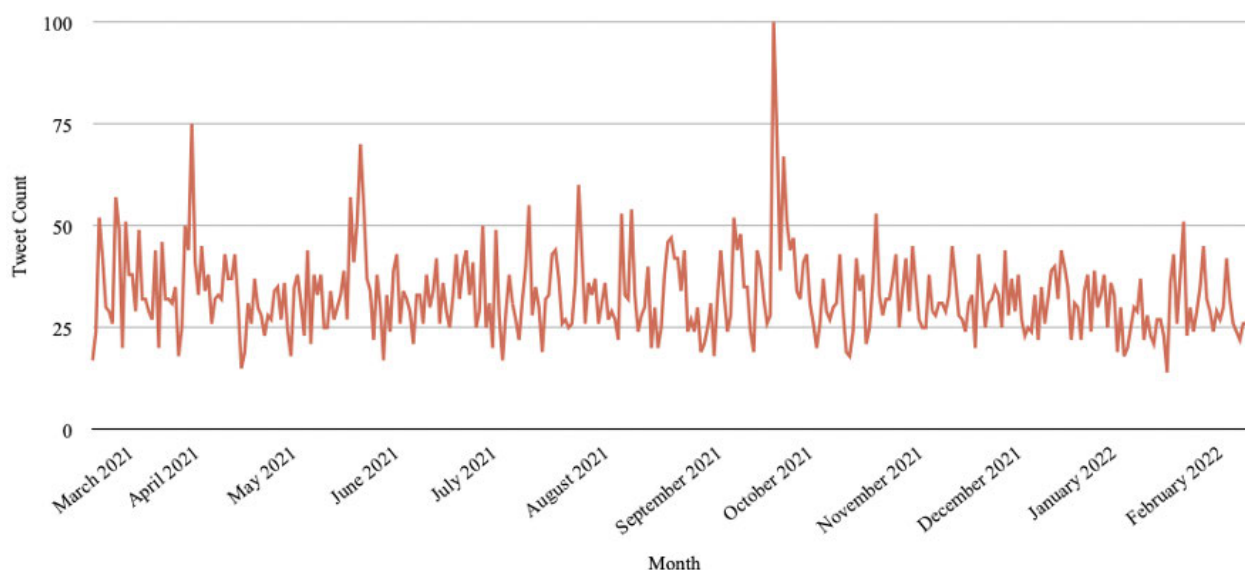
To determine the frequency of health effects that were mentioned in snus-related tweets, we filtered the data set by using a list of health-related keywords that were created in previous studies [22-24], which resulted in a set of 654 unique tweets with 1254 health-related keyword appearances. The list included the following nine major groups of health effects that are related to smoking and nicotine consumption: mouth (eg, gum, teeth, etc), respiratory (eg, lung, cough, etc), cardiovascular (eg, heart, etc), psychological (eg, stress, anxiety, etc), neurological (eg, numb, fatigue, etc), cancer (eg, lung cancer, mouth cancer, etc), throat, digestive, and other effects (eg, skin, liver, etc). For each major group of health effects, the number of occurrences of specific keywords belonging to the groups were counted. In addition, two authors hand-coded 200 randomly selected tweets to determine whether the users directly experienced the health symptoms mentioned or whether they believed that snus use might help with lowering the risk of the symptoms when compared to smoking. The Cohen κ statistic reached 0.73, indicating substantial agreement between the two coders.

Results

Temporal Analysis

To better understand the popularity of snus discussion, we examined the number of snus-related tweets over time during our study time period. As shown in Figure 1, the number of tweets per day typically oscillated between 25 and 50, with a few peaks occurring in April 10, 2021; May 31, 2021; and October 3, 2021.

Figure 1. Snus-related tweets from March 11, 2021, to February 26, 2022.



Perceptions of Snus on Twitter

To examine the public perception of snus on Twitter, we performed a sentiment analysis on tweets related to snus. The average sentiment score for 11,631 snus-related tweets was 0.080, which indicated that the overall sentiment in snus-related tweets was positive. Among these tweets, there were 4341 (37.32%) positive tweets, 3094 (26.60%) negative tweets, and 4196 (36.08%) neutral tweets. Further statistical analysis showed that the proportion of positive tweets was significantly higher than the proportion of negative tweets (4341/11,631, 37.32% vs 3094/11,631, 26.60%; $P<.001$). Our longitudinal analysis showed that there was no noticeable change in the proportion of positive tweets over time (Multimedia Appendix 1).

Topics Discussed in Snus-Related Tweets

To understand what might be responsible for different sentiments in snus-related tweets, we performed topic modeling for the tweets in the different sentiment groups. As shown in Table 1, among the positive sentiment snus-related tweets, the most popular topic was “Snus being a safer way of nicotine consumption” (1472/4341, 33.9%), followed by “Way of snus consumption” (1441/4341, 33.2%) and “Snus addiction and enjoyment” (1428/4341, 32.9%). Among the negative sentiment snus-related tweets, the top topic was “Risk comparison between snus and smoking” (1064/3094, 34.4%), followed by “Negative health impacts” (1018/3094, 32.9%) and “Other problems related to snus” (1012/3094, 32.7%). The topics for neutral sentiment snus-related tweets are included in Table S1 in Multimedia Appendix 2.

Table 1. Topics discussed in snus-related tweets with different sentiments.

Sentiment group and inferred topic	Keywords	Token percentage	Examples
Positive			
Snus addiction and enjoyment	<i>snus, good, make, time, day, love, feel, free, access, today, strong, man, back, coffee, pack, life, pretty, friend, enjoy, and week</i>	32.9	“Proper pint of bitter and a wintergreen snus. Perfect on a fair night like tonight”
Snus being a safer way of nicotine consumption	<i>pouch, vape, smoking, smoke, quit, cigarette, nicotine, safe, give, amp, year, alternative, smoker, start, risk, big, stop, switch, low, and option</i>	33.9	“For long-term nicotine use, data on safety are strongest for snus: decades of epidemiological studies. No harm. So if many people with mental health issues self-medicate with #safernicotine (they are), at least there is no harm. #qualityoflife”
Way of snus consumption	<i>snus, tobacco, product, Swedish, people, chew, work, thing, great, smokeless, put, dip, find, call, play, gum, nice, hard, flavor, and mouth</i>	33.2	“snus is a black tobacco product you chew or put on your gums. You don’t snort it or sniff it. He’s clearly closing one nostril to sniff smelling salts, which are commonly used in sports. Not rocket science.”
Negative			
Risk comparison between snus and smoking	<i>Tobacco, smoke, vape, cigarette, smoking, pouch, product, cancer, risk, low, nicotine, amp, quit, harm, gum, rate, smoker, chew, reduce, and smokeless</i>	34.4	“not just snus but the attempt to restrict and eliminate all lower risk products is astonishingly short sighted.”
Negative health impacts	<i>Snus, ban, make, stop, day, Swedish, year, give, feel, thing, death, man, start, high, mouth, kill, lose, addiction, long, and cig</i>	32.9	“not in epok which i assume is some zoomer snus? i dont know i only use odens and sometimes siberia which has no flavouring just tobacco. the nicotine content is pretty potent in those, would kill your average vaper no joke.”
Other problems related to snus	<i>snus, people, time, bad, work, put, hard, good, study, week, today, back, call, big, find, coffee, problem, and life</i>	32.7	“our big daddy is always the leader he is the familys captain and chief, but once i choked when my snus caught up in my throat cause there was our pop in the oak.”

Health Risks Mentioned in Snus-Related Tweets

To understand what health risks might be associated with snus, we explored the health symptoms mentioned in the snus-related tweets. Oral health (mouth effects) was the most mentioned health category in snus-related tweets (519/1254, 41.39%), followed by other effects (213/1254, 16.99%) and respiratory effects (182/1254, 14.51%). The other health categories had

relatively lower proportions of tweets. For example, the cancer category (cancer is a health effect that is often associated with nicotine consumption) only took up 5.34% (67/1254) of the total tweets. Further hand-coding results showed that of the 200 randomly selected tweets, 40 (20%) mentioned that the health symptoms were a direct result of snus consumption or mentioned a negative opinion about snus. In addition, 28% (56/200) of the

tweets discussed the harm reduction of snus, in terms of the health symptoms mentioned, when compared to smoking.

Discussion

Principal Findings

In our study, we showed that the proportion of snus-related tweets with a positive sentiment was significantly higher ($P < .001$) than the proportion of snus-related tweets with a negative sentiment. By using topic modeling, we observed that the positive sentiments toward snus might be the result of personal experiences and the perception that snus use is a safer alternative to smoking. In contrast, concerns about health risks might contribute to the negative sentiments in snus-related tweets. A further analysis showed that in snus-related tweets, the most popular health category was mouth effects, followed by other effects (eg, liver and skin effects) and respiratory effects.

Comparison With Previous Studies

Our temporal analysis showed an obvious peak in the number of snus-related tweets on October 3, 2021. After extracting all snus-related tweets from that day, we noticed that most of the tweets (67/100, 67%) discussed the possible use of snus by the son of a famous English former soccer player. This peak indicates the large impact of influencers on Twitter users.

Given that the top topic in snus-related tweets with a positive sentiment was related to switching from smoking to snus use, since snus was perceived as a safer option and there was no strong evidence in negative sentiment tweets indicating the gateway effect, it might be possible that Twitter users' perceptions on snus tend to lean toward the pathway hypothesis instead of the gateway hypothesis. This finding contradicts that of a focus group study, in which participants viewed snus use as a potential gateway to smoking [10]. There are 2 possible reasons for this inconsistency. First, the focus group was conducted in 2010, and the tweets used in our study were collected in 2021. It is possible that temporal differences might account for the difference in the perceptions of snus. Second, the conclusion from the focus group was based on a sample of 66 young adults who ranged in age from 18 to 26 years [10]. In comparison, our study included a broader range in terms of demographic characteristics, which may have led to the different results.

From the aspect of health risks, the health-related keywords identified in the tweets captured the majority of the potential health impact of snus. According to a report published by the Norwegian Institute of Public Health in 2019, the main potential adverse health effects of snus cover cancer, cardiovascular disease, mental disorders, and caries [25]. The health-related keyword frequency distribution from our study included these potential health effects through the oral, cardiovascular, cancer,

and psychological effect categories, demonstrating the consistency between our findings from Twitter data and previous findings on the health risks of snus.

Limitations

Our study has several limitations. Data collected from Twitter may contain some bias. A study on tourist attraction visit sentiment data sourced from Twitter suggested that the tourists' sentiments could be affected by factors other than the tourist attraction itself, including the number of attraction sites that are visited in 1 day and whether the tourists are local visitors, out-of-state visitors, or international visitors [26]. Another study in 2012 suggested that the demographic distributions of Twitter users are different from those of the general population [27]. For example, around 31% of young adults who ranged in age from 18 to 24 years used Twitter, while this proportion was only 17% for adults aged between 25 and 34 years [27]. Therefore, our findings, which are based on Twitter data, may not represent the general population.

With regard to data collection and preprocessing, the keyword set we used may not have been comprehensive. For example, when collecting the data, we only included *snus* as the single keyword, which may have resulted in us missing some relevant tweets in our study. Additionally, in the processed data set, there might have still been some bot accounts, which can automatically deliver messages. This may have introduced some bias in our results. With regard to topic modeling, inferences based on keywords involve subjective judgments, even with the support of example tweets. In addition, the mentioning of health symptoms in snus-related tweets does not imply any causal relationship between snus and health risks. Our hand-coding results further validated this notion. Moreover, our study did not include the demographic information of Twitter users. Different demographic groups might perceive snus differently.

Conclusion

Our study showed more positive sentiments in snus-related tweets from Twitter users, which might have been due to the relative safety of snus when compared to that of smoking. Our study provided an efficient measurement of the public perceptions of snus among a relatively large sample by using social media data. According to the health belief model, the perceived susceptibility, seriousness, benefits, and barriers of actions explain health-related behaviors [28]. Therefore, these perceptions of snus are possibly a predictor of the public's snus consumption patterns. Our study will help policy makers better anticipate consumption behavior changes and make necessary policy changes. The results from our study will provide insights to policy makers on further regulations for snus. Future studies could take demographic and geographic factors into consideration to explore potential disparities in snus-related perceptions and discussions.

Acknowledgments

The research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) Center for Tobacco Products under award number U54CA228110. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the FDA.

Data Availability

The data and scripts used for analysis and for creating the figures are available on request from the corresponding author (DL).

Authors' Contributions

ZX and DL conceived and designed this study. JC and SX analyzed the data. JC wrote the manuscript. ZX and DL assisted with the interpretation of analyses and edited the manuscript. All authors have approved the final article.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Proportion of snus-related positive tweets over time.

[[PNG File , 149 KB-Multimedia Appendix 1](#)]

Multimedia Appendix 2

Table S1. Topics mentioned in snus-related tweets with a neutral sentiment.

[[DOCX File , 15 KB-Multimedia Appendix 2](#)]

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Abbreviations

CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
NIH: National Institutes of Health
VADER: Valence Aware Dictionary and Sentiment Reasoner

Edited by T Hao; submitted 21.03.22; peer-reviewed by R Gore, J Li, A Dormanesh; comments to author 05.06.22; revised version received 20.07.22; accepted 22.07.22; published 29.08.22

Please cite as:

Chen J, Xue S, Xie Z, Li D
 Perceptions and Discussions of Snus on Twitter: Observational Study
 JMIR Med Inform 2022;10(8):e38174
 URL: <https://medinform.jmir.org/2022/8/e38174>
 doi: [10.2196/38174](https://doi.org/10.2196/38174)
 PMID:

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HHS Public Access

Author manuscript

Am J Prev Med. Author manuscript; available in PMC 2023 March 16.

Published in final edited form as:

Am J Prev Med. 2023 February ; 64(2): 204–212. doi:10.1016/j.amepre.2022.09.011.

Use of Traditional Smokeless, Snus, and Dissolvable Tobacco Among U.S. Youth

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Abstract

Introduction: Snus, dissolvable, and traditional smokeless tobacco product use is often amalgamated in youth epidemiologic research despite differences across these products. Prevalence, trends, and correlates of U.S. youth use across different classes of oral tobacco products are unknown.

Methods: Using 2011–2020 National Youth Tobacco Survey (N=193,933) data, the authors tested for cross-year linear and quadratic trends in the weighted prevalence of ever and current use of traditional smokeless tobacco, snus, and dissolvable tobacco. Multivariable logistic regressions estimated the demographic and tobacco use factors associated with the use of different oral tobacco products in 2020. Analyses were conducted in 2022.

Results: During 2011–2020, there were declines in the prevalence of ever use of traditional smokeless tobacco (11.0% to 5.6%; linear trend, $p<0.0001$) and snus (5.2% to 2.4%; $p<0.0001$) but no change in ever dissolvable tobacco use (0.8%–1.2%). In 2020, an estimated 1,546,000 U.S. youth ever used traditional smokeless tobacco (7.7% high school, 3.0% middle school), 662,000 ever used snus (high school: 3.5%, middle school: 1.0%), and 326,000 ever used dissolvables (high school: 1.5%, middle school: 0.8%). In 2020, females and non-Hispanic Blacks and Hispanics had lower smokeless or snus ever use odds than males and non-Hispanic Whites, respectively, whereas sexual minorities (than heterosexuals) or those speaking a language other than English at home were more likely to report ever use of dissolvable tobacco. Flavored tobacco use was common, particularly for dissolvable current users (72.8% used any flavor).

Conclusions: Differences in the epidemiology of oral tobacco use across product types among U.S. youth suggest that oral tobacco products should be disaggregated in future research and policy strategies.

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CREDIT AUTHOR STATEMENT

Hongying Daisy Dai: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration; Resources, Software, Supervision, Validation, Writing—original draft, Writing—review and editing. Adam M. Leventhal: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration; Resources, Supervision, Validation, Writing—original draft, Writing—review and editing.

SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at <https://doi.org/10.1016/j.amepre.2022.09.011>.

INTRODUCTION

Over the past 15 years, newer oral tobacco products, such as snus and dissolvable tobacco, started being marketed in the U.S.^{1,2} Unlike traditional oral (smokeless) tobacco products (e.g., loose chewing tobacco or moist snuff), snus and dissolvable tobacco come in prepackaged portions and do not require users to expel saliva byproducts.³ These 2 nontraditional oral tobacco products can be used more discreetly than traditional smokeless tobacco, which may be desirable for youth who wish to hide use from adults.⁴ In addition, snus and dissolvable products could appeal to youth because they are predominately marketed in flavors⁵ and may be perceived as less harmful than other tobacco products by young people.⁶ Use of oral tobacco increases the risk of gum disease, tooth decay, and tooth loss and is linked to cancer of the mouth, esophagus, and pancreas as well as nicotine addiction.^{7,8} However, some oral tobacco products avoid pulmonary exposure and might expose people to fewer harmful chemicals than combustible tobacco smoking.^{9–11}

In 2014, past-30-day use of snus in the National Youth Tobacco Survey (NYTS) was 1.9%, and dissolvable tobacco was 0.6%.¹² Since then, NYTS oral tobacco product use prevalence estimates have collapsed traditional (e.g., chewing tobacco, loose snuff, dip) and nontraditional (e.g., snus and dissolvable) products into a single oral tobacco category.¹³ A previous analysis of cross-year trends in youth oral tobacco product use in NYTS focused on smokeless tobacco use only,¹⁴ finding no significant change in prevalence between 2000 and 2011.

Reporting the updated national estimates of youth use of distinct oral tobacco product classes after 2011 is timely for several reasons. First, U.S. snus sales appreciably increased from 2014 to 2019, especially in mint flavors.⁵ In addition, the U.S. Food and Drug Administration (FDA) granted a first-ever modified risk tobacco product (MRTP) authorization to 8 Swedish Match snus products in October 2019 to market their products with claims of reduced harm.¹⁵ Second, manufacturers have shifted away from marketing dissolvables that contain compressed tobacco leaves and instead toward dissolvable products marketed as tobacco free that do not contain tobacco leaves.¹⁶ For example, Reynolds American Inc. ramped down Camel Orbs, strips, and sticks sales in 2013 and recently started selling dissolvable nicotine lozenges in berry, crema, dark mint, and mint under the Velo brand name.¹⁷ New nicotine lozenge brands have also emerged, such as Rogue's nicotine on demand.¹⁸ Some of these products are not FDA approved for smoking cessation, and their packaging sometimes resembles non-nicotine products, such as mints or traditional chewing gum.¹⁹ Third, new oral nicotine variants are increasingly marketed, including nontobacco nicotine pouches and nontherapeutic nicotine gums.^{20–22} These new products could bring more attention to the entire sector of nontraditional oral tobacco products, including snus or dissolvables, or they could displace existing products.

Four key pieces of evidence about the epidemiology of youth use of specific classes of oral tobacco products are unknown but important to inform future regulatory actions. First, identifying cross-year trends in the prevalence of specific oral tobacco products among U.S. youths can provide estimates of the national pediatric population health impact of each of these product classes. Second, understanding whether certain demographic populations

are more likely to use these oral tobacco products can inform whether and which of these products might impact health disparities. Although smokeless tobacco has historically been commonly used by White heterosexual males,²³ newer nontraditional products (e.g., dissolvables, snus) may not show such patterns. If the use of certain oral products is higher among vulnerable subpopulations (e.g., racial minorities, sexual minorities), future regulatory policies targeting these products merit consideration in efforts to improve health equity. Third, assessing the associations between the use of snus, dissolvables, and smokeless tobacco with each other and with inhaled tobacco product use is vital. Such information elucidates how oral tobacco product contributes to the problem of youth polytobacco product use—a use pattern associated with nicotine dependence and other adverse outcomes.^{24,25} Fourth, understanding the proportion of youth who use specific oral tobacco products in flavors can provide information to inform regulatory actions targeted to specific flavored products. These 4 streams of evidence could be applied to inform the U.S. FDA on whether to revisit already-authorized snus MRTPs and how to rule on pending MRTP applications currently under review (e.g., Camel snus). Such evidence could also inform FDA decisions on pending premarket tobacco product applications for Reynolds American Velo lozenges²⁶ and other snus and dissolvable products.

This cross-sectional study analyzed nationally representative data in U.S. youth participants in the 2011–2020 NYTS to (1) estimate the cross-year trends in the prevalence of ever and current use of traditional smokeless, snus, and dissolvable tobacco products; (2) examine the recent associations of demographic factors and tobacco use status with the use of each oral tobacco product among youth in 2020; and (3) provide detailed evidence on youth single, dual, and poly-use of oral tobacco products and specific flavors used.

METHODS

Study Sample

The NYTS is a cross-sectional and school-based survey conducted annually using a stratified sampling procedure without replacement at the 3-stage cluster.²⁷ The 2011–2020 NYTS consisted of 193,933 students, and survey administration typically occurred during January/February–May/June each year except in 2020 when the survey was ended early in March because of the coronavirus 2019 (COVID-19) pandemic, resulting in a lower school-level participation rate (49.9%) in 2020 than previous years (ranging from 72.6% in 2015 to 83.2% in 2010). However, the 2020 NYTS student participation rate remained high at 87.4% and was consistent with other survey years (ranging from 85.8% in 2019 to 91.7% in 2012).²⁸ The shortened timeline in 2020 did not impact the original survey design or the national representativeness of the weighted estimate of U.S. middle-school (grades 6–8) and high-school (grades 9–12) students.²⁹ Given the use of public data with deidentified information, this study is exempt from the University of Nebraska Medical Center IRB approval.

Measures

During each survey year, participants were asked, Which of the following tobacco products have you ever used, even just one time? (Select one or more), with separate response options

for each tobacco product. Those who selected Chewing tobacco, snuff, or dip, such as Redman, Levi Garrett, Beechnut, Skoal, Skoal Bandits, or Copenhagen were classified as traditional smokeless ever users. Snus ever users were those who selected Snus, such as Camel or Marlboro Snus in 2011–2015 or Snus, such as Camel, Marlboro, or General Snus in 2016–2020. Dissolvable ever users were those who selected Dissolvable tobacco products such as Ariva, Stonewall, Camel orbs, Camel sticks, Marlboro sticks, or Camel strips. Similarly, current use of each oral product (yes/no) was defined with the same response options in the past 30 days.

Past-30-day flavored oral tobacco use variables (*yes/no*) were created for each of the 3 products. In addition, for each of the 3 products, the specific flavors used were assessed by *What flavors were the [PRODUCT] that you have used in the past 30 days?* with 8 response options (Table 1 footnotes).

Ever versus never use variables for E-cigarettes, cigarettes, and any other inhaled tobacco product (i.e., cigars, hookahs, pipe tobacco, bidis, and/or heated tobacco products) was assessed. Responses were also recoded into a total number of tobacco products ever used variable that summed ever use for the 7 inhaled products plus the 2 other oral tobacco products not represented in the outcome variable, which was recoded as a 4-level variable (ever use of 0 versus 1 versus 2 versus 3 products). Parallel current use variables were included in supplementary analyses.

Demographic variables include sex (male or female), race/ethnicity (non-Hispanic [NH] White, NH-Black, Hispanic/Latino, or NH-others), school level (middle or high school), sexual minority status (heterosexual versus nonheterosexual, including gay/lesbian, bisexual, and not sure). We also include a variable about whether the participant speaks a language other than English at home (Yes or No).

Statistical Analysis

Ever and current use prevalences of traditional smokeless, snus, and dissolvable tobacco during 2011–2020 were reported. For each of the 3 products, average annual percentage change (AAPC) and 95% CI were also calculated using the Joinpoint Regression Program, Version 4.9.³⁰ Multivariable logistic regressions tested for linear and quadratic trends of survey year, accounting for gender, race/ethnicity, and grade level. The quadratic trend was reported when it was significant; otherwise, it was removed, and the linear trend was retested.

Using only the 2020 survey year data, weighted population estimates of the total number of U.S. youth tobacco product users were calculated. Next, logistic regressions estimated the associations of demographic factors and the total number of tobacco products used as regressor correlates with traditional smokeless, snus, and dissolvable ever use outcomes. For each oral tobacco use outcome, each correlate was tested in a multivariable model, yielding AOR association estimates. Missing covariate data were relatively small (Table 2 footnotes) and were managed with multi-imputation using 20 multiply imputed data sets.³¹

The authors also used the 2020 data to estimate cross-tabulations of prevalence (weighted percentage) and associations (Phi coefficients) for dual-product ever use of each oral product. Detailed weighted percentages of possible patterns of single-, dual-, or tri-oral tobacco product use in 2020 were presented. Prevalence estimates of flavors used in traditional smokeless, snus, and dissolvable tobacco among current users of each respective product were also calculated.

Sampling weights, survey strata, and primary sampling units were included in all analyses. Statistical analyses were performed using SAS 9.4 (Cary, NC) in 2022, and $p < 0.05$ (2 tailed) were considered statistically significant. Supplemental analyses reported the prevalence and correlates for current use statuses.

RESULTS

As depicted in Appendix Table 1 (available online), the analytical sample consisted of 193,933 participants, with 49.6% female, 56.2% high-school students, 57.4% NH-Whites, 13.8% NH-Blacks, 23.3% Hispanics, and 5.5% other races. Demographic characteristics were not significantly different across survey years.

Figure 1 presents the temporal trends of traditional smokeless, snus, and dissolvable tobacco use during 2011–2020. The prevalence of ever traditional smokeless tobacco use (Panel A) declined from 11.0% (95% CI=9.2, 12.7) in 2011 to 5.6% (95% CI=4.2, 6.9) in 2020, with an average of 5.8% reduction relative to that in the previous year (AAPC= -5.8; 95% CI= -7.3, -4.3) and progressively decreasing trend across 2011–2020 (linear trend, $p < 0.0001$). Prevalence of ever snus use declined from 5.2% (95% CI=4.2, 6.1) in 2011 to 2.4% (95% CI=1.8, 3.0) in 2020 with an average 4.8% of reduction relative to that in the previous year (AAPC= -4.8; 95% CI= -10.1, 0.8) (linear trend, $p < 0.0001$). The prevalence of ever dissolvable use did not change significantly from 2011 to 2020 (0.8% to 1.2%, linear trend, $p = 0.61$).

Trends in current oral tobacco product use from 2011 to 2020 are reported in Panel B and concord with ever use trends. There were linear declines in the prevalence of current smokeless tobacco use and snus use during 2011–2020 but no change in current dissolvable use prevalence.

The prevalence of oral tobacco product use stratified by study correlates is reported in Table 2. Detailed statistics of unweighted frequencies (ns), weighted population estimates (Ns), and p -values are reported in Appendix Tables 2–4 (available online).

In 2020, an estimated 1,546,000 total U.S. youth reported ever use of traditional smokeless tobacco products (high school: 7.7%, middle school: 3.0%). Snus ever use was reported by 662,000 youths (high school: 3.5%, middle school: 1.0%). Dissolvable tobacco ever use was reported by 326,000 youths (high school: 1.5%, middle school: 0.8%).

In multivariable models (Table 2), females were less likely to reported ever use of traditional smokeless tobacco (AOR=0.3; 95% CI=0.2, 0.4) and snus (AOR=0.7; 95% CI=0.6, 1.0) than males. NH-Black and Hispanic youths were less likely than NH-Whites to report ever use

of traditional smokeless tobacco or snus. Youth who were nonheterosexual were more likely to report dissolvable ever use than those who were heterosexual (AOR=1.7; 95% CI= 1.1, 2.5), and those who did not speak a language other than English at home were more likely to report dissolvable ever use than those who did (AOR=1.9; 95% CI= 1.2, 3.0).

As shown in Table 3, among never users of any other tobacco product, traditional smokeless ever use prevalence was 1.1%, and snus or dissolvable ever use was negligible (0.1%). For all the 3 oral tobacco products, the prevalence of ever use was progressively larger among youth with successively higher numbers of total other tobacco products ever used. For instance, the prevalence of ever snus use was 0.6% among users of 1 other tobacco product, 6.8% among users of 2 other products, and 20.4% among users of 3 or more other products. The magnitude of association between ever use of oral tobacco products with each other and with other tobacco products varied, with medium-sized associations between ever use of snus with cigarettes ($\phi=0.38$) or smokeless ($\phi=0.34$) and small statistically significant associations between ever use of dissolvable with E-cigarettes ($\phi=0.12$).

As shown in Table 1, 59.7% of current traditional smokeless users, 58.2% of current snus users, and 72.8% of current dissolvable users reported flavored oral tobacco use. Mint was the top flavor reported by 45.4%, 40.0%, and 43.5% of current smokeless, snus, and dissolvable users, respectively. Menthol was the second most common in smokeless (13.5%) and snus (18.2%) users, whereas fruit (30.4%) was the second most common flavor used among dissolvable tobacco users.

DISCUSSION

After a previously reported period of stable smokeless tobacco use prevalence between 2000 and 2011,¹⁴ this study provides new evidence of a declining trend of traditional smokeless tobacco use in U.S. youths during 2011–2020. It also provides the first national trends in youth use prevalence for other oral tobacco products, including novel evidence that snus use also exhibited a similar declining trend, but dissolvable tobacco product use did not change across time. The declining oral tobacco trends are paralleled by rising E-cigarette use among U.S. adolescents during the same period.^{13,32} These opposing ecologic population trends likely do not reflect an inverse relationship because individual-level data reported in this study show a positive association between E-cigarette and oral tobacco product use in 2020 (Table 3). The current results did not provide early evidence that youth snus use changed after the FDA's MRTP designation of Swedish Match's General Snus products in October 2019. Because public health resources are limited, these data are important for prioritizing tobacco control efforts. These findings do not indicate an increasing public health concern for youth use of smokeless tobacco or snus.

This study estimates that nearly 2 million U.S. youths reported ever use of 1 or more oral tobacco products in 2020, including 1,546,000 traditional smokeless tobacco ever users, 662,000 snus users, and 326,000 dissolvable users. Smokeless and snus ever users shared some demographic correlates; females and NH-Blacks and Hispanics reported lower odds of ever use than males and NH-Whites, respectively. However, dissolvable ever use exhibited different correlates from the other 2 oral tobacco products, with higher odds of use in sexual

minority (than in heterosexual) youth and those who reported speaking a language other than English at home. These findings raise the question as to whether dissolvable products and their marketing may differ from other oral tobacco products in terms of their proclivity to disproportionately attract sexual minority youth and youth with non-English-speaking immigrant family members.

Dissolvable products also differed from the other oral tobacco products in the proportion of youth who used flavored products. Whereas mint was the most commonly used flavor for all the 3 products, fruit was the second most commonly used flavor for only dissolvable products; menthol was the second most common for traditional smokeless tobacco and snus. Although these findings should be taken with caution given the small sample of current users, the high prevalence of flavored product use and the proclivity toward mint and fruit flavors for dissolvable product users bear similarity to youth E-cigarette use flavors.²⁹ Because the wording of the dissolvable product survey items in NYTS was keyed toward older brands, including some brands that are no longer widely marketed, it is plausible that this study captured only a subgroup of users on the spectrum of modern dissolvable nicotine and tobacco products. Hence, the small prevalence reported in this study is likely an underestimate of dissolvable product use. Updating future surveillance with dissolvable product survey items that represent the current market is warranted.

Exclusive oral tobacco use was rare among U.S. adolescents, and a greater number of other tobacco products used was positively associated with ever or current use of each of these 3 oral tobacco products. Previous studies have documented that dual use of multiple tobacco products increased the concentrations of known tobacco-related toxicants^{33,34} and is associated with elevated symptoms of nicotine dependence and addictions.³⁵ Future longitudinal research should examine whether young oral tobacco users initiate these products first and then transition to using other inhaled tobacco products or vice versa.

Limitations

This study has limitations. First, tobacco use status is self-reported, and they are subject to recall and social desirability biases.³⁶ Second, some youth could conflate different product classes (e.g., nontobacco nicotine pouches and snus) that could affect prevalence. Future measurement development research is needed to optimize the assessment and surveillance of youth oral tobacco product use. Third, multiple hypotheses testing was conducted to compare correlates associated with different oral tobacco use, and it might increase the false positive rate. Finally, this study did not assess the use of nicotine pouches, which are increasingly marketed²² and are becoming a growing product.^{21,37} The NYTS 2021 estimated that 3.0% and 0.6% of U.S. middle-school and high-school students, respectively, reported ever using nicotine pouches in 2021.²³ Because the 2021 NYTS was administrated online and because the interview setting (e.g., online versus school campus) may influence the prevalence of self-reported tobacco use, the authors did not include the 2021 NYTS data in the trended analyses per Centers for Disease Control and Prevention suggestions not to compare 2021 and 2020 results.²³

CONCLUSIONS

This study found that the trends and correlates of different oral tobacco product use among U.S. adolescents over 2011–2020 varied across traditional smokeless, snus, and dissolvable tobacco products. Although this study found that dissolvable tobacco product use was more common in sexual minority youth and had high proportions of flavored tobacco users, previous studies aggregating oral tobacco products into a combined category have not found such results.^{13,23} Continuous surveillance and longitudinal investigations of the patterns of tobacco product use and poly-use trajectories across the spectrum of oral nicotine and tobacco products are warranted.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGMENTS

The content of this study is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration. The funding agency had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Research reported in this publication was supported by the National Cancer Institute under Award Number U54CA180905 (AML) and the National Institute on Drug Abuse under Award Number K24DA048160 (AML). The National Youth Tobacco Survey data are publicly available and can be downloaded from https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm.

No financial disclosures were reported by the authors of this paper.

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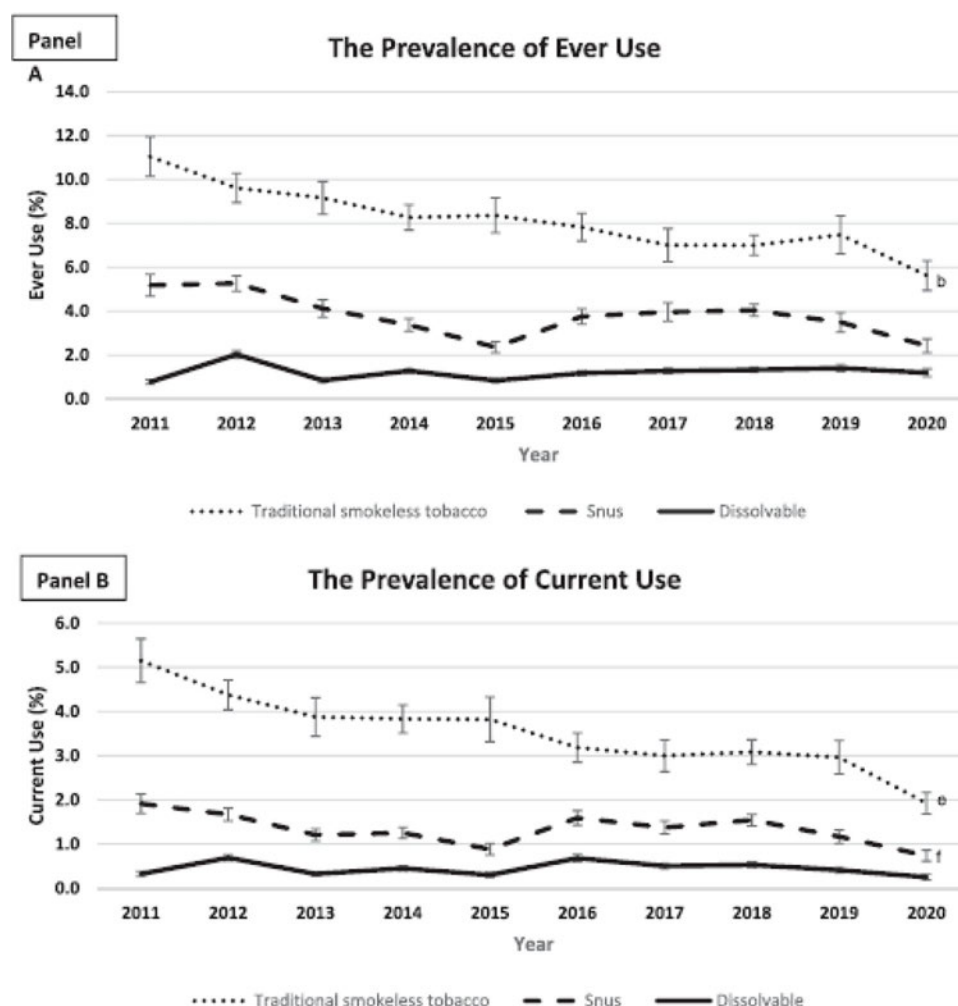


Figure 1.

Trends in the prevalence of ever and current traditional smokeless, snus, and dissolvable tobacco product use, ^a 2011–2020 NYTS (N=193,933).

Note: Error bars indicate SEs.

^a Sampling weights, survey stratum, and primary sampling units were included in the analysis to account for the complex survey design. AAPC and 95% CI were calculated using Joinpoint Regression Program, Version 4.9. Linear and quadratic trends were assessed by multivariable logistic regressions, adjusting by gender, race/ethnicity, and grade level.

^b Traditional smokeless tobacco: AAPC= −5.8 (95% CI= −7.3, −4.3) with linear trend $p<0.0001$.

^c Snus=AAPC= −4.8 (95% CI= −10.1, 0.8) with linear trend $p<0.0001$.

^d Dissolvable tobacco product=AAPC=0.2 (95% CI= −8.5, 8.9) with linear trend $p=0.61$.

^e Traditional smokeless tobacco=AAPC= −7.6 (95% CI= −9.8, −5.4) with linear trend $p<0.0001$.

^f Snus=AAPC= −3.6 (95% CI= −9.6, 2.4) with linear trend $p<0.0001$.

^g Dissolvable tobacco product=AAPC= −0.7 (95% CI= −9.6, 9.1) with linear trend $p=0.28$.

AAPC, average annual percentage change; NYTS, National Youth Tobacco Survey.

Table 1.

Flavored Traditional Smokeless Tobacco, Snus, and Dissolvable Tobacco Product Use Prevalence Among Current Users, 2020 NYTS

Current users	Traditional smokeless tobacco (n=274), N (weighted %)	Snus (n=108), n (weighted %)	Dissolvable tobacco (n=39), n (weighted %)
Used 1 non-tobacco flavor ^a	166 (59.7)	67 (58.2)	32 (72.8)
Flavor(s) used in the past 30 days ^b			
Menthol	36 (13.5)	22 (18.2)	15 (27.8)
Mint	121 (45.4)	47 (40.0)	20 (43.5)
Clove	10 (4.1)	6(5.1)	6(13.1)
Fruit	32 (11.2)	17 (13.1)	15 (30.4)
Chocolate	13 (4.4)	11 (8.2)	7(14.7)
Alcohol	10 (3.1)	7 (4.6)	9(17.9)
Candy	19 (6.9)	16 (12.4)	8(16.6)
Other	30 (11.2)	6(6.5)	1 (3.2)

NYTS, National Youth Tobacco Survey.

^aPast-30-day flavored oral tobacco use variables (yes/no) for each of the 3 products were assessed by the question, *Which of the following tobacco products that you used in the past 30 days were flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate or other sweets?* (CHOOSE ALL THAT APPLY).

^bNot mutually exclusive with 8 response options: *Menthol, Mint, Clove or spice, Fruit, Chocolate, Alcoholic drinks (such as wine, cognac, margarita, or other cocktails), Candy, desserts, or other sweets, and Some other flavor not listed here.*

Table 2.
Prevalence and Correlates of Ever Use of Each Type of Oral Tobacco Product, 2020 NYTS

Ever use	Traditional smokeless tobacco ^a		Snus ^b		Dissolvable tobacco ^c	
	Weighted % (95% CI) ^d	AOR (95% CI) ^e	Weighted % (95% CI) ^d	AOR (95% CI) ^e	Weighted % (95% CI) ^d	AOR (95% CI) ^e
Overall	5.6 (4.3, 7.0)	n/a	2.4 (1.8, 3.0)	rVa	1.2 (0.8, 1.5)	n/a
Grade						
Middle school	3.0 (2.3, 3.6)	ref	1.0 (0.7, 1.3)	ref	0.8 (0.6, 1.1)	ref
High school	7.7 (5.5, 9.9)	0.9 (0.7, 1.4)	3.5 (2.5, 4.5)	0.9 (0.7, 1.3)	1.5 (0.9, 2.0)	0.6 (0.4, 1.0)
Sex						
Male	5.5 (6.4, 10.6)	ref	3.0 (2.1, 3.9)	ref	1.4 (1.0, 1.9)	ref
Female	2.7 (2.0, 3.4)	0.3 (0.2, 0.4)	1.8 (1.3, 2.3)	0.7 [0.6, 1.0]	1.0 (0.6, 1.3)	0.7 (0.5, 1.1)
Race/ethnicity						
NH-White	7.8 (5.7, 9.9)	ref	3.3 (2.3, 4.2)	ref	1.3 (0.9, 1.8)	ref
NH-Black	3.1 (2.2, 4.1)	0.5 (0.3, 0.7)	0.8 (0.2, 1.3)	0.3 (0.2, 0.6)	1.0 (0.2, 1.7)	1.0 (0.5, 2.2)
Hispanic	3.2 (2.3, 4.1)	0.3 (0.2, 0.5)	2.0 (1.4, 2.5)	0.6 (0.4, 1.0)	1.2 (0.8, 1.5)	0.6 (0.4, 1.0)
Another race/ethnicity	3.5 (1.5, 5.6)	0.6 (0.3, 1.1)	1.3 (0.4, 2.2)	0.6 (0.3, 1.5)	0.8 (0.0, 1.5)	0.6 (0.2, 1.6)
Sexual minority						
Heterosexual	5.8 (4.3, 7.3)	ref	2.2 (1.6, 2.9)	ref	1.0 (0.6, 1.3)	ref
Nonheterosexual ^f	4.7 (3.3, 6.0)	0.8 (0.6, 1.0)	3.2 (2.2, 4.2)	1.2 (0.9, 1.7)	2.1 (1.3, 2.9)	1.7 (1.2, 2.5)
Language other than English at home						
No	6.3 (4.7, 7.9)	ref	2.6 (1.9, 3.4)	ref	1.0 (0.6, 1.4)	ref
Yes	4.0 (2.9, 5.1)	0.9 (0.8, 1.2)	1.9 (1.3, 2.5)	0.9 (0.6, 1.3)	1.4 (1.0, 1.9)	1.9 (1.2, 3.0)

Note: Boldface indicates statistical significance ($p < 0.05$).

n/a, not applicable; NH, non-Hispanic; Ns, weighted population estimates; NYTS, National Youth Tobacco Survey.

^a Ever use of chewing tobacco; snuff; or dip, such as Redman, Levi Garrett, Beechnut Skoal, Skoal Bandits, or Copenhagen, even just a small amount ($n=14,999$).

^b Ever use of Snus, such as Camel, Marlboro, or General Snus, even just 1 time ($n=14,425$).

^c Ever use of dissolvable tobacco products (e.g., Ariva, Stone wall, Camel Orbs, Camel sticks, Marlboro sticks, or Camel strips), even just 1 time ($n=14,428$).

^d Row percentage.

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Multivariable logistic regression model, including all variables in the table and the total number of other tobacco products used (0, 1, 2, and 3) (Table 3 note) as simultaneous regressors. Missing covariate data (Ns missing range: 0–466) managed with multi-imputation using 20 multiply imputed data sets.

^f Students who reported being gay or lesbian, bisexual, or not sure.

Table 3.

Association of Ever Use of Traditional Smokeless, Snus, and Dissolvable Products With Each Other and Other Tobacco Products, 2020 NYTS

Ever use	Traditional smokeless tobacco, weighted % (95% CI)	Snus, weighted % (95% CI)	Dissolvable tobacco, weighted % (95% CI)
Total number of tobacco products ever used ^a			
Prevalence in never users of any other tobacco	1.1 (0.7, 1.4)	0.0 (0.0, 0.1)	0.1 (0.0, 0.2)
Prevalence in users of 1 other tobacco product	6.3 (4.9, 7.7)	0.6 (0.2, 1.0)	0.4 (0.2, 0.7)
Prevalence in users of 2 other tobacco products	15.6 (11.9, 19.2)	6.8 (4.4, 9.2)	2.6 (1.5, 3.8)
Prevalence in users of 3 other tobacco products	32.8 (25.9, 39.7)	20.4 (16.7, 24.1)	9.3 (6.8, 11.9)
Traditional smokeless tobacco use			
Prevalence in never smokeless tobacco users	n/a	1.2 (0.9, 1.4)	0.7 (0.5, 0.9)
Prevalence in ever smokeless tobacco users	n/a	24.0 (19.0, 28.9)	9.7 (6.6, 12.9)
Association with ever smokeless tobacco use status. Phi coefficient (<i>p</i> -value)	n/a	0.34 (<i>p</i> <0.0001)	0.20 (<i>p</i> <0.0001)
Snus use			
Prevalence in never snus users	4.3 (3.4, 5.3)	n/a	0.6 (0.4, 0.8)
Prevalence in ever snus users	55.0 (44.9, 65.1)	n/a	22.5 (16.4, 28.6)
Association with ever snus use status. Phi coefficient (<i>p</i> -value)	0.34 (<i>p</i> <0.0001)	n/a	0.31 (<i>p</i> <0.0001)
Dissolvable tobacco product use			
Prevalence in never dissolvable tobacco users	5.1 (3.9, 6.3)	1.9 (1.4, 2.4)	n/a
Prevalence in ever dissolvable tobacco users	45.6 (33.8, 57.5)	46.8 (37.3, 56.4)	n/a
Association with ever dissolvable tobacco use status. Phi coefficient (<i>p</i> -value)	0.20 (<i>p</i> <0.0001)	0.31 (<i>p</i> <0.0001)	n/a
Cigarette use			
Prevalence in never cigarette users	2.8 (2.2, 3.4)	0.2 (0.2, 0.3)	0.4 (0.3, 0.6)
Prevalence in ever cigarette users	26.4 (20.2, 32.5)	18.5 (15.1, 21.9)	6.8 (5.1, 8.5)
Association with ever cigarette use status. Phi coefficient (<i>p</i> -value)	0.32 (<i>p</i> <0.0001)	0.38 (<i>p</i> <0.0001)	0.19 (<i>p</i> <0.0001)
E-cigarette use			
Prevalence in never E-cigarette users	1.8 (1.3, 2.2)	0.4 (0.2, 0.6)	0.4 (0.2, 0.6)
Prevalence in ever E-cigarette users	16.1 (12.4, 19.8)	8.0 (5.9, 10.0)	3.4 (2.2, 4.5)
Association with ever E-cigarette use status. Phi coefficient (<i>p</i> -value)	0.28 (<i>p</i> <0.0001)	0.21 (<i>p</i> <0.0001)	0.12 (<i>p</i> <0.0001)
Other inhalable tobacco product use ^b			
Prevalence in never other inhalable tobacco product users	2.7 (2.1, 3.4)	0.8 (0.6, 1.0)	0.3 (0.2, 0.5)
Prevalence in ever other inhalable tobacco product users	23 (17.8, 28.2)	12.3 (9.5, 15.1)	6.4 (4.6, 8.2)
Association with ever other inhalable tobacco product use status. Phi coefficient (<i>p</i> -value)	0.30 (<i>p</i> <0.0001)	0.27 (<i>p</i> <0.0001)	0.20 (<i>p</i> <0.0001)

r/a, not applicable: NYTS, National Youth Tobacco Survey.

^aThe sum of ever use across the following products: cigarettes, E-cigarettes, cigars (cigars, little cigars, and cigarillos), hookahs, pipe tobacco, bidis, heated tobacco products, and the 2 other oral tobacco products not represented in the outcome variable (snus and dissolvable for smokeless models, smokeless and dissolvable for snus model, and smokeless and snus for dissolvable model). Rang?: 0–9, recoded as a 4-level variable of 0.1, 2, and 3 products.

^bOther inhalable tobacco products include cigars (cigars, little cigars, and cigarillos), hookahs, pipe tobacco, bidis, and heated tobacco product.

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World Journal of *Meta-Analysis*

World J Meta-Anal 2022 June 28; 10(3): 74-194



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INDEXING/ABSTRACTING

The WJMA is now abstracted and indexed in Reference Citation Analysis, China National Knowledge Infrastructure, China Science and Technology Journal Database, and Superstar Journals Database.

RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: Hua-Ge Yu; Production Department Director: Xiang Li; Editorial Office Director: Jin-Lei Wang.

NAME OF JOURNAL

World Journal of Meta-Analysis

ISSN

ISSN 2308-3840 (online)

LAUNCH DATE

May 26, 2013

FREQUENCY

Bimonthly

EDITORS-IN-CHIEF

Saurabh Chandan, Jing Sun

EDITORIAL BOARD MEMBERS

<https://www.wjnet.com/2308-3840/editorialboard.htm>

PUBLICATION DATE

June 28, 2022

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Review with meta-analysis relating North American, European and Japanese snus or smokeless tobacco use to major smoking-related diseases

Peter Nicholas Lee, Katharine Jane Coombs, Janette Susan Hamling

Specialty type: Statistics and probability

Provenance and peer review: Unsolicited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): 0
Grade C (Good): C, C
Grade D (Fair): 0
Grade E (Poor): 0

P-Reviewer: Aggarwal P, India; Seid AA, Ethiopia

A-Editor: Zhu JQ; China

Received: February 10, 2022

Peer-review started: February 10, 2022

First decision: April 13, 2022

Revised: April 25, 2022

Accepted: May 28, 2022

Article in press: May 28, 2022

Published online: June 28, 2022



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Abstract

BACKGROUND

While extensive information exists relating cigarette smoking to the risk of lung cancer, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD) or acute myocardial infarction (AMI), and stroke, far less information is available on risks from moist snuff ("snus") or smokeless tobacco (ST) in United States/Canada, Europe or Japan.

AIM

To summarize data from the selected countries on risks of the four diseases associated with current ST or snus use.

METHODS

Publications in English in 1990-2020 were considered that, based on epidemiological studies in North America, Europe or Japan, estimated risks of lung cancer, COPD, IHD/AMI, or stroke according to use of ST or snus. The studies should involve at least 100 cases of the disease considered, and not be restricted to those with specific other diseases. Medline literature searches were conducted, selecting papers initially from examination of titles and abstracts, and then from full texts. Further papers were sought from reference lists in selected papers, reviews and meta-analyses. For each disease, relative risk estimates adjusted at least for age were extracted relating ST or snus use to risk, and combined using random-effects meta-analysis. The estimates were mainly for current vs. never or non-current use, but results for ever vs never use were also considered.

RESULTS

Seven publications reported results for ST use from six United States studies. The

most useful results came from four studies which provided results for current vs. never use. Random-effects meta-analyses of these results showed an increased risk for each disease, clearest for lung cancer (relative risk 1.59, 95% confidence interval 1.06-2.39, based on 4 estimates) and COPD (1.57, 1.09-2.26, $n = 3$), but also significant (at $P < 0.05$) for IHD (1.26, 1.10-1.45, $n = 4$) and stroke (1.27, 1.03-1.57, $n = 4$). Also including results for ever vs. never use from two other studies increased the lung cancer estimate to 1.80 (1.23-2.64, $n = 6$), but had little effect on the other estimates. For snus, 16 publications described results from 12 studies, one in Norway and the rest in Sweden. There were no results for COPD, and only three for lung cancer, with these reporting a relative risk of 0.80 (0.40-1.30) for current vs never use. More extensive data were available for IHD/AMI and stroke. Using the latest results from each study, combined estimates for current vs. never use were 1.00 (0.91-1.11, $n = 5$) for IHD/AMI and 1.05 (0.95-1.17, $n = 2$) for stroke, while for current vs. non-current use they were 1.10 (0.92-1.33, $n = 9$) for IHD/AMI and 1.12 (0.86-1.45, $n = 9$) for stroke. Meta-analyses including earlier results from some studies also showed no significant association between snus use and IHD/AMI or stroke. No relevant results were found for Japan.

CONCLUSION

Risks of smoking-related diseases from snus use in Scandinavia are not demonstrated, while those from ST use in the United States are less than from smoking.

Key Words: Smokeless tobacco; Moist snuff; Lung disease; Cardiovascular disease; Meta-analysis; Review

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Core Tip: United States studies show that, in never users of other products, current smokeless tobacco use associates with a significant ($P < 0.05$) increase in risk of the four major smoking-related diseases, with relative risks, compared to never users, of almost 1.6 for lung cancer and chronic obstructive pulmonary disease (COPD) and 1.3 for ischaemic heart disease (IHD)/acute myocardial infarction (AMI) and stroke. This increase is substantially less than for smoking. In Scandinavia, current snus use, does not significantly increase risk of IHD/AMI, stroke or lung cancer, with no data for COPD. Smokers unwilling to quit might consider these smokeless products.

Citation: Lee PN, Coombs KJ, Hamling JS. Review with meta-analysis relating North American, European and Japanese snus or smokeless tobacco use to major smoking-related diseases. *World J Meta-Anal* 2022; 10(3): 130-142

URL: <https://www.wjgnet.com/2308-3840/full/v10/i3/130.htm>

DOI: <https://dx.doi.org/10.13105/wjma.v10.i3.130>

INTRODUCTION

It is well established[1,2] that cigarette smoking markedly increases the risk of a range of diseases, particularly lung cancer, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD) and acute myocardial infarction (AMI), and stroke. Meta-analyses[3] have shown that in North American and European populations, current cigarette smokers, compared with those who have never smoked cigarettes, have about a ten-fold increase in risk of lung cancer, with the extent of the increase rising with amount smoked and earlier age of starting. Relative risks (RRs) exceed three for COPD and, in younger individuals, two for cardiovascular disease[4]. Pipe and cigar smoking is also associated with a clear increase in risk of smoking-related disease[2].

Here, we study the association between current use of smokeless tobacco (ST) and four major smoking-related diseases (lung cancer, COPD, IHD/AMI, and stroke). Our analyses are based on studies published from 1990, and separate out the effects of ST as used in North America, and the effects of moist snuff ("snus") as mainly used in Sweden and neighbouring countries. Coupled with a separate ongoing attempt to provide updated meta-analyses relating the same diseases to current cigarette, cigar and pipe smoking, our results should help to provide a good picture of the relative effects of the different nicotine products on the major smoking-related diseases.

MATERIALS AND METHODS

Study inclusion and exclusion criteria

Attention was restricted to publications in English in the years 1990 to 2020 which provide results relating use of current ST or snus) in non-smokers to the risk of lung cancer, COPD, IHD/AMI or stroke, based on epidemiological cohort or case-control studies conducted in North America, Europe or Japan, and involving at least 100 cases of the disease of interest. The studies selected should not be restricted to those with specific other diseases.

Literature searches

The search procedures are described in detail in [Supplementary material](#) and are summarized below. First, separate literature searches on Medline were conducted for lung cancer, COPD or cardiovascular disease, the aim being to identify from these searches not only publications that described studies satisfying the inclusion criteria, but also meta-analyses and reviews that may themselves cite other relevant publications. Then, for each of the three searches, a print-out of the Medline output for title and abstract was examined by Katharine J Coombs (Coombs KJ) to identify publications of possible relevance, the selection then being checked by Peter N Lee (Lee PN), with any disagreements resolved in discussion. The selected publications (and where relevant supplementary files and also other publications linked to them in the Medline search) were then obtained, and examined by Lee PN, and classified as either an accepted publication possibly including relevant data, a reject (giving reason), a relevant review or a relevant meta-analysis. The suggested rejects were then checked by Coombs KJ, with any disagreements resolved. Then additional accepted publications not detected by the Medline searches were sought from examination of reference lists of the accepted papers and of the relevant reviews and meta-analyses.

The accepted publications from the three searches combined were then examined to eliminate those giving results superseded by a later publication, those not providing new data, and those not providing results relating current ST or snus use specifically for the four diseases of interest.

Meta-analyses

Using standard methods[5] individual study RR estimates were combined using fixed-effect and random-effects meta-analysis, with the significance of between-study heterogeneity also estimated.

For studies on ST use in North America, preference was given to results for those who had never used cigarettes, pipes or cigars which compared current and never ST use, but results from studies which only compared ever and never ST use were also considered in some meta-analyses.

For studies on snus use, use of pipes and cigars was disregarded as this was often not reported, and such use is rare in Scandinavia. RRs comparing current snus users both with never users and with non-users (*i.e.* non-current users, including both former and never users) were separately considered, as a number of studies only presented results compared to non-use. In some cases these estimates were derived from data separately by current, former and never use. Only age-adjusted RR estimates were considered, with the estimates adjusted for the most other factors generally being used.

RESULTS

Literature searches

The results of the searches are given in detail in Additional File 1 and are summarized below and in [Figure 1](#).

For lung cancer, 131 papers were identified in the Medline searches, with 32 considered possibly relevant from examination of title and abstract, and a further 12 identified from comments on these papers. Examination of the full text from the 44 papers led to 10 being accepted as providing apparently relevant study data, with 23 being reviews or meta-analyses and 11 rejected for various reasons.

For COPD, the Medline searches identified 46 papers with six initially considered possibly relevant based on title and abstract, and no further papers identified from comments. The full text examination led to one of the six papers being accepted and three rejected, with the other two being reviews.

For cardiovascular diseases, the Medline searches identified 308 papers, with 80 initially considered possibly relevant, a number extended to 97 after identification of comments on these papers. Of these 27 were accepted, with 52 being reviews or meta-analyses and 18 rejected.

Examination of reference lists in accepted papers, reviews and meta-analyses led to ten further papers being considered possibly relevant, but only one of these was a paper describing relevant results (for COPD). The total of 39 accepted papers for the diseases combined, was then reduced to 26, as three had been accepted in two separate searches, four did not give results for non-smokers, one did not separate results for IHD and stroke, and five were only comments on other accepted papers and provided no new data. Of the 26 papers, 18 gave results for snus, and eight for ST as used in the United States (US), considered separately below. No relevant results were found for Japan.

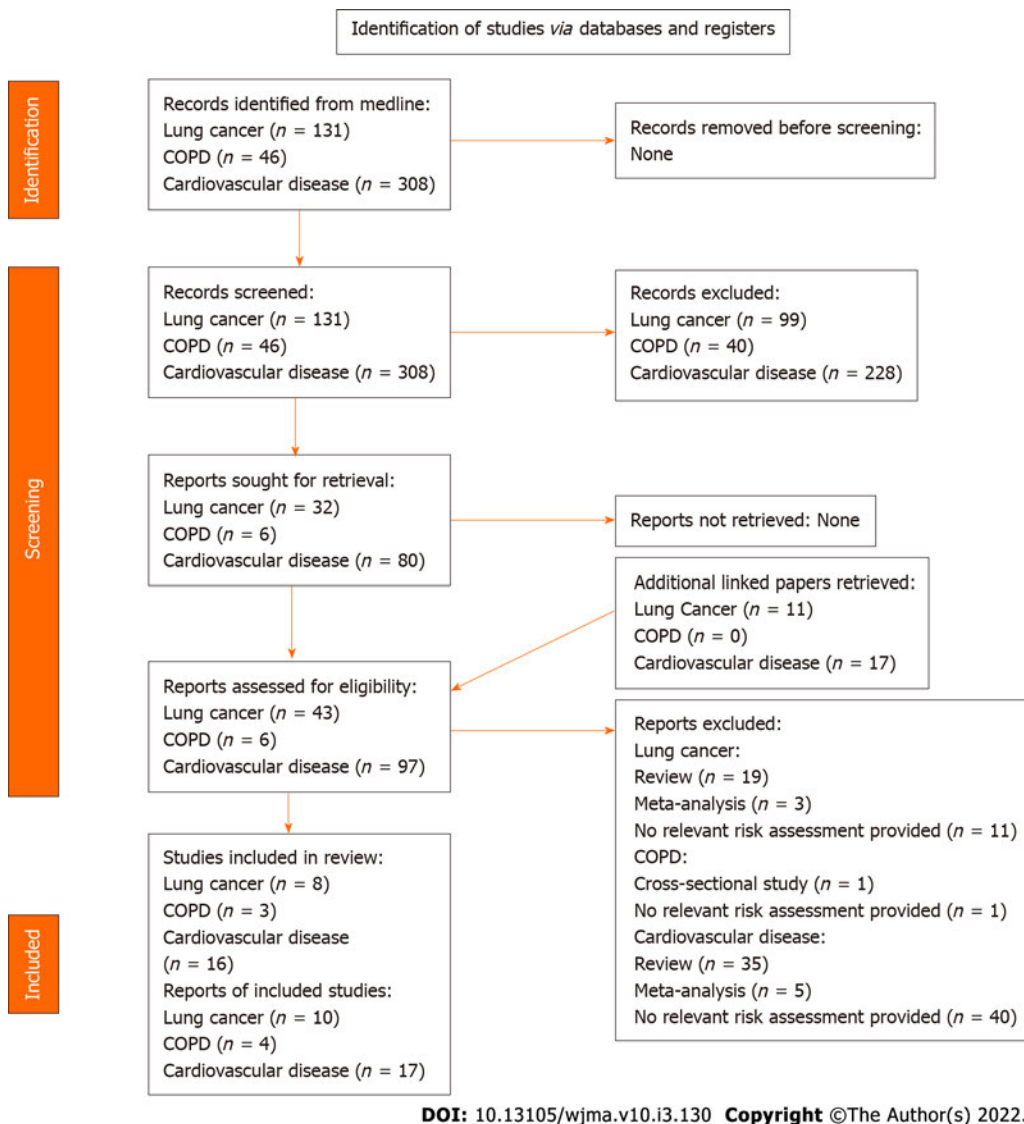


Figure 1 Literature searches. COPD: Chronic obstructive pulmonary disease.

ST use in the US

Each of the eight publications identified[6-13] reports results from a prospective study. Results from one [10] were not considered further as a later publication[11] provides corrected results from the same study.

The most relevant results, comparing risks for current *vs* never ST users in those who had never used cigarettes, pipes or cigars, come from four studies. For Cancer Prevention Studies I and II (CPS-I and CPS-II), separate results for each of the four diseases are available in one publication[9]. For the National Longitudinal Mortality Study (NLMS), results for IHD and stroke from one publication[13] are preferred to those from another[8], due to the longer follow-up considered, though results for lung cancer are only available from the latter publication[8]. For the National Health Interview Surveys (NHIS), the results from one publication[11] are preferred, as they provide results for all four diseases, and for a longer follow-up than do other publications[8,12].

Less useful are results from two studies. For the Agricultural Health Study (AHS), the results[7] are only for lung cancer, and only compare ever and never ST use. For the first National Health and Nutrition Examination Survey (NHANES), the results[6], for all the diseases except COPD, only compare ever and never ST use, with pipe and cigar smokers not excluded.

Table 1 gives a summary description of the six studies considered, including timing, population studied, and relevant diseases considered, as well as the ST exposure index used and whether pipe and cigar smokers are excluded from the results for never smokers.

Table 2 gives the RRs and 95% confidence intervals (CIs), both as reported for the individual studies and as estimated for the combined studies using random-effect meta-analysis, as well as the available results by sex, and the adjustment factors taken into account. Two studies report results only for males, three for sexes combined and only one for the sexes separately. All the RRs were adjusted for age and a

Table 1 Studies considered in analyses of smokeless tobacco risk among never smokers in the United States

Study	Ref.	Study type ¹	Timing	Population	Diseases considered	Excludes pipe/cigar	Exposure index
Main sources							
CPS-I ²	Henley <i>et al</i> [9], 2005	P	1959 to 1971	Families of volunteers' friends and neighbours	LC, COPD ³ , IHD, Stroke	Yes	Current <i>vs</i> never
CPS-II ²	Henley <i>et al</i> [9], 2005	P	1982 to 2000	Families of volunteers' friends and neighbours	LC, COPD ⁴ , IHD, Stroke	Yes	Current <i>vs</i> never
NHIS ⁵	Inoue-Choi <i>et al</i> [10], 2019; Inoue-Choi <i>et al</i> [11], 2020	P	1991-2010 to 2015	Civilian non-institutionalized	LC, COPD ⁶ , IHD, Stroke	Yes	Current <i>vs</i> never
NLMS ⁷	Timberlake <i>et al</i> [13], 2017	P	1985-2011 to 2011	Civilian non-institutionalized	IHD, Stroke	Yes	Current <i>vs</i> never
NLMS ⁷	Fisher <i>et al</i> [8], 2019	P	1993-2005 to 2010	Civilian non-institutionalized	LC	Yes	Current <i>vs</i> never
Other sources							
NHANES ⁸	Accortt <i>et al</i> [6], 2002	P	1971-75 to 1992	Civilian non-institutionalized	LC, IHD, Stroke	No	Ever <i>vs</i> never
AHS ⁹	Andreotti <i>et al</i> [7], 2017	P	1993-97 to 2010-11	Pesticide applicators and their spouses	LC	Yes	Ever <i>vs</i> never

¹Prospective study.²CPS: Cancer Prevention Study.³Respiratory symptom diseases (ICD7 470-527).⁴Chronic obstructive pulmonary disease (ICD9 490-492, 496).⁵NHIS: National Health Interview Surveys.⁶Chronic lower respiratory disease (ICD10 J40-J47).⁷NLMS: National Longitudinal Mortality Study.⁸NHANES1: First National Health and Nutrition Examination Survey.⁹AHS: Agricultural Health Study.

COPD: Chronic obstructive pulmonary disease.

varying list of other factors, including sex where relevant.

The combined evidence from the main studies (CPS-I, CPS-II, NHIS, NLMS) shows a statistically significant increase in risk relating to current ST use which is somewhat greater for lung cancer (RR 1.59, 95%CI: 1.06-2.39) and COPD (1.57, 1.09-2.26) than for IHD (1.26, 1.10-1.45) and stroke (1.27, 1.03-1.57). Including also the evidence from the other two studies (AHS, NHANES) somewhat increased the combined RR estimate for lung cancer (to 1.80, 1.23-2.64) but left the RRs for the other three diseases virtually unchanged. Significant evidence of heterogeneity between the estimates was only seen in the analyses for IHD, where due to a rather higher estimate from NHIS, the associated *P* value was 0.019 for the estimate based only on the four main results, and 0.015 when also including the results from NHANES.

There is also information from three of the studies on variation in risk by type of ST (chewing tobacco or snuff). For CPS-II[9] RRs were reported, for lung cancer, IHD and stroke, respectively of 1.97 (95%CI: 1.10-3.54), 1.25 (1.03-1.51) and 1.38 (1.02-1.86) for exclusive chewing tobacco use, and of 2.08 (0.51-8.45), 1.59 (1.06-2.39) and 0.62 (0.23-1.67) for exclusive snuff use. For AHS[7] the RR of lung cancer for chewing tobacco of 2.20 (0.98-4.97) was similar to that of 2.21 (1.11-4.42) for overall ST use. No result was given for snuff, as there were only three cases of lung cancer in the exposed group. For NLMS[13] RRs for IHD were 1.11 (0.88-1.42) for exclusive chewing tobacco and 1.30 (1.03-1.63) for exclusive snuff use. In all three studies, the RRs did not vary significantly by type of ST.

Snus use in Scandinavia

Of the 18 publications on snus[14-31], one[16] describes results from a study in Norway, with the rest describing studies in Sweden. Most describe results from a single study, but one[14] presents separate results from two studies, while two[20,21] present results from eight studies, one for AMI and the other for stroke. All the available results are for males.

Two papers were not considered further. One[30] only reported results for ever *vs* never snus use, reported RRs in never smokers only for combined cardiovascular death (RR 1.15, 95%CI: 0.97-1.37) and respiratory death (0.8, 0.2-3.0), and did not separate out results for IHD/AMI, stroke or COPD. The other[14] mainly considered heart failure, the limited results for AMI being unrestricted to non-smokers and not adjusted for any potential confounding factors.

Table 2 Relative risks in analyses of smokeless tobacco risk among never smokers in the United States

Study	Sex	Lung cancer	Chronic obstructive pulmonary disease	Ischaemic heart disease	Stroke	Adjustment factors
Main sources						
CPS-I	M	1.08 (0.64-1.83)	1.86 (1.12-3.06)	1.12 (1.03-1.21)	1.46 (1.31-1.64)	Age, alc, asp, bmi, edu, ex, fat, f/v, race
CPS-II	M	2.00 (1.23-3.24)	1.28 (0.71-2.32)	1.26 (1.08-1.47)	1.40 (1.10-1.79)	Age, alc, asp, bmi, edu, emp, ex, fat, f/v, race
NHIS	M + F	1.43 (0.51-4.01)	1.35 (0.39-4.76)	1.66 (1.30-2.13)	1.09 (0.56-2.11)	Age, edu, race, sex, year
NLMS	M + F	2.98 (0.91-9.76)	-	1.24 (1.05-1.46)	0.92 (0.67-1.27)	Lung cancer: age, edu, hea, inc, race, sex IHD and CVD: age, edu, inc, race, sex
Random-effects meta-analysis		1.59 (1.06-2.39) (<i>n</i> = 4)	1.57 (1.09-2.26) (<i>n</i> = 3)	1.26 (1.10-1.45) (<i>n</i> = 4)	1.27 (1.03-1.57) (<i>n</i> = 4)	
Other sources						
NHANES	M	-	-	0.6 (0.3-1.2)	0.7 (0.2-2.0)	Lung cancer: age, alc, ex, f/v, pov, race, reg IHD: age, alc, bmi, chol, ex, f/v, pov, race, sbp CVD: age, alc, ex, f/v, pov, race, sbp
NHANES	F	9.1 (1.1-75.4)	-	1.4 (0.8-2.2)	1.0 (0.3-2.9)	
AHS	M + F	2.21 (1.11-4.42)	-	-	-	Age, alc, edu, race, reg, sex
All sources						
Random-effects meta-analysis		1.80 (1.23-2.64) (<i>n</i> = 6)	1.57 (1.09-2.26) (<i>n</i> = 3)	1.24 (1.08-1.43) (<i>n</i> = 6)	1.24 (1.02-1.52) (<i>n</i> = 6)	

Alc: Alcohol, asp: Aspirin use; bmi: Body mass index; chol: Cholesterol; edu: Education; emp: Employment, ex: Exercise; f/v: Fruit and vegetable intake; hea: Health status; inc: Income; pov: Poverty; reg: Region; sbp: Systolic blood pressure; year: Year of survey.

The other 16 studies all present results for snus use in non-smokers or non-regular smokers, in some where the comparison is between current and non-use rather than between current and never use, and one where it is between ever and never use. Table 3 gives details, by study and publication, of the study type, timing, population, relevant diseases considered, and the unexposed group considered. In total there are results from 12 studies, with multiple publications describing results from some studies. For no study did any of the publications present simple updates of results given in another publication. All but the Two Counties study is of prospective design, though some results from the MONICA study are based on case-control analyses.

From Table 3 it can be seen that there are no results at all for COPD (or a closely related endpoint) and only three publications present results for lung cancer. The most useful result[29] is based on follow-up of construction workers interviewed in 1978-92, including 15 cases in current users and three in former users, with a RR of 0.80 (95%CI: 0.40-1.30) for current vs. never ST use and of 0.80 (0.45-1.45) for current vs non ST use. An earlier result from this study[17] can be ignored, as it is based on no more than three lung cancer cases in current users, and based on interviews in 1971-74, when coding of smoking status was problematic[29]. A RR of 0.96 (0.26-3.56) from the Norway study[16] is for ever vs never use and based on only three cases in ever users. No meta-analyses seemed to be worth conducting for lung cancer.

As illustrated in Table 4, much more evidence is available for IHD/AMI and stroke, both for current vs. non snus use and for current vs never use, each RR estimate being adjusted for age and varying other factors. Based on the estimate from the latest publication, where data for a study provides a choice, Table 5 shows no evidence of an increased risk in current snus users, whether the comparison group is never users (IHD/AMI: RR 1.00, 95%CI: 0.91-1.11; stroke: 1.05, 0.95-1.17), or is non users (IHD/AMI: 1.10, 0.92-1.33; stroke 1.12, 0.86-1.45). No significant association is also seen when, less satisfactorily, all available RRs are combined, regardless of whether in some studies some disease occurrences may be counted more than once.

DISCUSSION

The results of the meta-analyses for ST use in the US show that, in those who have never used cigarettes, cigars or pipes, current use, compared to never use, is associated with a significant increase in risk of all four major smoking-related diseases studied, the increases estimated from the four main sources of data

Table 3 Studies considered in analysis of current snus use among non-smokers in Scandinavia

Study ¹	Source	Study type ²	Timing	Population	Diseases considered	Unexposed snus ³
CWC	Bolinder <i>et al</i> [17], 1994	P	1971-74 to 1985	Construction workers	LC, IHD, stroke	Non
	Hergens <i>et al</i> [23], 2007		1978-93 to 2004		AMI	Never
	Luo <i>et al</i> [29], 2007		1978-92 to 2004		LC	Never
	Hergens <i>et al</i> [24], 2008		1978-92 to 2003		CVD	Never
	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014		1978-93 to 2004		AMI, stroke	Non
MALMÖ	Janzon and Hedblad [27], 2009	P	1991-96 to 2004	Population-based, Malmö city	AMI, stroke	Non
	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014				AMI, stroke	Non
MONICA	Asplund <i>et al</i> [15], 2003	NCC	1986-99 to 2000	Population-based, Norrbotten and Västerbotten counties	CVD	Non
	Wennberg <i>et al</i> [31], 2007	NCC	1986-99 to 1999		AMI	Never
	Huhtasaari <i>et al</i> [25], 1992	CC	1989-91		AMI	Non
	Huhtasaari <i>et al</i> [26], 1999	CC	1991-93		AMI	Non
	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	P	1986-2004 to 2004		AMI, stroke	Non
NMC	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	P	1997 to 2004	Participant in charity walk	AMI, stroke	Non
NORWAY	Boffetta <i>et al</i> [16], 2005	P	1964-67 to 2001	Population sample and relatives of emigrants	LC	Ever vs never
SALLS	Johansson <i>et al</i> [28], 2005	P	1988-89 to 2000	Civilian non-institutionalized	IHD	Non
SALT	Hansson <i>et al</i> [19], 2009	P	1998-2002 to 2005	Twins born in Sweden 1926-1958	IHD, stroke	Never
	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014		1998-2002 to 2004		AMI, stroke	Non
Scania-PHC	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	P	2002 to 2004	Population-based, Skåne County	AMI, stroke	Non
Stockholm-PHC	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	P	2002 to 2004	Population-based, Stockholm County	AMI, stroke	Non
ULF	Haglund <i>et al</i> [18], 2007	P	1988-89 to 2003	Civilian, non-institutionalized	IHD, stroke	Non
Two Counties	Hergens <i>et al</i> [22], 2005	CC	1992-94	Randomly selected, Stockholm and Västernorrland counties	AMI	Never
WOLF	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	P	1992-98 to 2004	Employed in three counties	AMI, stroke	Non

¹CWC: Construction workers cohort; MONICA: Monitoring of trends in cardiovascular disease; NMC: National March Cohort; PHC: Public Health Cohort; SALLS: Swedish Annual Level of Living Survey; SALT: Screening across the lifespan twin study; ULF: Swedish survey of living conditions; WOLF: Work, lipids and fibrinogen.

²CC: Case control; NCC: Nested case control, P: Prospective.

³Exposed group: Current unless stated. In some studies the unexposed group may include non-regular tobacco users.

(CPS-I, CPS-II, NHIS, NLMS) being almost 30% for IHD and stroke and almost 60% for COPD and lung cancer. These increases are less than those associated with cigarette smoking, *e.g.*[4]) and suggest that ST, as used in the US, is a safer, but not harmless, alternative method of nicotine exposure than cigarette smoking for smokers not willing to quit. While some of the publications we consider[6,10] have concluded that an excess risk of smoking-related disease associated with ST use in the US has been

Table 4 Relative risks in analyses of ischaemic heart disease/acute myocardial infarction and stroke in relation to current snus use among never smokers in Scandinavia

Study	Source ¹	Current vs never		Current vs non		Adjustment factors ²
		IHD/AMI	Stroke	IHD/AMI	Stroke	
CWC	Bolinder <i>et al</i> [17], 1994	-	-	1.35 (1.13-1.62) ³	1.29 (0.83-1.99) ³	Age, res
CWC	Hergens <i>et al</i> [23], 2007	1.02 (0.92-1.14)	-	1.03 (0.93-1.15)	-	Age, BMI, res
CWC	Hergens <i>et al</i> [24], 2008	-	1.05 (0.95-1.17)	-	1.06 (0.96-1.18)	Age, BMI, res
CWC	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	-	-	1.01 (0.90-1.14)	1.03 (0.90-1.17)	Age, BMI ⁴
MALMÖ	Janzon and Hedblad[27], 2009	-	-	0.75 (0.30-1.80)	0.59 (0.20-1.50)	Age, BMI, dia, hyp, mar, occ, phys
MALMÖ	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	-	-	1.00 (0.37-2.70)	1.23 (0.50-2.99)	Age, BMI ⁴
MONICA	Asplund <i>et al</i> [15], 2003	-	-	-	0.87 (0.41-1.83)	Age, chol, cohort, edu, dia, hyp, mar, year
MONICA	Wennberg <i>et al</i> [31], 2007	0.82 (0.46-1.43)	-	0.85 (0.48-1.50)	-	Age, BMI, chol, edu, phys, res, year
MONICA	Huhtasaari <i>et al</i> [25], 1992	-	-	0.89 (0.62-1.29)	-	Age
MONICA	Huhtasaari <i>et al</i> [26], 1999	-	-	0.58 (0.35-0.94)	-	Age, chol, dia, edu, her, hyp, mar, res
MONICA	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	-	-	0.77 (0.35-1.69)	0.65 (0.23-1.80)	Age, BMI ⁴
NMC		-	-	No IHD cases in current snus users	1.28 (0.40-4.10)	Age, BMI ⁴
SALLS		1.41 (0.61-3.28)	-	-	-	Age, BMI, dia, hyp, phys
SALT	Hansson <i>et al</i> [19], 2009	0.85 (0.51-1.41)	1.18 (0.67-2.08)	0.85 (0.51-1.40)	1.15 (0.66-2.02)	Age, chol, dia, hyp
SALT	Hansson <i>et al</i> [20], 2012; Hansson <i>et al</i> [21], 2014	-	-	1.56 (0.98-2.48)	0.98 (0.52-1.83)	Age, BMI ⁴
Scania-PHC		-	-	1.90 (0.90-4.00)	3.17 (1.50-6.70)	Age, BMI ⁴
Stockholm-PHC		-	-	1.21 (0.48-3.08)	0.58 (0.14-2.45)	Age, BMI ⁴
ULF		-	-	1.15 (0.54-2.41)	1.01 (0.35-2.92)	Age, heal, ill, phys, res, ses
Two Counties		0.73 (0.35-1.50)	-	0.73 (0.35-1.51)	-	Age, area
WOLF		-	-	3.30 (0.63-17.1)	0.96 (0.28-3.30)	Age, BMI ⁴

¹See Table 2 for source if the study is only analysed by one publication or by the two pooled analyses by Hansson *et al*[20] only.

²Abbreviations used: BMI: Body mass index; chol: Cholesterol; dia: Diabetes; edu: Education; heal: Self-reported health; her: Heredity; hyp: Hypertension; ill: Self-reported longstanding illnesses; mar: Marital status; occ: Occupation; phys: Physical activity; res: Region of residence; ses: Socioeconomic status; year: Recruitment year.

³Estimated from results given for two groups by age at entry to the study.

⁴Body mass index adjusted for in the analyses of stroke, but not acute myocardial infarction.

All results are for men. Where results in any row are given for both comparison groups (never and non) for the same disease, the result for the comparison group non were estimated from data provided in the source paper.

shown, some are more cautious, regarding the evidence as limited[9,13].

Limitations of the evidence for US ST include the fact that a number of the studies considered are quite old, with three of the seven studies summarized in Table 1 involving follow-up periods ending over 20 years ago, ignoring the possibility that the nature of the products studied may have changed over time. Another limitation is the fairly sparse evidence comparing risk by type of ST product. Although this does not suggest any marked differences in risk between those who use chewing tobacco or use snuff, the data are insufficient to reliably detect smaller differences. Also, it is possible that some misclassification of smoking status has taken place, with some of the effects attributed to ST use actually being a consequence of unreported current or past smoking of cigarettes, pipes or cigars.

Table 5 Meta-analyses of ischaemic heart disease/acute myocardial infarction and stroke results in relation to snus use among never smokers in Scandinavia

Disease	Comparison group	All data or latest	Random-effects meta-analysis relative risk (95%CI)	Heterogeneity		
				Chi sq	DF	P value
IHD/AMI	Never	Latest	1.00 (0.91-1.11)	2.33	4	NS
	Non	All	1.04 (0.92-1.18)	24.87	15	0.052
		Latest	1.10 (0.92-1.33)	9.18	8	NS
Stroke	Never	Latest	1.05 (0.95-1.17)	0.16	1	NS
	Non	All	1.06 (0.98-1.14)	12.69	13	NS
		Latest	1.12 (0.86-1.45)	10.26	8	NS

Where the comparison group is non users, there are (see Table 4) estimates for some studies from multiple publications. For these studies, the estimate "Latest" includes only the result from the latest publication, while the estimate "All" includes all the results. Where the comparison group is never users, no study provides more than one estimate. NS: Not significant ($P \geq 0.1$).

Even if the magnitude of the effect on risk of current ST use in the US may be somewhat inaccurately measured in our meta-analyses, there seems little doubt that it is substantially less than that for cigarette smoking. For lung cancer, for example, RRs for current cigarette smoking for the US have been estimated as 11.68 in one meta-analysis[3], with RRs increasing with increasing amount smoked and earlier age of starting to smoke, and higher for squamous cell carcinoma than for adenocarcinoma. While we have not attempted to quantify risk of ST use in the US by amount or duration of use, or by subdivision of the diseases considered, this does not affect the conclusion that the risks of the four diseases for ST are less than for cigarette smoking.

The results of our meta-analyses for current snus use, based on studies in Scandinavia, show no clear evidence of any increased risk, whether the comparison group is never or non-users. While there is little evidence for lung cancer, and there are no useful results for COPD, the evidence for cardiovascular disease is based on as many as 12 studies, the results from some being reported in multiple publications (see Table 4). As shown in Table 5, RR estimates for IHD/AMI and for stroke vary only from 1.00 to 1.12, and none are statistically significant. Though a lack of effect cannot be demonstrated, and it is possible that there is a true small increase in risk by perhaps about 5%, it seems likely that any increase is less than for US ST, and much less than that for cigarette smoking. Certainly the great majority of the publications from which we derived data[14-16,18-22,25-31] considered that no increased risk in current snus users had been demonstrated for any of the smoking-related diseases we considered, many concluding that components of tobacco smoke other than nicotine appear to be involved in the relationship of smoking with heart disease and stroke. However, possible effects were noted for cardiovascular disease[17] based on early and unreliable data[29], fatal AMI and fatal stroke[23,24] and for heart failure[14]. The at most very weak association of snus with the smoking-related diseases considered was also the conclusion of a review of the evidence on snus[32], though this review also noted a possible effect of snus on reduced survival from AMI and on heart failure, arguing that further investigation was needed to investigate possible confounding by socio-economic status or other factors.

In the last few years there have been a number of reviews and meta-analyses on the effects of ST, *e.g.* [33-42], many unrestricted to effects in the US and Scandinavia, and some restricted to specific diseases. Where effects are claimed, they often relate to products used in Africa or Asia, *e.g.* [42], or to other diseases, such as oral or pancreatic cancer. For oral cancer, however, evidence of an increased risk from snus has not emerged from meta-analyses[32], while for US ST any increase is mainly evident in studies before 1980[43]. Also, for pancreatic cancer, claims of any increased risk associated with snus use[33,34] are weakly based, with the evidence for any association with ST use essentially disappearing[32] following publication of pooled analyses[44,45]. For lung cancer, the reviews, *e.g.* [33,34,38,46] generally consider that no increased risk from snus has been demonstrated, though one[39] points to increased risk from US ST. COPD is little considered in the reviews, though one[39] does refer to the increased risk seen in the CPS-I study shown in Table 2. The risks of IHD/AMI and stroke are more extensively considered in the reviews, and some, *e.g.* [35] refer to a possible increase in risk of fatal AMI and stroke. However, this increase is mainly dependent on the results for US ST, where we have found a significant increase in our analyses. For snus, where the evidence considered derives from studies of fatal cases only, of non-fatal cases only, or of first occurrences of a case (fatal or non-fatal), where separate results are not always reported by fatality, there is no clear evidence of an increased risk specifically in fatal cases[32]. As noted in this review, confounding may occur due to snus users reporting disease later, or having less medical care when they do. Even if, for some reason, there is a slight adverse effect of snus on fatal AMI and stroke, it is clearly less than for cigarette smoking. This conclusion is consistent with a recent follow-up of almost 75000 patients admitted with a first percutaneous intervention, which found

that snus use was not associated with increased mortality, new revascularisation or hospitalisation for heart failure[47].

Taken as a whole, the conclusions reached in the reviews are consistent with our findings that, for the four major diseases considered, effects of the smokeless products commonly used in the US are less than those for cigarette smoking, and they are not clearly evident for Swedish snus. Our analyses provide no information on risks from ST as used in Africa and Asia.

CONCLUSION

Studies in the US show that, in those who never used other tobacco products, current ST use is associated with an increased risk of the four major smoking-related diseases. However, this increase, though statistically significant (at $P < 0.05$), is much less than for cigarette smoking. Scandinavian studies show no significant increase in risk of IHD/AMI, stroke or lung cancer in current snus users, with no data available for COPD. Though the data have limitations, providing information only on risks from the major smoking-related diseases, and none on risks from the smokeless products used in Africa or Asia, our findings clearly show that risks of the diseases considered from US ST and snus use are much less than for smoking.

ARTICLE HIGHLIGHTS

Research background

There are extensive data on the risks from cigarette smoking, but far less on the risks from moist snuff ("snus") or smokeless tobacco (ST) as used in Western populations and Japan.

Research motivation

To obtain recent evidence as part of a project comparing risks from use of various tobacco products.

Research objectives

To summarize data relating snus and ST use in North America, Europe and Japan to risk of the four main smoking related diseases – lung cancer, chronic obstructive pulmonary disease (COPD), ischaemic heart disease (IHD) (including acute myocardial infarction (AMI) and stroke.

Research methods

Medline searches sought English publications in 1990-2020 providing data on risks of each of the diseases relating to current (or ever) use of snus or ST in the selected regions. The studies had to include at least 100 cases of the disease considered, and not be based on individuals with specific diseases. Relative risk estimates adjusted at least for age were extracted for each study and combined using random-effects meta-analyses.

Research results

Six United States studies provided ST results. For current vs. never use (4 studies), significant increases were seen for each disease, with the RRs higher for lung cancer (1.59) and COPD (1.57) than for IHD/AMI (1.26) and stroke (1.25). Including also results for ever vs. never use, increased the lung cancer RR to 1.80, but little affected the other RRs. Twelve Scandinavian studies provided snus results, with no data on COPD. For the other diseases, RRs for current vs. never use were never significant, the highest RR being 1.05 for stroke. There were no relevant studies in Japan.

Research conclusions

Risks from ST use in North America are much less than for smoking, while no risks were demonstrated for snus.

Research perspectives

The results suggest that smokers unwilling to give up nicotine may substantially reduce their risk of the four diseases by switching to ST (as used in North America) or snus.

ACKNOWLEDGEMENTS

We thank Yvonne Cooper for typing the various drafts of the paper and obtaining the relevant references.

FOOTNOTES

Author contributions: Lee PN planned the study; Literature searches were carried out by Coombs KJ and checked by Lee PN; Statistical analyses were carried out by Hamling JS and checked by Lee PN; Lee PN drafted the text, which was checked by Coombs KJ and Hamling JS.

Conflict-of-interest statement: The authors have carried out consultancy work for many tobacco organizations.

PRISMA 2009 Checklist statement: The authors have read the Prisma 2009 Checklist, and the manuscript was prepared and revised according to the Checklist's requirements.

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MRTP claim authorisation and General Snus sales in the USA: evidence from a difference-in-differences model

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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/tc-2022-057890>).

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Received 7 December 2022

Accepted 7 June 2023

ABSTRACT

Background The 2009 Tobacco Control Act granted the US Food and Drug Administration (FDA) regulatory authority over tobacco products, including the ability to authorise modified-risk tobacco product (MRTP) claims. In October 2019, the FDA authorised the first-ever MRTP claim for General Snus, which allowed the product to be marketed as reduced risk (relative to cigarettes). MRTP authorisation may increase otherwise low rates of snus use in the USA (<0.5% for children and adults).

Methods Using 2017–2021 Nielsen sales data from 19 US states, we conducted a difference-in-differences analysis to determine whether logged unit sales of General Snus were affected by the MRTP authorisation, compared with (1) sales of other snus brands and (2) sales of non-snus smokeless products; we also examined (3) if sales of non-General Snus brands were affected by General Snus's MRTP authorisation, compared with sales of non-snus smokeless tobacco products.

Results Although sales declined in absolute terms, sales of General Snus relative to other snus brands were unchanged after MRTP authorisation (−9.0%, 95% CI −19.6% to 1.60%, $p=0.098$). However, compared with non-snus smokeless brand sales, sales of General Snus (+14.7%, 95% CI 5.23% to 24.2%, $p=0.002$) rose after MRTP authorisation. Compared with non-snus smokeless products, sales of non-General Snus brands also rose after MRTP authorisation (+23.7%, 95% CI 9.5% to 38.0%, $p=0.001$).

Conclusions Although only General Snus received MRTP authorisation, this designation appears to have slowed declines for the entire snus category. This suggests consumers may make determinations regarding product risk to a product class rather than individual products.

INTRODUCTION

In October 2019, the US Food and Drug Administration (FDA) authorised its first-ever modified-risk tobacco product (MRTP) claim.¹ The authorisation allows Swedish Match to use the following claim when marketing eight General Snus products in the USA: 'Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis'.¹ As of this writing, no other snus brands have been authorised to make MRTP claims. An MRTP application for snus market leader Camel Snus was under evaluation by the FDA for 5 years before the manufacturer withdrew its application in December 2022.²

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Tobacco product manufacturers have pursued and obtained designations from the US Food and Drug Administration to market specific products with reduced risk and exposure claims. Manufacturers have also begun using these authorised claims in marketing campaigns.

WHAT THIS STUDY ADDS

⇒ This is the first known study to examine the association of a modified-risk tobacco product (MRTP) claim authorisation with product sales. We found no evidence that General Snus gained any sales advantages relative to its snus competitors after receiving MRTP authorisation. However, MRTP authorisation for General Snus was associated with relative increases in sales of all snus brands, compared with the wider US smokeless market.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ An MRTP designation may aid sales of the granted product or similar tobacco products sold by other companies.

MRTP claim authorisation may give Swedish Match a competitive advantage over other snus and smokeless tobacco brands. For instance, the General Snus MRTP claim may lead users of other snus products or users of non-snus smokeless tobacco products to switch to General Snus. Moreover, the MRTP claim may encourage combustible tobacco product users to transition down the tobacco harm continuum by switching from combustibles to General Snus. The MRTP claim could also increase General Snus sales among non-tobacco users. This study examines the association of the General Snus MRTP claim authorisation on US sales. Recent data from the USA indicate that past 30-day snus use rates are relatively low, 0.4% of US youth (according to 2021 National Youth Tobacco Survey) and 0.3% of US adults (2020 Population Assessment of Tobacco and Health Study),^{3 4} but MRTP authorisation^{1 2} could increase snus use over time.

METHODS

We analysed smokeless sales data from Nielsen's Scantrack Service divided into 4-week intervals between 5 March 2017 and 6 November 2021 (the MRTP designation occurred on 19 October 2019). Nielsen provides snus and smokeless tobacco sales



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To cite: Liber AC, Seidenberg AB, Pesko MF. *Tob Control* Epub ahead of print: [please include Day Month Year]. doi:10.1136/tc-2022-057890

and price data by universal product code (UPC) for 19 states that collectively account for 70% of the US population. Nielsen collected the data directly from electronic scanners in convenience stores (including gas stations) and eXtended All Other Channels (xAOC; eg, food/grocery stores, drug stores and mass market stores) and provided UPC-level descriptors enabling categorisation. States were not included if they (1) were not in the Nielsen data ($n=21$), (2) did not include both convenience and xAOC stores ($n=6$) or (3) conferred a discount on excise taxes to products with MRTP designations ($n=5$; Colorado, Connecticut, Kentucky, North Carolina and Washington). We calculated logged standard unit sales for the three largest US snus brands: Camel, Skoal and General. These brands collectively accounted for 99.8% of snus sales in the Nielsen sales data.

Additionally, we calculated the same for all brands of other smokeless tobacco products that recorded a sale in each 4-week interval of the data: moist snuff ($n=15$ brands), dry snuff ($n=20$), chewing tobacco ($n=38$), nicotine pouches ($n=2$) and non-nicotine herbal smokeless products ($n=3$). As every General Snus product in the Nielsen dataset received MRTP orders, we aggregated UPC-level sales to the brand level for General. We also aggregated sales of the two other snus brands (Camel Snus and Skoal Snus) to the brand level. Finally, we aggregated all other non-snus smokeless products ($n=78$) to the brand level. As such, our analytical file is a balanced panel of sales and prices of 81 brands across 62 4-week periods ($81 \times 62 = 5022$ observations in total).

We performed difference-in-difference (DiD) regression analysis to evaluate the association of the MRTP authorisation on 19 October 2019. We used brand-level logged standardised unit sales as the primary outcome, where standardised units are 1 ounce for moist snuff, dry snuff, snus, nicotine pouches and herbal chew, and 3 ounces for chewing tobacco. We used real prices for each brand as secondary outcome variables to observe whether price changes can explain results using sales outcomes.

Within the DiD framework, we used three combinations of treatment/control groups and dropped unused brands. First, we examined whether General Snus sales changed after MRTP authorisation compared with sales of Skoal Snus and Camel Snus (model 1). Second, we compared General Snus sales with all other non-snus smokeless brand sales (model 2). Third, we compared sales of non-General Snus brands (Skoal and Camel) to non-snus smokeless brands (model 3).

We used the Callaway and Sant'anna -csdid- command in Stata/MP V.16.1 for the DiD estimation.⁵ Additionally, we used -csdid- to produce event studies for each outcome/model showing associations in the time period leading up to and after MRTP designation. Fixed effects are included for each of the 62 4-week periods (capturing national changes in tobacco product use over time, such as those due to the COVID-19 pandemic) and for each included brand in the analysis, depending on the model. SEs using a multiplicative wild bootstrap procedure were clustered at the brand level.

RESULTS

Mean sales before and after October 2019 for each of the three product categories are presented in online supplementary table S1. Sales of General Snus and non-snus smokeless products fell over the study period, and prices rose for all three product categories. While General Snus sales declines suggest that MRTP authorisation did not increase absolute sales, the designation may have reduced the rate of decline for affected brands (thus contributing to higher sales than the counterfactual world

without MRTP designation). Our empirical approach allows us to test this hypothesis.

Online supplementary table S1 also shows sales before and after MRTP authorisation for disaggregated categories of non-snus smokeless products. Pre-MRTP, sales of moist snuff were the largest, followed by chewing tobacco, dry snuff, herbal smokeless and pouches. The only category to grow throughout the study period was nicotine pouches (eg, Swedish Match's ZYN), whose unit sales increased over ninefold pre-MRTP and post MRTP.

Figure 1 presents event studies for all three models. Showing that trends are parallel between treated and control groups in the preperiod reduces concern about omitted time-varying variables affecting smokeless products differently and is a necessary but not sufficient condition for causal interpretation.⁶ While there is some noise in the preperiod, there is little evidence of a consistent trend before MRTP authorisation that would otherwise suggest a violation of the parallel trend assumption. In the postperiod, coefficients suggest relative decreases in General Snus sales in model 1, relative increases in General Snus sales in model 2 and relative increases in non-General Snus sales in model 3. We also note in figure 1 the date of MRTP authorisation (October 2019) and the first known example of the MRTP claim appearing in General Snus marketing (January 2020).^{7 8}

Overall estimates are shown in online supplementary table S2. For model 1, the association of MRTP authorisation on General Snus sales (compared with all other snus brands) was a statistically insignificant 9.0% relative decrease in sales volumes (95% CI -19.6% to 1.6%, $p=0.098$). In model 2, the association on General Snus sales (compared with all other non-snus smokeless brands) was a statistically significant 14.7% relative increase (95% CI 5.2% to 24.2%, $p=0.002$). In model 3, the association on non-General Snus brands (compared with all other non-snus smokeless brands) was a 23.7% relative increase (95% CI 9.5% to 38.0%, $p=0.001$). Lastly, models examining price as an outcome (online supplementary figure S1 and online supplementary table S2) did not find evidence that these changed differentially between treatment and control brands. The last two columns of online supplementary table S2 estimates the models using Stata's -xtreg- command instead of -csdid- and find somewhat larger same-signed results.

DISCUSSION

This is the first known study to examine the association of MRTP authorisation with product sales. We found no evidence that General Snus gained any sales advantages relative to its snus competitors after the MRTP designation. However, we identified a significant positive association of MRTP authorisation on sales of General Snus and other snus brands compared with the wider US smokeless marketplace. Therefore, the MRTP claim for General Snus may have slowed declining sales in the entire snus category. These relative snus sales increases could have been driven by the product halo effect, where consumers infer the claim applied to other snus brands.⁹ Research has not examined whether General Snus MRTP designation changed consumer risk perceptions, leaving a gap in understanding.

Sales data provide an objective proxy for product use and are not subject to recall or social desirability biases. However, sales data do not provide information on the types of consumers purchasing snus products, which are needed to elucidate the public health impact of MRTP claim authorisation. For instance, population health would likely improve from people using

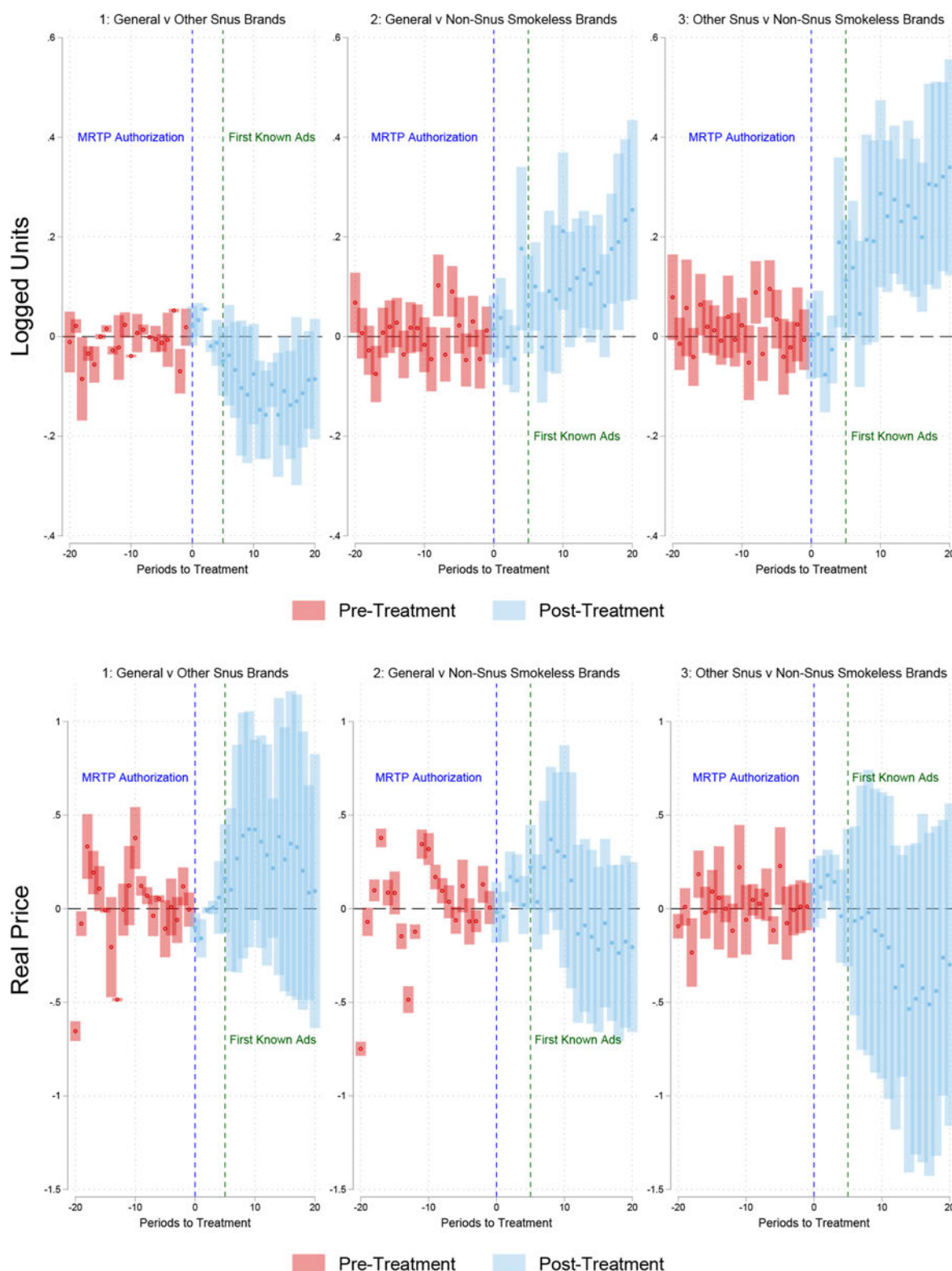


Figure 1 Sales event studies. Note: event studies were produced using the `-csdid` Stata command.⁵ States included in the analysis were Alabama, Arizona, California, Florida, Georgia, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Missouri, New Jersey, New York, Ohio, Oregon, Pennsylvania, Tennessee, Texas and Virginia. MRTP, modified-risk tobacco product.

General Snus instead of combustible tobacco products; however, it suffers from people using General Snus that would not otherwise use any form of tobacco. Future research studying the effect of MRTP authorisation on different populations will help expand on early findings from sales data.

Our study has two primary limitations. First, the generalisability of our General Snus finding may be limited because we estimated our models using Nielsen sales data for only 19 states that included data on both store types and that did not have an MRTP tax discount. Second, an ongoing shift in consumer

preferences towards pouched nicotine products like snus and nicotine pouches (eg, ZYN, on! and VELO) may have contributed to the observed sales patterns. However, the lack of a divergent trend for sales of snus brands before the MRTTP in the event studies lends credence to the idea that the MRTTP accounted for relative sales increases.

The MRTTP pathway allows manufacturers to provide tobacco product relative risk and exposure information to consumers for authorised products, which may help encourage tobacco users to transition to less harmful products. This study found evidence that the MRTTP claim authorised for General Snus increased snus sales relative to other smokeless products. It suggests that MRTTP claims can affect sales not only for products that receive the designation but also for other similar products. Future work should uncover factors that drive an MRTTP claim authorisation's effect on sales including marketing expenditure or timing and competition within a category. In the case of General Snus's marketing timing, the earliest use of the MRTTP claim we could find was January 2020, several months after claim authorisation.^{7 8} This may have caused the MRTTP's effects to be delayed compared with having advertised it immediately. Additional evaluations are needed to understand the population-level impact of this and other MRTTP designations (eg, IQOS, VLN cigarettes and Copenhagen Snuff).

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Acknowledgements We thank Serena Phillips for contributing her calculation of the US adult snus usage rate to the Introduction section of this article.

Contributors ACL performed the analysis, wrote the first draft and critically revised the manuscript; ABS conceptualised the study, helped write the first draft and revised the manuscript; MFP assisted with modelling and critically revised the manuscript.

Funding Research reported in this publication was supported by the National Institute on Drug Abuse of the National Institutes of Health (under award number R01DA045016) and by a pilot project award from the Center for the Assessment of Tobacco Regulations, which is funded by the US National Cancer Institute (NCI) and the US Food and Drug Administration (FDA) (grant U54CA229974). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The content of this article does not necessarily reflect the official opinion or policy of the NCI, the National Institutes of Health, the FDA or the Truth Initiative.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Swedish snuff (snus) dipping, cigarette smoking, and risk of peripheral artery disease: a prospective cohort study

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Tobacco smoking is an important risk factor for peripheral artery disease (PAD), but it remains unknown whether smokeless tobacco, such as Swedish snuff (snus), is also associated with this disease. We used data from the Cohort of Swedish Men including 24,085 men. Individuals were grouped into never, past, and current snus dippers as well as never, past quitting ≥ 10 years, past, quitting < 10 years, and current smokers. Incident PAD cases were defined by linkage of the cohort with the Swedish National Patient Register. Cox proportional hazards regression was used to analyze the data. Over a mean follow-up period of 9.1 years (from July 1, 2009 to December 31, 2019), 655 incident PAD cases were ascertained. Cigarette smoking but not Swedish snus dipping was associated with an increased risk of PAD. Compared with never snus dippers, the hazard ratio of PAD was 0.95 (95% confidence interval [CI] 0.73–1.24) for past snus dippers and 0.88 (95% CI 0.66–1.17) for current snus dippers. Compared to never smokers, the hazard ratio of PAD was 1.38 (95% CI 1.14–1.68) for past smoker who stopped smoking for ≥ 10 years, 2.61 (95% CI 1.89–3.61) for past smoker who stopped smoking for < 10 years, and 4.01 (95% CI 3.17, 5.08) for current smoker. In conclusion, cigarette smoking but not Swedish snus dipping increases the risk of PAD.

Peripheral artery disease (PAD) is a common atherosclerotic cardiovascular disease with a global prevalence of 5.6%¹. It was estimated that PAD affected around 237 million individuals aged above 25 years worldwide in 2015¹. Traditional cardiovascular risk factors, like smoking, diabetes, dyslipidemia, and hypertension, and several metabolic and inflammatory factors have been associated with PAD risk in populations in Western countries². Among these factors, tobacco smoking is an important modifiable risk factor for PAD³, and the causality of the association has been strengthened in recent Mendelian randomization studies^{4,5}. Nicotine is one of the detrimental chemicals in tobacco and has the potential of impairing cardiovascular system via unfavorable impacts on heart rate, blood lipids, blood pressure, blood viscosity, and vasoconstriction as well as on endothelial function^{6–8}.

Oral snuff is a smokeless tobacco product containing nicotine but limited other detrimental components from cigarette smoking. Studies have suggested that snuff dippers are exposed to similar or higher doses of nicotine than smokers⁹. Snuff in different countries and areas may be largely varying in addiction potential and patterns of usage¹⁰ and have different impacts on cardiovascular disease¹¹. In Sweden, approximately 11–13% of the population used Swedish snuff (snus) and 7–12% of the population smoked daily in a recent decade¹². Previous studies on snus revealed that snus dipping was not associated with risk of overall heart disease¹³, stroke¹⁴, acute myocardial infarction¹⁵ or ischemic heart disease¹⁶ but associated with an increased risk of cardiovascular mortality¹⁷. However, limited data are available on the effect of Swedish snus dipping on PAD risk. Here, we aimed to explore the association between snus dipping and incident PAD using data from a cohort of middle-aged and older men. We also examined the association for tobacco smoking as a positive control.

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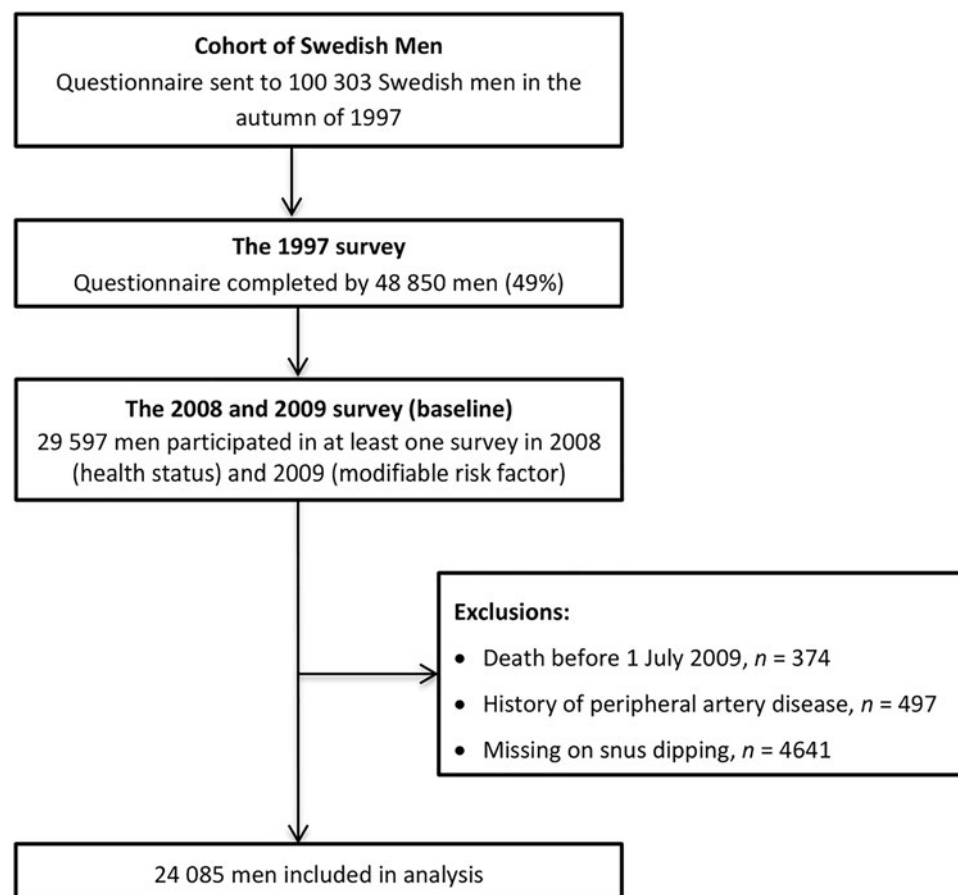


Figure 1. Flow chart of the final study population.

Materials and methods

Study population. We included individuals from the Cohort of Swedish Men (COSM) that was initiated in the late autumn of 1997 by inviting 100,303 Swedish men aged 45 to 79 living in Västmanland or Örebro county¹⁸. Around 49% of invited individuals (48,850) responded the questionnaire in 1997. The second surveys were conducted in 2008 and 2009 when 37,861 and 29,068 COSM members who were still alive and residing in the study areas received questionnaires about health status (2008) and modifiable risk factors (2009), respectively. Around 78% (29,531) and 90% (26,161) of men completed the 2008 and 2009 questionnaires, respectively. A total of 29,597 men participated in at least one survey in 2008 and 2009. After removal of individuals who died before July 1, 2009, those with a prior diagnosis of PAD, and those with missing information on snus dipping (in the analysis of snus dipping), 24,085 men were included in the analysis. The flow chart of the final study population is presented in Fig. 1. Data used in this study were permitted under Project simpl2020002. The study has been approved by the Swedish Ethical Review Authority (Dnr: 2019-03986). All participants have provided informed consent. The research was performed in accordance with the Declaration of Helsinki.

Assessment of snus dipping and tobacco smoking. Snus dipping and tobacco smoking were measured by a self-administrated questionnaire in 2009. Participants were asked to answer the question “mark if you have used snus regularly (more than 5 servings per week)” by choosing one of three predefined categories, including “No, I have never used snus regularly”, “Yes, I use snus” and “Yes, but I stopped using snus”¹⁹. Three statuses (never, past, and current snus dippers) were defined based on this question. Likewise, tobacco smoking was defined using corresponding information on “mark if you have smoked cigarettes regularly (more than 5 cigarettes per week)”. Four categories (never, past with quitting time ≥ 10 years, past with quitting time < 10 years and current smoker) were defined when taking time of stopping smoking into consideration. Individuals without smoking information ($n = 1172$) were grouped into one category named “missing” in the analysis. Never snus dipper and never smoker were defined as the reference groups in the analysis of snus dipping and tobacco smoking, respectively, in relation to PAD risk.

Ascertainment of cases and follow-up. Incident PAD cases were ascertained by the clinical diagnosis based on codes from the 9th (440.0, 440.2, 440.3, 440.4, 440.9, 443.9) and 10th (I70.0, I70.2, I70.3, I70.4, I70.5, I70.6, I70.7, I70.9, I703.9) International Classification of Disease revision with information identified by linkage

Characteristics	Snus dipping			Total
	Never	Past	Current	
Individuals	18,789	2946	2350	24,085
Age, mean \pm SD, years	71.2 \pm 8.4	66.8 \pm 7.0	67.0 \pm 7.2	70.2 \pm 8.3
Body mass index ^a , mean \pm SD, kg/m ²	25.6 \pm 3.1	26.1 \pm 3.1	26.0 \pm 3.3	25.7 \pm 3.2
Post-secondary education ^a , %	21.8	15.0	13.5	20.1
Hypertension, %	39.4	44.3	40.4	40.1
Hypercholesterolemia, %	25.3	30.8	25.1	25.8
Diabetes, %	9.6	11.2	10.5	9.8
Smoking status^a, %				
Never smoker	52.0	15	16.7	44.3
Past smoker	34.8	75.2	60.3	42.3
Current smoker	8.9	5.3	11.0	8.5
Physical activity^a, %				
< 10 min/day	5.7	5.2	7.1	5.8
10–30 min/day	15.4	15.1	19.6	15.7
31–60 min/day	50	48.9	48.2	49.6
> 60 min/day	27.6	29.8	23.5	27.7
DASH score, mean \pm SD	18.1 \pm 3.2	18.1 \pm 3.1	17.3 \pm 3.1	18.0 \pm 3.2
Coffee consumption, servings, mean \pm SD	2.8 \pm 1.8	3.1 \pm 2.0	3.1 \pm 2.0	2.8 \pm 1.9

Table 1. Age-standardized baseline characteristics of 24,085 Swedish men by snus dipping status. *SD* standard deviation. ^aProportion of missing was 3.32% for body mass index, 0.24% for education levels, 4.89% for smoking status, and 11.9% for physical activity.

of the cohorts to the Swedish Patient Register. The register has an nearly complete coverage of hospital-based inpatient and outpatient care²⁰. Individuals were followed up from July 1, 2009 until the date of diagnosis of PAD, date of death, or end of follow-up (i.e., 31 December 2019), whichever came first. Death information was obtained from the Swedish Death Registry.

Assessment of covariables. Information on age, body mass index, highest education attainment, history of hypertension, hypercholesterolemia, and diabetes mellitus, physical activity (walking/cycling and exercise combined), diet quality (measured by modified Dietary Approaches to Stop Hypertension) and coffee consumption was reported in the 2008 and 2009 questionnaires. The modified Dietary Approaches to Stop Hypertension diet included fruits, vegetables, nuts and legumes, whole grains, and low-fat dairy products as healthy components and red and processed meat and sweetened beverages as unhealthy components²¹. Individuals were assigned a score from 1 to 5 according to the quintiles of consumption of each food and the scores were summed to create a diet score (7–35). A high score indicates a high adherence to the modified Dietary Approaches to Stop Hypertension diet pattern.

Statistical analysis. The Kaplan–Meier method and log-rank test were used to compare the probability of being free of PAD diagnosis across snus dippers and cigarette smokers. Cox proportional hazard regression was used to estimate the associations of snus dipping and tobacco smoking with risk of incident PAD with age as the underlying time scale. The assumption of proportionality was verified using Schoenfeld residuals. We obtained estimates from an age-adjusted model and a multivariable-adjusted model with adjustment for age, body mass index (underweight, normal, overweight and obesity), education levels (≤ 9 , 10–12, > 12 years), history of hypertension, hypercholesterolemia, and diabetes mellitus (yes or no), tobacco smoking in the analysis of snus dipping, snus dipping in the analysis of tobacco smoking, physical activity (0–10, 11–30 and 31–60 and > 60 min per day), and diet score (continuous). The proportion of missing data was 3.32% for body mass index, 0.24% for education level, 16.9% for smoking status, and 11.9% for physical activity. A separate group was created for each variable with missing values. All statistical tests were two-sided, and the analyses were performed in Stata/SE (version 15.0; StataCorp, Texas, USA). An association with a *p* value below 0.05 was deemed as statistically significant.

Results

The mean age of the population at baseline was 70.2 \pm 8.3 years. A total of 655 incident PAD cases were ascertained during a mean follow-up period of 9.1 years and 220,127 person-years (from July 1, 2009 to December 31, 2019). The age of PAD onset was 78.2 \pm 8.0 years, and the incidence rate was 3.0 per 1000 person-years. The age-standardized baseline characteristics by snus dipping are displayed in Table 1. Snus dippers were more likely to be younger men with low education level, low physical activity, and with a history of hypertension, hypercholesterolemia, diabetes, and past or current cigarette smokers.

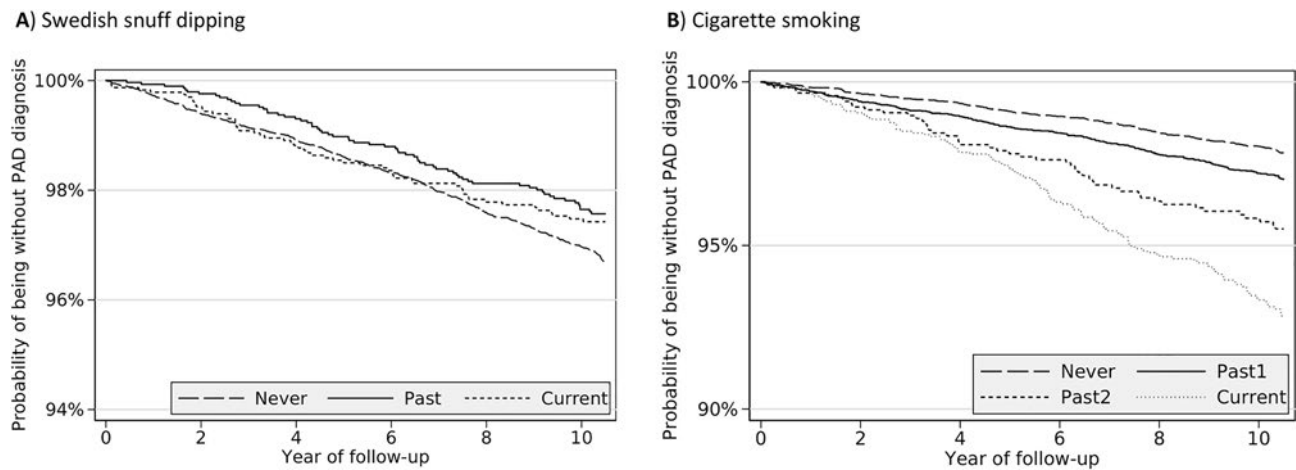


Figure 2. Kaplan–Meier survival curve of peripheral artery disease risk across snus dippers and smokers. Past1 indicates past smoker who stopped smoking for ≥ 10 years and Past2 indicates past smoker who stopped smoking for < 10 years.

Group	Cases	Person-years	HR (95% CI) ^a	HR (95% CI) ^b
Snus dipping				
Never	533	169,425	Ref	Ref
Past	66	28,445	1.03 (0.79, 1.33)	0.95 (0.73, 1.24)
Current	56	22,256	1.10 (0.83, 1.45)	0.88 (0.66, 1.17)
Tobacco smoking				
Never	203	98,924	Ref	Ref
Past, quitting ≥ 10 years	236	82,688	1.48 (1.23, 1.79)	1.38 (1.14, 1.68)
Past, quitting < 10 years	48	10,977	2.90 (2.11, 3.98)	2.61 (1.89, 3.61)
Current	124	18,044	4.51 (3.60, 5.65)	4.01 (3.17, 5.08)

Table 2. Associations of tobacco smoking and snus dipping with risk of peripheral artery disease. ^aHazard ratios (HRs) were obtained from the age-adjusted model. ^bHRs were obtained from the model adjusted for age, body mass index (underweight, normal, overweight and obesity), education levels (≤ 9 , $10-12$, > 12 years), history of hypertension, hypercholesterolemia, and diabetes mellitus (yes or no), tobacco smoking in the analysis of snus dipping, snus dipping in the analysis of tobacco smoking, physical activity (0–10, 11–30 and 31–60 and > 60 min per day), and diet score (continuous).

The Kaplan–Meier survival curve showed that past snus dippers had higher probability of being free of PAD diagnosis compared to never snus dippers (Fig. 2, p for log-rank test = 0.02). However, snus dipping was not associated with the risk of PAD in either the age-adjusted or the multivariable-adjusted model (Table 2). Compared with never snus dippers, the multivariable-adjusted hazard ratio of PAD was 0.95 (95% confidence interval (CI) 0.73, 1.24) for past snus dippers and 0.88 (95% CI 0.66, 1.17) for current snus dippers.

In Kaplan–Meier analysis, never smokers had higher probability of being free of PAD diagnosis compared to past or current smokers (Fig. 2, p for log-rank test < 0.001). Tobacco smoking also showed a robust and strong association with incident PAD in Cox regression (Table 2). Hazard ratios of PAD were 1.38 (95% CI 1.14, 1.68), 2.61 (95% CI 1.89, 3.61) and 4.01 (95% CI 3.17, 5.08) for past smoker who stopped smoking for ≥ 10 years, past smoker who stopped smoking for < 10 years, and current smoker, compared to never smoker. The direction and magnitude of associations remained stable in the analysis excluding individuals without smoking information (data not shown).

Discussion

The present study found that cigarette smoking, but not Swedish snus dipping was associated with an increased risk of PAD in a cohort of middle-aged and older Swedish men. This is the first study examining the association between snus dipping and incident PAD.

Previous studies on snuff dipping in relation to other cardiovascular diseases showed no association with risk of atrial fibrillation or heart failure^{22,23}, but reported conflicting results for myocardial infarction and stroke^{11,13–16,24,25}. A recent cohort study found that Swedish snus dipping was not associated with risk of major heart and valvular diseases, abdominal aortic aneurysm, or cardiovascular mortality, but possibly with an increased risk of stroke¹⁹. The discrepancy in these studies may be caused by residual confounding (e.g., weight

gain after starting dipping snus since snus is often used to quit smoking), varying ways of treating smoking status (adjusting for it as confounders or restricting analysis to never smokers), different baseline age, inadequate statistical power, and diverse effects of snus (nicotine) on different cardiovascular diseases. Given that obesity is not an important risk factor for PAD² and that many important cofounders were adjusted for in our analyses, our findings are less likely to be biased by confounding from weight change and other lifestyle factors. Nevertheless, the association may be challenged by inadequate power caused by a small number of cases despite of a long follow-up of this study. However, we observed that the hazard ratios of PAD for past and current snus dippers were below one.

Tobacco smoking has been identified as an important modifiable risk factor for PAD and the magnitude of the association was larger than that for coronary artery disease^{2–5,26}. Even though nicotine has been proposed to affect the cardiovascular systems in an unfavorable manner^{6–8}, our study did not support a detrimental role of snus (rich in nicotine) dipping in PAD. Considering a comparably reduced risk of PAD in past smoker versus current smoker, the nicotine replacement therapy to help cessation appears to be a practical strategy for PAD prevention after the assessment of potential side-effects. As for the different associations of snus dipping and cigarette smoking with PAD risk, the difference in components of snus and tobacco may convey the clues that certain chemical components contained in tobacco or generated in cigarette smoking, such as arsenic²⁷ and carbon monoxide²⁸ but not nicotine elevate the risk of developing PAD.

There are several underlying mechanisms explaining the positive association between tobacco smoking and PAD risk. Smoking is associated with high risk of developing metabolic disorders, such as type 2 diabetes²⁹, hypertension⁵, and obesity⁵, which are risk factors for PAD. In addition, smoking may increase PAD risk through systemic inflammation^{30,31}, endothelial dysfunction³², and coagulation factors³³. The null finding on the association between Swedish snuff dipping and PAD risk may be explained by limited peripheral arterial atherosclerosis effects of nicotine which is rich in snus products.

There are strengths and limitations of the present study. Strength includes a large sample size, a long follow-up period, and accurate diagnostic information from register. We used tobacco smoking as the positive control and a strong association between tobacco smoking and PAD risk validated the case definition. Snus dipping and tobacco smoking information was obtained from a self-reported questionnaire, which may lead to misclassification of the exposure. Over the follow-up period, individuals may change their tobacco and snus use, which may also introduce misclassification of the exposure. Even though we adjusted for important lifestyle factors in the analysis, we could not completely rule out the possibility that our results might be affected by residual confounding caused by unadjusted factors, like sleep features³⁴ and mental factors³⁵, although these factors have not been robustly associated with the development of PAD. This study included middle-aged and elderly men only. Thus, whether findings can be generalized to younger individuals and to women needs assessment. The power of the study was generally confined by a small number of PAD cases. In addition, we could not assess the association between Swedish snus dipping and PAD risk in never smokers also due to few cases (2 cases and 4 cases in past and current snus dippers in never smoker, respectively). However, any residual confounding from cigarette smoking cannot explain our null finding for snus dipping and PAD risk.

In conclusion, cigarette smoking but not Swedish snuff dipping likely increases the risk of PAD. Along with previous null findings on the associations of snus dipping with stroke and coronary heart diseases^{13–16,19}, our findings indicate that Swedish snus dipping is unlikely to have an important impact on the development of vascular diseases.

Data availability

De-identified SIMPLER data are available for researchers upon application (<http://www.simpler4health.se/>). Data can be accessed by a reasonable request to the corresponding author.

Received: 9 March 2022; Accepted: 11 July 2022

Published online: 15 July 2022

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Acknowledgements

We want to acknowledge the participants and investigators of SIMPLER for provisioning of facilities and experimental support. SIMPLER receives funding through the Swedish Research Council under Grant number 2017-00644. The computations were performed on resources provided by SNIC through Uppsala Multidisciplinary Center for Advanced Computational Science (UPPMAX) under Project simpl2020002. SIMPLER data can be applied via an application to <https://www.simpler4health.se/>.

Author contributions

S.Y. and S.C.L. conceived and designed the study. S.Y. undertook the statistical analyses and wrote the first draft of the manuscript. All authors provided important comments to the manuscript.

Funding

Open access funding provided by Karolinska Institute. Funding for this study came from the Karolinska Institutet's Research Foundation Grants (Grant number 2020-01842), the Swedish Research Council (Vetenskapsrådet; Grant Number 2019-00977), the Swedish Research Council for Health, Working Life and Welfare (Forte; 2018-00123) and the Swedish Heart-Lung Foundation (Hjärt-Lungfonden; Grant number 20210351). S.M.D. is supported by IK2-CX001780.

Competing interests

The authors declare no competing interests.

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Summary of All Manufacturing Deviations

Product:	General Dry Mint Portion Original Mini
SKU Number:	4800
FDA Tracking number:	PM0000011 / MR0000021
Reporting Period:	October 1, 2022 to September 30, 2023

Deviation Number	Type of Manufacturing Deviation	Production Date (YYYY-MM-DD)	Description of Deviation	Design Feature	Deviation May Affect the Characteristics of the Final Product (Yes/No)	Product With Deviation Distributed at Retail Level (Yes/No)
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Justification; why product that reached retail would not affect public health

---	No manufacturing deviations to report.
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--- = Not applicable.

Summary of All Manufacturing Deviations

Product:	General Portion Original Large
SKU Number:	4880
FDA Tracking number:	PM0000012 / MR0000022
Reporting Period:	October 1, 2022 to September 30, 2023

Deviation Number	Type of Manufacturing Deviation	Production Date (YYYY-MM-DD)	Description of Deviation	Design Feature	Deviation May Affect the Characteristics of the Final Product (Yes/No)	Product With Deviation Distributed at Retail Level (Yes/No)
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Justification; why product that reached retail would not affect public health

---	No manufacturing deviations to report.
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--- = Not applicable.

Summary of All Manufacturing Deviations

Product:	General Mint Portion White Large
SKU Number:	4352
FDA Tracking number:	PM0000014 / MR0000025
Reporting Period:	October 1, 2022 to September 30, 2023

Deviation Number	Type of Manufacturing Deviation	Production Date (YYYY-MM-DD)	Description of Deviation	Design Feature	Deviation May Affect the Characteristics of the Final Product (Yes/No)	Product With Deviation Distributed at Retail Level (Yes/No)
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Justification; why product that reached retail would not affect public health

---	No manufacturing deviations to report.
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--- = Not applicable.

Summary of All Manufacturing Deviations

Product:	General Portion White Large
SKU Number:	4881
FDA Tracking number:	PM0000016 / MR0000028
Reporting Period:	October 1, 2022 to September 30, 2023

Deviation Number	Type of Manufacturing Deviation	Production Date (YYYY-MM-DD)	Description of Deviation	Design Feature	Deviation May Affect the Characteristics of the Final Product (Yes/No)	Product With Deviation Distributed at Retail Level (Yes/No)
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Justification; why product that reached retail would not affect public health

---	No manufacturing deviations to report.
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--- = Not applicable.

Summary of All Manufacturing Deviations

Product:	General Wintergreen Portion White Large
SKU Number:	4882
FDA Tracking number:	PM0000017 / MR0000029
Reporting Period:	October 1, 2022 to September 30, 2023

Deviation Number	Type of Manufacturing Deviation	Production Date (YYYY-MM-DD)	Description of Deviation	Design Feature	Deviation May Affect the Characteristics of the Final Product (Yes/No)	Product With Deviation Distributed at Retail Level (Yes/No)
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Justification; why product that reached retail would not affect public health

---	No manufacturing deviations to report.
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--- = Not applicable.