

December 21, 2023

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FOOD AND DRUG ADMINISTRATION
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Subject: Unsolicited PMTA Amendment(s) of Scientific Content and Labeling and Marketing Plans for: ZYN® Flagship Varieties¹ FDA STNs: PM0000593 - PM0000612.

Dear Secretary,

Swedish Match USA Inc. ("Swedish Match" or "we") submits this "Amendment" to the U.S. Food and Drug Administration ("FDA") for new tobacco products, collectively the original ZYN Flagship Varieties or ZYN Products, listed in **Table 1** below ("new products"). The Amendment submission is for a group of tobacco products previously submitted as a grouped Premarket Tobacco Product Application (PMTA) submission associated with FDA Submission Tracking Numbers (STNs): PM0000593 - PM0000612 (collectively, the "PMTA"). The Amendment amends the PMTAs and is accompanied by a completed copy of Form 4057a – Premarket Tobacco Product Application Amendment and General Correspondence Submission(s).

While Swedish Match is confident that the PMTA demonstrates that the marketing of the ZYN Products is appropriate for the protection of the public, Swedish Match amends the

¹ In FDA STNs: PM0000593-PM0000612, the candidate products were referred to as "ZYN." Herein, the candidate products are referred to as "the original ZYN Flagship Varieties" or "ZYN Products."

PMTA to augment the original application and to provide the most current scientific information that has been collected and/or published since Swedish Match originally submitted the PMTA on March 4, 2020.^{2,3} Swedish Match provides the Amendment to highlight current 2023 National Youth Tobacco Survey (“NYTS”) data and to provide our 2024 marketing program which expresses our plan to eliminate branded merchandise and curtail brand signage.

The Amendment amends the PMTA with respect to all ZYN Products subject to the PMTA. Through the Amendment Swedish Match amends certain of its PMTA submission(s) contents. Specifically, Swedish Match amends the “Literature Search” section of the PMTA. Further, the addition of labeling and marketing plans content amends the “Description of Marketing Plans” section the PMTA. The scientific content of the Amendment reinforces the lack of adoption of nicotine pouch products by nonusers and youth. The included labeling and marketing plans provide our 2024 marketing program, which eliminates branded merchandise and limits branded signage. Swedish Match believes that the PMTA, as amended by this Amendment, further demonstrates that marketing of the ZYN Products is appropriate for the protection of the public health.

Table 1 New Tobacco Products, Original ZYN Flagship Varieties

New Product Name and Strength	Item no.	STN
ZYN Cool Mint 3 mg	900510	PM0000593
ZYN Cool Mint 6 mg	900520	PM0000594
ZYN Peppermint 3 mg	901510	PM0000595
ZYN Peppermint 6 mg	901520	PM0000596
ZYN Spearmint 3 mg	902510	PM0000597
ZYN Spearmint 6 mg	902520	PM0000598
ZYN Wintergreen 3 mg	903510	PM0000599
ZYN Wintergreen 6 mg	903520	PM0000600
ZYN Citrus 3 mg	907510	PM0000601
ZYN Citrus 6 mg	907520	PM0000602
ZYN Coffee 3 mg	904510	PM0000603
ZYN Coffee 6 mg	904520	PM0000604
ZYN Cinnamon 3 mg	906510	PM0000605
ZYN Cinnamon 6 mg	906520	PM0000606
ZYN Smooth 3 mg	914510	PM0000607
ZYN Smooth 6 mg	914520	PM0000608
ZYN Chill 3 mg	920510	PM0000609
ZYN Chill 6 mg	920520	PM0000610

² In response to clarification questions posed by the FDA, Swedish Match also provided amendments to the ZYN PMTAs on September 24, 2020, and March 7, 2022.

³ Swedish Match provided unsolicited amendment(s) of scientific content to the ZYN PMTAs on October 12, 2023.

ZYN Fresh 3 mg ⁴	921510	PM0000611
ZYN Fresh 6 mg ⁴	921520	PM0000612

FDA Form 4057a – Premarket Tobacco Product Application Amendment and General Correspondence Submission(s) is included for this group of tobacco products previously submitted as a grouped PMTA submission.

The Amendment contains non-public, trade secret, proprietary and confidential information that is protected under state and federal law from public disclosure. Swedish Match reserves the right to redact information it considers to be confidential prior to any part of the Amendment being made public. This information should therefore be handled in accordance with the security procedures adopted by the FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact me.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr., Esq.
Vice President, General Counsel & Secretary
Swedish Match USA, Inc.

⁴(b) (4)

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Document Attachments (List).

Attachment 1 - FDA Form 4057a
Attachment 2 - Morbidity and Mortality Weekly Report 3NOV2023
Attachment 3 -Swedish Match 2024 Marketing Program

Acronyms

APPH	Appropriate for the Protection of Public Health
CORESTA	Cooperation Centre for Scientific Research Relative to Tobacco
CTP	Center for Tobacco Products
ENDS	Electronic Nicotine Delivery Systems
FDA	Food and Drug Administration
FD&C	Food, Drug, and Cosmetic
LOU	Likelihood of Use
mg	Milligrams
MGO	Marketing Granted Order
NYTS	National Youth Tobacco Survey
PMTA	Premarket Tobacco Product Application
POU	Patterns of Use
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
STN	Submission Tracking Number
TNP	Tobacco and Nicotine Product
TPMF	Tobacco Product Master File
TPPI	Tobacco Product Perceptions and Intentions
U.S.	United States
UTUS	Underage Tobacco Use Study

MODULE 1 ZYN FLAGSHIP PMTA AMENDMENT

1.0 Integrated Summary

In this Premarket Tobacco Product Application (“PMTA”) Amendment, Swedish Match USA, Inc., herein referred to as Swedish Match, provides our 2024 marketing program, which eliminates the use of branded merchandise and curtails brand signage. In addition, the Amendment provides new data and expanded discussion of previously submitted assessments of surveys and published literature supporting that marketing of the original ZYN® Flagship Varieties⁵ (Chill, Cinnamon, Citrus, Coffee, Cool Mint, Fresh/Menthol⁶, Peppermint, Smooth, Spearmint, Wintergreen, each in 3 mg and 6 mg nicotine strengths) are appropriate for the protection of public health (“APPH”). The bundled PMTA and previous amendments thereto are collectively referred to as the original ZYN Flagship PMTA.

1.0.1 Introduction

On March 4, 2020, Swedish Match submitted a grouped PMTA for the original ZYN Flagship Varieties referenced in **Table 1** of the Cover Letter. Since then, more information has become available, including the most current scientific information. This information continues to demonstrate that marketing the new tobacco products is APPH. Swedish Match submits this Amendment to provide this information to the Food and Drug Administration (FDA) to support its review of the PMTA. We proactively provide new content as well as highlight previously submitted surveys and published literature to augment the original application. This information further demonstrates that marketing the new tobacco products is APPH.

Since the March 4, 2020 application was submitted, more information on the consumer behavior of the users of this smokeless oral nicotine product category has become available. We recently provided a Use Behavior Information assessment for our ZYN Flagship Varieties applications via an October 12, 2023 PMTA amendment. Similarly, with this Amendment, we wish to provide new and updated information, including scientific survey results, to inform the evaluation of the ZYN Flagship Varieties PMTA.

The information in this Amendment will update previous survey result content provided to FDA, for its review of our ZYN Flagship Varieties applications.

For the purposes of this Amendment we:

- ... briefly summarize the contents of our recent October 12, 2023 amendment, and discuss the information in that amendment in the context of the 2023 National Youth Tobacco Survey (“NYTS”) release as well as information concerning the state of the smokeless tobacco product market;
- ... provide new information from the 2023 NYTS to augment the original application and our subsequent amendments, which further demonstrates that marketing the new tobacco products is APPH;
- ... provide information concerning our 2024 Marketing Program;

⁵ In FDA submission tracking numbers [STNs]: PM0000593-PM0000612, the candidate products were referred to as “ZYN.” Herein, the candidate products are referred to as “the original ZYN Flagship Varieties” or “ZYN Products.”

⁶ (b) (4)

- ... reiterate why the new and updated information from these recent releases continues to support a finding of APPH for the ZYN Flagship Varieties applications.

We discuss these findings, their relevance to our ZYN Flagship Varieties PMTA, and our 2024 Marketing Program in the subsequent paragraphs, below. This information is presented in the corresponding sections as follows:

- [Section 1.1](#) Consumer Use Behavior
- [Section 1.2](#) Swedish Match 2024 Marketing Program
- [Section 1.3](#) Conclusion

The new information provided and referenced in the October 12, 2023 amendment is hereby incorporated by reference to the administrative record of the new tobacco products listed in **Table 1** of the Cover Letter.

1.1 Consumer Use Behavior

1.1.1 *Brief Summary of Relevant Use Behavior Information provided in the October 12, 2023 Amendment, and the State of the Smokeless Tobacco Market*

In our October 12, 2023 amendment, Swedish Match provided consumer behavior data, which demonstrates that nonusers of tobacco products and youth/young adults continue to not show interest in oral nicotine pouches and that ZYN Products are instead appealing to their intended consumers, adult current users of tobacco products. As demonstrated in the October 12, 2023 amendment, almost all ZYN Product users (b) (4) were current tobacco product users prior to first using ZYN Products, and at the time of starting ZYN Product use, (b) (4) of the users reported smoking cigarettes (b) (4), and (b) (4) of the users reported using moist snuff (b) (4).

2022 NYTS data continued to demonstrate an absence of appeal and uptake of nicotine pouches among youth. The overall nicotine pouch use prevalence for United States (“U.S.”) youth was approximately 1%.⁷ Further, published literature supports the finding that nicotine pouch uptake is low among youth. Estimates from the Altria Client Services Underage Tobacco Use Study (“UTUS”), a repeated cross-sectional survey collecting data on underage tobacco use on a quarterly basis, were similar to those based on NYTS data (Cheng, Vansickel, & Largo, 2023).

The lack of substantial youth uptake of oral nicotine pouches shown from UTUS data is noteworthy, particularly among underage young adults who are not well covered among school-based surveys like NYTS. Nicotine pouch use estimates remained low throughout the May 2020 – August 2022 UTUS study period at less than 0.5% among youth (ages 13-17) and 1.7% or less among underage young adults (ages 18-20).

NYTS has included questions regarding nicotine pouch use for two years (2021 and 2022, the two most recent NYTS data collections currently available). NYTS data continue to demonstrate an absence of appeal and uptake of nicotine pouches among youth, augmenting the results on nicotine pouch use among U.S. youth from other

⁷ Based on surveys of middle and high school students, overall use prevalence for U.S. youth was approximately 1% (2021: 0.76% [95% CI: 0.54% - 0.98%]; 2022: 1.06% [95% CI: 0.74% - 1.38%]; see also Gentzke et al. (2022) and Park-Lee et al. (2022)). Frequent pouch use (on 20 or more of the past 30 days) was rare in both 2021 and 2022 estimates; the 2021 estimate was 0.13% (95% CI: 0.06% - 0.20%) and the 2022 estimate was 0.27% (95% CI: 0.19% - 0.36%) of U.S. youth.

published literature. The most current survey results (i.e., 2023) show that nicotine pouch uptake remains low among this important unintended user group.

As noted above, the UTUS and NYTS data, which show low use of oral nicotine pouches generally, are consistent with ZYN Product-specific data, which shows that ZYN products are instead used almost exclusively by their intended consumers, adult current users of tobacco products. The lack of substantial youth/young adult and nonuser uptake of ZYN Products is unsurprising given that the ZYN Products are offered in flavors that are not youth-attractive, and which are consistent with flavored smokeless tobacco products that are already lawfully marketed. Berry, cherry, apple, sunberry, peach, tropical citrus, and grape smokeless products have been permitted on the market since at least 2018.⁸ Other grandfathered smokeless tobacco products come in flavors such as cinnamon, peach, anise (licorice), blackberry, vanilla, and cranberry.⁹ And mint flavored smokeless tobacco products have long been a significant part of the smokeless product market.¹⁰

1.1.2 Updated Relevant Use Behavior Information from the November 3, 2023 National Youth Tobacco Survey

In the brief time period since we submitted our most recent assessment of recent surveys and published literature as part of the October 12, 2023 amendment, the U.S. Department of Health and Human Services (“HHS”) Centers for Disease Control and Prevention (“CDC”)¹¹ published a report and data from the 2023 installment of NYTS. This report was featured in the November 3, 2023, Morbidity and Mortality Weekly Report (“MMWR”) and provides important conclusions from the 2023 NYTS for all tobacco product categories. The MMWR notes that “[a]djustments were made to the survey weights to reduce the potential for nonresponse bias” and therefore “2023 NYTS estimates may be compared with 2022 NYTS estimates for the same population groups.”¹²

The NYTS is an annual, school-based survey of middle school (grades 6-8) and high school students (grades 9-12) conducted by the CDC and FDA, which measures tobacco-related behaviors and attitudes. Given the importance of the NYTS findings, and the position of esteem this survey occupies among respected public health institutions, Swedish Match includes these results in this Amendment to the ZYN Flagship Varieties PMTA.

⁸ See, e.g., FDA Letter Swedish Match’s Peach Flavored Snuff at 9 (Dec. 16, 2019), <https://www.fda.gov/media/139243/download?attachment>; FDA Letter U.S. Smokeless Tobacco Co.’s Berry and Cherry Flavored Snuff at 5 (Sept. 24, 2019), <https://www.fda.gov/media/136145/download?attachment>; FDA Letter U.S. Smokeless Tobacco Co.’s Apple Flavored Snuff at 3 (June 17, 2019), <https://www.fda.gov/media/134281/download?attachment>; FDA Letter House of Oliver Twist’s Sunberry Flavored Chewing Tobacco at 3 (Mar. 29, 2019), <https://www.fda.gov/media/132939/download?attachment>; FDA Letter at 2-3 (Mar. 29, 2019), <https://www.fda.gov/media/132939/download?attachment>; FDA Letter Swisher International Inc.’s Grape Flavored Snuff at 2 (Oct. 22, 2018), <https://www.fda.gov/media/126590/download?attachment>.

⁹ Skoal Dry Cinnamon, GF1704027; Revel Cinnamon, GF1200209; Peach Sweet, GF1200393; McChrystal’s Anisette Snuff, GF1702941; Southern Pride Blackberry Blend; Skoal Long Cut Vanilla Blend, GF1200224; Offroad Cranberry Strong, GF1300720, all available at <https://www.accessdata.fda.gov/scripts/ctppx/>.

¹⁰ FDA, Technical Project Lead Review Memorandum for PM0000010-PM0000017 (Mar. 11, 2015), at 25, <https://www.fda.gov/media/94582/download>; FDA Letter Swedish Match’s Peppermint Flavored Snuff at 1 (July 17, 2018), <https://www.fda.gov/media/123104/download?attachment>; FDA Letter U.S. Smokeless Tobacco Co.’s Wintergreen Flavored Snuff at 2 (Sept. 24, 2019), <https://www.fda.gov/media/136145/download?attachment>; see also Catch Dry Peppermint, GF1300607, <https://www.accessdata.fda.gov/scripts/ctppx/>.

¹¹ Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182. DOI: <http://dx.doi.org/10.15585/mmwr.mm7244a1>.

¹² *Id.*

Background: The 2023 NYTS presents assessments of the percentage of middle and high school student youths who ever reported using tobacco products as well as used tobacco products in the previous 30 days. The 2023 NYTS showed reductions in overall rates of current tobacco product use, defined as use within the past 30 days, by high school students from the 2022 NYTS (12.6% vs. 16.5%). The most popular tobacco product category among those surveyed remained e-cigarettes, with past-30 day use among all students at 7.7%. However, this rate constituted a meaningful decline from the rate of e-cigarette use observed in the 2022 NYTS. The reported use of certain tobacco product categories remained low and/or largely unchanged, year-to-year. Tobacco products identified as being currently used by the survey participants included cigarettes (1.6%), cigars (1.6%), nicotine pouches (1.5%), smokeless tobacco (1.2%), other oral nicotine products (1.2%), hookahs (1.1%), heated tobacco products (1.0%), and pipe tobacco (0.5%).

Results: The results from the 2023 NYTS supports that non-combusted products like the original ZYN Flagship Varieties oral nicotine pouches, continue to provide population and individual level benefits by offering reduced-risk options to current, adult TNP users, without appealing to never and former users of tobacco products, or youth. We discuss the updated information from the 2023 results in the context of the PMTA in subsequent paragraphs.

Most relevant to our ZYN Flagship Varieties PMTA is a comparison of use behavior surrounding the oral nicotine pouch category. The 2023 NYTS shows that 1.5% (95% CI: 1% - 2.1%) of middle and high school students report current use (defined as any use within the past 30 days) of any nicotine pouch. These findings are consistent with those of the 2021 and 2022 NYTS. The weighted results (see Table 2, below) and overlapping 95% Confidence Intervals from 2021, 2022, and 2023 NYTS demonstrate that oral nicotine products continue to have little attractiveness to, and actual use by, youth.

Table 2 Comparison of Past 30-day Use (%) (95% CI Range) from 2023 NYTS Oral Nicotine Pouches

2021	2022	2023
95% CI: 0.6 – 1.0 (0.8)	95% CI: 0.8 – 1.2 (1.1)	95% CI: 1.0 – 2.1 (1.5)

A further comparison of the results from 2021 – 2022 and 2022 – 2023 do not suggest any meaningful increase in actual use of products in the oral nicotine pouch product category.¹³ The results from the 2023 NYTS are consistent with those observed in the previous year, reflecting that the significant declines observed in the use of e-cigarettes, the most popular tobacco product category among youth surveyed, were not associated with increased use of this tobacco product category. In other words, nicotine pouch patterns of use do not reflect any so-called “whack-a-mole” phenomenon¹⁴ of tobacco product switching behavior, involving switching of former current, past 30-day users of e-cigarettes to nicotine pouches. Similar declines in past 30-day cigar use, past 30-day combusted tobacco product use, and past 30-day any tobacco product use also did not result in a corresponding “whack-a-mole” increase

¹³ Please note the 95% confidence intervals of the ranges expressed in Table 2, above, do provide a robust degree of overlap between the results.

Regardless, the weighting process used in the 2023 NYTS, in order to reduce the potential for non-response bias, and make its results comparable to previous years’ results, may contribute to the trend in past 30-day use identified in Table 2.

¹⁴ This colloquial expression is often used to describe inter-and-intra tobacco product category switching behaviors. Whether these individuals choose or are forced out of a category due to availability or legality, they may find themselves transitioning to other tobacco product categories.

in the category of smokeless oral nicotine pouches. Rather, the 2023 NYTS results show the same low usage of this tobacco product category among youth observed in the 2021 NYTS and 2022 NYTS.¹⁵

Conclusions: The findings of the NYTS across the most-recently evaluated time periods (i.e., 2021 – 2023) continue to demonstrate that the oral nicotine pouch category is not attractive to youth or young adult users. Even with significant declines in use of the most popular tobacco product categories (i.e., e-cigarettes’ significant fall from 14% to 10% current use among high school students), there has not been a corresponding increase in use of this tobacco product category.

1.2 Swedish Match 2024 Marketing Program

While Swedish Match believes that the PMTA, as amended, continues to demonstrate that marketing of the ZYN Products is APPH, Swedish Match has updated its 2024 marketing program to eliminate the use of branded merchandise and limits branded signage. Swedish Match believes this change to its already robust marketing program will further support that marketing of the ZYN Products is APPH. **See Attachment-Swedish Match 2024 Marketing Program.**

1.3 Conclusion

Swedish Match is confident that the PMTA, as amended, demonstrates that marketing of the ZYN Products is APPH. Further, Swedish Match anticipates that post-market surveillance studies evaluating consumer behavior would provide further support for the evidence identified by the use behavior of the NYTS. Based on the totality of evidence within the PMTA, as amended demonstrate that the ZYN Products are a help to enable current, adult tobacco product users to switch to products lower on the continuum of risk without appealing to nonusers or youth. That unintended users of these products demonstrate little interest in the smokeless oral nicotine pouch category over three years of NYTS, with no “whack-a-mole” switching behaviors, further supports the APPH nature of the Zyn Products. Thus, granting a marketing order for the original ZYN Flagship Varieties would be APPH.

¹⁵ The 2023 NYTS results also did not show, among the limited number of middle school and high school students reporting current use of a flavored nicotine pouch product, meaningful use on particular types of flavors. See Centers for Disease Control and Prevention (U.S.) “SUPPLEMENTARY TABLE 3. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023” vol. 72, no. 44, 2023, <https://stacks.cdc.gov/view/cdc/134702#tabs-3>.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB Control No. 0910-0879
Expiration Date: 12/31/2025
(See Burden Statement on last page.)

Premarket Tobacco Product Application Amendment and General Correspondence Submission

The Applicant Identification section is comprised of three parts: Current Applicant Information; Request to Change Ownership; and the Addition, Update, Replacement, or Removal of information. Please provide the Applicant information most recently provided to the FDA under the heading: Subsection A: Current Applicant Information. Please provide the proposed new Applicant information under the heading: Subsection B: Request for Change in Ownership. The addition of other new information should be provided under the heading: Subsection C: Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact.

SECTION I – APPLICANT IDENTIFICATION

Subsection A.

Current Applicant Information (The person or organization (manufacturer/importer) seeking a marketing granted order for a new tobacco product)

Date of Submission

December 21, 2023

Name of Applicant (Provide only either a person's name or an organization's name)

Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title

Organization Name

Swedish Match USA Inc.

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

(b) (4)

Company Headquarters' D&B DUNS® Number

(b) (4)

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

1021 E., Cary Street

Address 2 (Apt., Suite, Bldg., etc.)		City
Suite 1600		Richmond
State, Province, or Territory	Country	ZIP or Postal Code
VA	USA	23219

Current Contact Name (Optional, for use only if Applicant is an organization)

Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Mr.	Gerard	J.	Roerty
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title
Jr.	Esg.		VP, Gen Counsel & Sec
Telephone (Include Country Code if applicable)		FAX	Email Address
804-787-5100			gerry.roerty@swedishmatch.com

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box)

☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Subsection B.**Request for Change in Ownership****Proposed New Applicant Information** *(Complete this section to change the current Applicant Information, the owner of the PMTA)*

Effective Date of Ownership Change

Name of Applicant *(Provide only either a person's name or an organization's name)*

Prefix (e.g., Mr., Mrs., Dr.)

First Name

M.I.

Last Name

Generational Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B Duns® Number

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Telephone *(Include Country Code if applicable)*

FAX

Email Address

New Contact Name *(Optional, for use only if Applicant is an organization)*

Prefix (e.g., Mr., Mrs., Dr.)

First Name

M.I.

Last Name

Generational Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Telephone *(Include Country Code if applicable)*

FAX

Email Address

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box)

☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

☐ A notice is included stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new applicant.☐ A notice is included stating the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the PMTA.**Transfer Requests**☐ Request to transfer all related submissions for the named product(s) to the new owner

Tobacco Product Name (Brand/Sub-brand)

Related Submissions: List the FDA Submission Tracking Numbers (STNs) for all your previous submissions for the tobacco product.

Related Submission Type	Related Submission STN	Submission Date

Subsection C.**Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact (Optional)****Addition, Update, Replacement, or Removal of Applicant Identification Information***If "Add" or "Replace" (not allowed for Current Applicant Information; use Subsection B.) is selected, provide all demographic information for the new party.**If "Update" is selected, provide only Person's Name and/or Organization's Name and the information which will replace previously submitted information.**If "Remove" is selected, provide only the Person's Name and/or Organization's Name of the party to be removed.*

Select type of Applicant Identification Information (Select only one)

- ☐ Applicant (Address and Contact information only) ☐ Authorized Representative ☐ U.S. Agent
☐ Manufacturer

Effective Date of Change

Select one *(If "Update" is selected, FDA will update the Applicant Identification address or contact information that was previously submitted):*

- ☐ Add ☐ Update ☐ Replace ☐ Remove

Person's Name *(Provide a person's name for Authorized Representative or U.S. Agent; optional for the Manufacturer)*

Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title

Organization Name (Provide an organization name for the Manufacturer)

Address and Contact Information

Primary Address (Street Address, P.O. Box; Provide the postal address for the Authorized Representative; optional for the Manufacturer or the U.S. Agent)

Street Address (Provide the physical location for the Manufacturer or the U.S. Agent; optional for the Authorized Representative)

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone (Include Country Code if applicable)	FAX	Email Address

New Contact Name *(Optional, for use only if Applicant is an organization; do not use in conjunction with Subsection B)*

Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title
Telephone (Include Country Code if applicable)	FAX	Email Address	

Organization Name and Address Information *(Optional, use for the Applicant only if a person (do not use in conjunction with Subsection B); also may be used for Authorized Representative, or U.S. Agent)*

Organization Name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code

Addition, Update, or Removal of Point of Contact

If "Add" is selected, provide all demographic information for the new party.

If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.

If "Remove" is selected, provide only the Company/Institution Name of the party to be removed.

Select type of Point of Contact Information (Select only one)

- | | | |
|-------------------------------------|--|--|
| <input type="checkbox"/> Applicant | <input type="checkbox"/> Manufacturer (Other than Applicant) | <input type="checkbox"/> Authorized Representative |
| <input type="checkbox"/> U.S. Agent | <input type="checkbox"/> Other, Regulatory | <input type="checkbox"/> Other, Technical |

Select one (If "Update" is selected, FDA will update the Point of Contact address or contact information that was previously submitted):

- ☐ Add ☐ Update ☐ Remove

Alternate Point of Contact Name

Company Name

Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title

Alternate Point of Contact Address and Contact Information

Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)		City
State, Province, or Territory	Country	ZIP or Postal Code
Telephone (Include Country Code if applicable)	FAX	Email Address

SECTION II – TOBACCO PRODUCT INFORMATION

(Note: Use this section to correct previously submitted information. This section is not intended to be used in place of submissions required for modifications for new tobacco products)

Unique Identification of Previously Submitted New Tobacco Product

(This Subsection is optional and to be used only to change previously submitted information)

For individual tobacco products, fill in the Individual Tobacco Product sub-section below.

For a co-packaged tobacco product, complete Section II for each new tobacco product included within the co-package.

For grouped submissions complete a separate Section II for each tobacco product.)

Individual Tobacco Product

(Only the Previously Submitted New Tobacco Product Name is required. Provide other information only for updates to previously submitted information. Refer to Form 4057, Section VIII, Appendix B to select the appropriate Product Category and Subcategory or Tobacco Product Properties.)

Select to Update or Withdraw New Tobacco Product ☒ Update ☐ Withdraw

Previously Submitted New Tobacco Product Name (Brand/Sub-Brand)

ZYN Cool Mint, Peppermint, Spearmint, Wintergreen, Citrus, Coffee, Cinnamon, Smooth, Chill, Fresh (3mg and 6mg)

Updated New Tobacco Product Name (Brand/Sub-Brand) *(if applicable)*

Update New Tobacco Product Category or Subcategory or Update New Tobacco Product Subcategory

(Complete only if Category or Subcategory is different than previously submitted)

Previously Submitted New Tobacco Product:

Category:

Subcategory:


Updated New Tobacco Product:

Category:

Subcategory:

Tobacco Product Properties Needed to Uniquely Identify the Product

(Update previously submitted Tobacco Product Properties Needed to Uniquely Identify Product by selecting Add, Update, or Remove and providing the Property Name. When updating properties provide both the previously submitted target value and the updated target value for the previously submitted new tobacco product.)

		New Tobacco Product Name (as provided above)	
Action (Add, Update, Remove)	Property Name	Previously Submitted Target Value	Updated Target Value
			

To submit information on additional tobacco product(s), use one or more copies of Section II as appropriate.

SECTION III – SUBMISSION INFORMATION**Type of Submission (Select only one)**

- ☒ Amendment (If selected, provide Date of FDA Letter, if applicable; select Amendment Response Type; and indicate the Scientific Content in Section IV - Amendment Contents)
- ☐ General Correspondence *(if selected, provide Subject of Correspondence)*

FDA Submission Tracking Number (STN) to be amended: PM0000593 - PM0000612

Date of FDA Letter *(if applicable mm/dd/yy)*:

Amendment Response Type (Select one)

- ☐ Deficiency Letter
- ☒ Unsolicited (Describe in Submission Summary)
- ☐ Other (Describe in Submission Summary)

Subject of Correspondence (Select all that apply)

- ☐ Request for Change in Ownership (Section I)
- ☐ Change in Authorized Representative, U.S. Agent, or Manufacturer Address or Contact Information (Section I)
- ☐ Addition or Removal of a Point of Contact (Section I)
- ☐ Update to Unique Identification Information (Section II)
- ☐ Change in Cross-referenced Content or Related Submissions (Section III)
- ☒ Change in Submission Contents (Section IV)
- ☐ Change in Manufacturing/Packaging/Sterilization Site Information (Section V)
- ☐ Adverse Experience Report (Describe in Submission Summary)
- ☐ Periodic Report (e.g., Annual Report) (Describe in Submission Summary)
- ☐ Request to Withdraw the PMTA

☐ Select to indicate if the withdrawal is due to a health or safety concern related to the tobacco product
- ☒ Other (Describe in Submission Summary)

Submission Summary (Required if instructed to "Describe" by a previous selection)

FDA STNs to be amended: PM0000593 - PM0000612. Providing the amendment to add/highlight recent 2023 NYTS data and provide our 2024 marketing program which states our intent to eliminate branded merchandise and sponsorships.

Purpose of Application (Check only one)

- ☐ This PMTA Amendment is for a single new tobacco product
- ☒ This PMTA Amendment is for a group of PMTA Amendments containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product

Cross-referenced Content
(Optional, use this subsection to add new cross-referenced content, or update or remove previously submitted information)

Select to Add, Update, or Remove Cross-referenced Content

- ☐ Add
- ☐ Update
- ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

- ☐ Select if this update to Cross-referenced Content is relevant to all amended products in this submission

Identify Cross-referenced Submission Types as one of the following: PMTA, Tobacco Product Master File, or Modified Risk Tobacco Product (MRTPA)

Cross-referenced Submission Type	Cross-referenced Submission STN

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Cool Mint 3mg and 6 mg

☒ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000593
PMTA Amendment	PM0000594
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Peppermint 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000595
PMTA Amendment	PM0000596
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

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Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Spearmint 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000597
PMTA Amendment	PM0000598
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

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(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Wintergreen 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000599
PMTA Amendment	PM0000600
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Citrus 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000601
PMTA Amendment	PM0000602
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Coffee 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000603
PMTA Amendment	PM0000604
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Cinnamon 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000605
PMTA Amendment	PM0000606
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Smooth 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000607
PMTA Amendment	PM0000608
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Chill 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000609
PMTA Amendment	PM0000610
**See additional Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

ZYN Fresh 3mg & 6mg

☐ Select if this update to Related Submission(s) is relevant to all amended products in this submission

Related Submission Type	Related Submission STN
PMTA Amendment	PM0000611
PMTA Amendment	PM0000612
**FINAL Page 8 copies for STNs	

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

Submission STN	Meeting Held Date

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Description of Marketing Plans

Inspections

(List the categories of Inspections content provided by this Amendment)

Scientific Content*(Select the categories of Scientific Content provided by this Amendment)*

Description of Scientific Content:

Published Literature; Tobacco Product Use Among U.S. Middle and High School Students — NYTS,2023 (MMWR)

Check all that apply

- | | |
|--|---|
| <input type="checkbox"/> General Information | <input checked="" type="checkbox"/> Literature Search |
| <input type="checkbox"/> Descriptive Information | <input type="checkbox"/> Organized References |
| <input type="checkbox"/> Product Samples | <input type="checkbox"/> Health Risk Investigations |
| <input type="checkbox"/> Statement of Compliance with 21 CFR part 25 | <input type="checkbox"/> Study Report(s) |
| <input type="checkbox"/> Summary | <input type="checkbox"/> Case Report Form(s) |
| <input type="checkbox"/> Product Formulation | <input type="checkbox"/> Analyzable Data Set(s) |
| <input type="checkbox"/> Manufacturing | |
| <input type="checkbox"/> Other (Specify below) | |

Other Content *(Describe the other content provided by this Amendment)***SECTION V – MANUFACTURING/PACKAGING/STERILIZATION SITE RELATING TO A SUBMISSION***(This section is optional.**If "Add" is selected, provide all demographic information for the new site.**If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.**If "Remove" is selected, provide only the Company/Institution Name of the site to be removed.)*

Select to Add, Update, or Remove Manufacturing/Packaging/Sterilization Site

- ☐
- Add
- ☐
- Update
- ☐
- Remove

Company/Institution Name

Specify type of Manufacturing/Packaging/Sterilization site

- ☐
- Manufacturer
- ☐
- Contract Manufacturer
- ☐
- Contract Sterilizer
- ☐
- Re-packer/Relabeler

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Division Name (if applicable)

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Telephone *(Include Country Code if applicable)*

FAX

Email Address

Contact Name			
Prefix (e.g., Mr., Mrs., Dr.)	First Name	M.I.	Last Name
Generational Suffix (e.g., Jr., III)	Professional Suffix (e.g., MD, Ph.D.)		Position Title
The Manufacturing/Packaging/Sterilization Site is ready for inspection <input type="checkbox"/> Yes <input type="checkbox"/> No			

SECTION VI – CERTIFICATION STATEMENT

Select one of the following, then enter Name of Applicant (or person signing on behalf of the Applicant if Applicant is an organization), Authorized Representative, or U.S. Agent, and the name of the Applicant in the body of the statement.

I am signing as a/an: ☐ Applicant ☒ Authorized Representative ☐ U.S. Agent

I,	First Name Gerard	M.I. J.	Last Name Roerty	Generational Suffix (e.g., Jr., III) Jr.
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on behalf of the applicant, Swedish Match USA Inc.

hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

Signature	(b) (6)	Date	12/21/23
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**APPENDIX
INSTRUCTIONS FOR USE**

This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for a Premarket Tobacco Product Application (PMTA) Amendment and General Correspondence Submission.

Section I – Applicant Identification

Subsection A – Current Applicant Information

- Complete the Date of Submission
- Complete Name of Applicant name and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Complete Applicant address information as previously submitted, and optionally provide contact name, telephone, and email address. (Changes to the current Applicant information should be made only in Subsection C.)
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.

Subsection B – Request for Change in Ownership 21 CFR 1114.13

- Provide the effective date of the change in ownership.
- Complete the Name of the New Applicant and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Provide the Applicant address information, and optionally provide contact name, telephone, and email address.
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.
- Indicate if any notices are included in the submission regarding the transfer of ownership. (List the notice(s) in Section IV under Administrative contents.)
- Indicate if you are transferring all related submissions related to a brand or brands. If so, provide the tobacco product names and corresponding STNs subject to the change in ownership

**Subsection C – Addition, Update, or Removal of Applicant Identification Information or Point of Contact
21 CFR 1114.9**

- Optionally select the type of Applicant information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, replace, or remove Applicant Information.
- To add a new party, complete all information. An Authorized Representative or U.S. Agent must be a person. Provide the person's name, address, and contact information.
- To update or remove party information, the Person's Name or Organization Name must match previously submitted information. For updates, the Address and Contact information provided will be used to update previously provided information.
- To replace a party, the Person's Name or Organization Name must match previously submitted information. It is not necessary to provide address information.
- To provide additional Applicant Identification Information, select "Update Additional Applicant Identification Information" on the form.
- Optionally select the type of Point of Contact information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, or remove Point of Contact information.
- Provide the Company Name associated with the Point of Contact
- To add a new Point of Contact, complete all information. Provide the contact's name, address, and contact information.
- To update or remove information for a Point of Contact, the Person's Name must match previously submitted information.
- To provide information for an addition Point of Contact, the Person's Name must match previously submitted information

Section II – Tobacco Product Identification 21 CFR 1114.7(c)

- For an individual tobacco product, provide the previously submitted new tobacco product's names.
 - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a co-packaged tobacco product, provide the new tobacco products' names for all products in the co-packaged tobacco product.
 - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a grouped submission, add an individual or co-packaged tobacco product by selecting "Add Section II" on the form.

Section III – Submission Information

- Indicate whether the submission is an Amendment or General Correspondence.
 - For Amendments, provide the Date of FDA Letter, if applicable, and select the Amendment Response Type. If the type of response, is "Unsolicited" or "Other", describe the purpose of the submission in the Submission Summary. Also indicate the subject of the amendment provided in Section IV – Amendment and General Correspondence Contents.
 - For General Correspondence, select Subject(s) of Correspondence and provide the appropriate information in the Section indicated. If "Other", describe the subject of the correspondence in the Submission Summary. Also describe the subject of the correspondence in Section IV - Amendment and General Correspondence Contents
 - Provide the FDA STN being amended. The Premarket Tobacco Application Amendment and General Correspondence Submission should be used to update only one STN.
 - If instructed to do so, based on the selection of either Amendment Response Type or Subject of Correspondence, or otherwise optionally, complete the Submission Summary.
 - Indicate whether the Amendment submission is for a single individual tobacco product or for a group of tobacco products previously submitted as a grouped PMTA submission.
 - Optionally add, update, or remove cross-referenced content, including Tobacco Product Master Files
 - Provide the New Tobacco Product Name for which the cross-referenced content is relevant. Optionally, indicate if the content is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.
 - Provide metadata for each document to identify the cross-referenced content.
 - Select "Update Cross-Referenced Content Information" to add metadata for an additional document.
 - Optionally add, update, or remove related submissions, (e.g., ITP, SE Report, MRTPA).
 - Provide the New Tobacco Name for which the related submission is relevant. Optionally, indicate if the submission is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.
-

Section IV – Amendment and General Correspondence Contents

- Select the categories of document submitted from among Administrative, Labeling and Marketing Plans, Inspections, Scientific Content, or Other. For each category (except Scientific Content), list the sub-categories that describe the submission contents. For Scientific Content, select the all the content categories that apply to content provided in this amendment submission. For Scientific Content that does not fit into one of the listed categories, select “Other” and describe the content in the space provided.
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Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023

Jan Birdsey, MPH¹; Monica Cornelius, PhD¹; Ahmed Jamal, MBBS¹; Eunice Park-Lee, PhD²; Maria R. Cooper, PhD²; Jia Wang, MPH²; Michael D. Sawdey, PhD²; Karen A. Cullen, PhD²; Linda Neff, PhD¹

Abstract

Tobacco product use during adolescence increases the risk for lifelong nicotine addiction and adverse health consequences. CDC and the Food and Drug Administration analyzed data from the 2023 National Youth Tobacco Survey to assess tobacco product use patterns among U.S. middle school (grades 6–8) and high school (grades 9–12) students. In 2023, 10.0% of middle and high school students (2.80 million) reported current (i.e., past 30-day) use of any tobacco product. Current use of any tobacco product by high school students declined by an estimated 540,000, from 2.51 million in 2022 to 1.97 million in 2023. From 2022 to 2023, current e-cigarette use among high school students declined from 14.1% to 10.0%. Among middle and high school students, e-cigarette products were the most used tobacco product in 2023 (7.7%; 2.13 million), followed by cigarettes (1.6%), cigars (1.6%), nicotine pouches (1.5%), smokeless tobacco (1.2%), other oral nicotine products (1.2%), hookahs (1.1%), heated tobacco products (1.0%), and pipe tobacco (0.5%). Among students who had ever used an e-cigarette, 46.7% reported current use. In 2023, among students reporting current e-cigarette use, 89.4% used flavored products and 25.2% used an e-cigarette daily; the most commonly reported brands were Elf Bar, Esco Bars, Vuse, JUUL, and Mr. Fog. Given the number of middle and high school students that use tobacco products, sustained efforts to prevent initiation of tobacco product use among young persons and strategies to help young tobacco users quit are critical to reducing U.S. youth tobacco product use.

Introduction

Commercial tobacco use* among U.S. youths can lead to lifelong nicotine addiction (1) and subsequent disability,

disease, and death (2). This report presents findings from the 2023 National Youth Tobacco Survey (NYTS) and describes the prevalence of ever use (i.e., ever having used, even once or twice) and current use of nine tobacco product types, flavored tobacco products, and e-cigarette use behaviors among U.S. middle and high school students. In addition, 2023 NYTS results are compared with those reported for 2022 NYTS data (3).

Methods

Data Collection

The NYTS is a cross-sectional, school-based, self-administered web-based survey of U.S. middle and high school students. A stratified, three-stage cluster sampling procedure

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*The term “tobacco” as used in this report refers to commercial tobacco products and not to sacred and traditional use of tobacco by some American Indian communities.



was used to generate a nationally representative sample of U.S. students attending private or public middle (grades 6–8) and high (grades 9–12) schools. In 2023, data were collected during March 9–June 16; a total of 22,069 students from 179 schools participated, with an overall response rate of 30.5%.

Data Analysis

National weighted prevalence estimates, 95% CIs, and population totals[†] were calculated for ever use (i.e., ever having used, even once or twice) and current use (i.e., use on ≥1 days during the past 30 days) of nine commercial tobacco products[§] (e-cigarettes, cigarettes, cigars, smokeless tobacco, nicotine pouches,[¶] hookahs, pipe tobacco, heated tobacco

products,^{**} and other oral nicotine products) by student characteristics. Three composite measures were also reported for use of any tobacco product,^{††} any combustible tobacco product,^{§§} and multiple tobacco products.^{¶¶} Current e-cigarette use (i.e., use on ≥1 day during the past 30 days) was reported by frequency of use, device type,^{***} brand,^{†††} and flavor.^{§§§}

[†] Data were weighted to account for complex survey design and to adjust for nonresponse. The weighted proportions of students in each grade matched national population proportions for U.S. public and private schools derived from data from Market Data Retrieval Inc. 2021–2022 Common Core of Data and the National Center for Education Statistics 2019–2020 Private School Universe Study. Population total estimates were rounded down to the nearest 10,000 persons.

[§] Products include e-cigarettes, cigarettes, cigars (cigars, cigarillos, or little cigars), smokeless tobacco (chewing tobacco, snuff, dip, or snus), hookahs, heated tobacco products, nicotine pouches, pipe tobacco, bidis (small brown cigarettes wrapped in a leaf), and other oral nicotine products (lozenges, discs, tablets, gums, dissolvable tobacco products, and other products). In 2023, dissolvable tobacco products were reclassified from smokeless tobacco to other oral nicotine products.

[¶] Small, flavored pouches contain nicotine that comes from tobacco. Users place them in their mouth. Nicotine pouches are different from other smokeless tobacco products such as snus, dip, or chewing tobacco, because they do not contain any tobacco leaf.

^{**} Heated tobacco products heat processed tobacco leaf in the form of sticks (“heatsticks”), plugs, or capsules to produce a vapor that the user inhales. They are different from e-cigarettes, which heat a liquid to produce a vapor.

^{††} Any tobacco product use was defined as use of one or more of the following tobacco products: e-cigarettes, cigarettes, cigars, smokeless tobacco, hookahs, heated tobacco products, nicotine pouches, pipe tobacco, bidis, or other oral nicotine products.

^{§§} Any combustible tobacco product use is defined as use of one or more of the following tobacco products: cigarettes, cigars, hookahs, pipe tobacco, or bidis.

^{¶¶} Multiple tobacco product use was defined as use of two or more of the following tobacco products: e-cigarettes, cigarettes, cigars, smokeless tobacco, hookahs, heated tobacco products, nicotine pouches, pipe tobacco, bidis, or other oral nicotine products.

^{***} Categories used are “disposables,” “prefilled or refillable pods or cartridges,” “tanks or mod system,” or “don’t know the type.” Disposable e-cigarettes come prefilled with e-liquid and are designed to be discarded once empty. Some pods or cartridges come prefilled with e-liquid that is replaced after use, although others can be refilled by the user. Tank or mod-type devices can also be refilled but are also usually customizable.

^{†††} Brand response options included blu, Breeze, Elf Bar, Esco Bars, Fume, HQD, JUUL, Kangvape (including Once Stick), Logic, Mr. Fog, NJOY, SMOK (including NOVO), Suorin (including Air Bar), Vuse, “some other brand(s) not listed here” with space for a write-in name, and “not sure/I don’t know the brand.” Write-in responses corresponding to an original response option were recoded.

^{§§§} Flavor type was determined by response to the question, “In the past 30 days when you used e-cigarettes, what flavors did you use? (Select one or more).” Those who selected “some other flavor not listed here” could provide a write-in response; write-in responses corresponding to an original response option were recoded.

The *MMWR* series of publications is published by the Office of Science, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. *MMWR Morb Mortal Wkly Rep* 2023;72:[inclusive page numbers].

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Changes in current-use prevalence since 2022 were estimated using t-tests; details of the 2022 NYTS data collection and estimates have been published previously (3). P-values <0.05 were considered statistically significant. Analyses were conducted using SAS-callable SUDAAN software (version 11.0.4; Research Triangle Institute). Estimates with an unweighted denominator <50 or a relative SE >30% were suppressed. This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.^{¶¶¶}

Results

Tobacco Product Use by Population

In 2023, 22.2% of U.S. middle and high school students reported ever using any tobacco product, corresponding to 6.21 million persons (Table 1); 10.0% of students reported current use of any tobacco product, corresponding to 2.80 million persons (Table 2). Overall, current use of any tobacco product was reported by 11.2% of female, 8.9% of male, 12.6% of non-Hispanic multiracial (multiracial), 11.7% of Hispanic or Latino (Hispanic), 9.5% of non-Hispanic White (White), 9.3% of non-Hispanic Black or African American (Black), and 8.0% of non-Hispanic American Indian or Alaska Native (AI/AN) students.^{****} Current use of any combustible tobacco product was reported by 4.7% of Black, 3.9% of Hispanic, 3.7% of multiracial, and 2.7% of White and AI/AN students.

Types of Tobacco Products Used

E-cigarettes were the most commonly reported currently used tobacco product among all students (7.7%) and both middle school (4.6%) and high school students (10.0%). Other currently used tobacco products included cigarettes (1.6%), cigars (1.6%), nicotine pouches (1.5%), smokeless tobacco (1.2%), other oral nicotine products (1.2%), hookahs (1.1%), heated tobacco products (1.0%), and pipe tobacco (0.5%). Among students who had ever used e-cigarettes, 46.7% reported current e-cigarette use.

Characteristics of E-cigarette Use

Among students reporting current e-cigarette use, 25.2% reported using e-cigarettes daily. Frequent use (≥20 of the past 30 days) was reported by 34.7% of current e-cigarette users (Table 3). Disposable e-cigarettes were the most commonly reported device type used (60.7%), followed by prefilled or refillable pods or cartridges (16.1%), and tanks or mod systems

(modifiable devices allowing users to customize the substances in the device) (5.9%). Among students who currently used e-cigarettes, Elf Bar was the most commonly reported brand (56.7%), followed by Esco Bars (21.6%), Vuse (20.7%), JUUL (16.5%), and Mr. Fog (13.6%).

Among students reporting current e-cigarette use, 89.4% reported using a flavored product during the past 30 days, excluding those who only used tobacco-flavored or unflavored e-cigarettes (Table 3). Among students who currently used e-cigarettes, fruit- (63.4%) and candy- (35.0%) flavored categories were reported most commonly; 6.4% of students reported use of tobacco-flavored e-cigarettes. Among those who currently used disposable e-cigarettes, the top reported flavor categories were fruit (70.5%), candy (39.8%), mint (32.0%), menthol (18.7%), unflavored (7.8%), alcoholic drinks (7.2%), and tobacco-flavored (5.4%) (Supplementary Table 1, <https://stacks.cdc.gov/view/cdc/134700>). Among students reporting current use of any tobacco product, 86.9% used a flavored product, ranging from 40.4% of cigarette users (menthol) to 89.4% of e-cigarette users (Supplementary Table 2, <https://stacks.cdc.gov/view/cdc/134701>). Among students currently using tobacco products, use of products with “ice” or “iced”^{††††} included in the flavor name was reported by 57.9% of e-cigarette users, 25.9% of nicotine pouch users, and 22.6% of cigar users; use of concept flavors^{§§§§} was reported by 16.1% of e-cigarette users and 13.4% of cigar users (Supplementary Table 3, <https://stacks.cdc.gov/view/cdc/134702>).

Tobacco Product Use Over Time

From 2022 to 2023, among high school students, statistically significant declines ($p<0.05$) occurred in current use of any tobacco product (from 16.5% to 12.6%), e-cigarettes (from 14.1% to 10.0%), cigars (from 2.8% to 1.8%), and any combustible tobacco product (from 5.2% to 3.9%). Among middle school students, statistically significant increases ($p<0.05$) occurred in current use of any tobacco product (from 4.5% to 6.6%) and multiple tobacco products (from 1.5% to 2.5%). Among middle school and high school students combined, no

^{††††} Current users were asked, “Did any of the flavors you used in the past 30 days have names or descriptions that included the word ‘ice’ or ‘iced’ (for example, blueberry ice or strawberry ice)?” Those who reported using only “unflavored” e-cigarettes (n = 60) or nicotine pouches (n = 11) were not asked the question.

^{§§§§} Current users were asked, “Did any of the flavors that you used in the past 30 days have a name that did not describe a specific flavor, such as ‘solar,’ ‘purple,’ ‘jazz,’ ‘island bash,’ ‘fusion,’ or some other word or phrase?” Those who reported using only “unflavored” e-cigarettes (n = 60) or nicotine pouches (n = 11) were not asked the question.

^{¶¶¶} 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

^{****} Estimates among non-Hispanic Asian and non-Hispanic Native Hawaiian or other Pacific Islander students were statistically unreliable for all current measures and are not reported.

TABLE 1. Percentage of middle and high school students who reported ever using tobacco products,* by product, overall and by school level, sex, and race and ethnicity — National Youth Tobacco Survey, United States, 2023

Tobacco product	% (95% CI)									Total estimated weighted no. [§]
	Sex		Race and ethnicity [†]							
	Female	Male	AI/AN, NH	Asian, NH	Black or African American, NH	White, NH	Hispanic or Latino	Multiracial, NH	Total	
Overall										
Any tobacco product [¶]	23.7 (21.5–26.0)	20.8 (18.9–22.8)	22.7 (16.8–30.0)	12.1 (6.5–21.5)	20.1 (17.7–22.6)	23.1 (20.2–26.2)	23.8 (22.2–25.4)	27.9 (22.5–33.9)	22.2 (20.5–23.9)	6,210,000
E-cigarettes	19.4 (17.5–21.5)	14.7 (13.2–16.3)	15.4 (10.7–21.8)	—**	12.9 (11.1–14.8)	18.4 (15.9–21.1)	18.2 (16.3–20.2)	20.8 (15.9–26.8)	17.0 (15.6–18.5)	4,750,000
Cigarettes	7.0 (6.0–8.1)	6.5 (5.4–7.7)	9.5 (5.6–15.5)	—	4.1 (2.9–5.8)	7.5 (6.3–8.9)	7.4 (5.9–9.2)	8.7 (6.0–12.4)	6.7 (6.0–7.6)	1,840,000
Cigars ^{††}	3.8 (2.9–4.8)	5.8 (4.8–7.0)	—	—	4.7 (3.4–6.4)	5.2 (4.1–6.6)	4.7 (4.0–5.5)	6.9 (4.8–9.8)	4.8 (4.0–5.6)	1,300,000
Hookahs	3.4 (2.4–4.8)	2.7 (1.9–3.8)	—	—	4.5 (2.7–7.2)	2.5 (1.7–3.5)	3.5 (2.7–4.5)	3.6 (2.4–5.2)	3.0 (2.4–3.9)	820,000
Smokeless tobacco (composite) ^{††}	2.2 (1.7–2.9)	3.7 (2.8–4.8)	—	—	1.3 (0.8–2.1)	3.4 (2.5–4.6)	2.9 (2.2–3.8)	5.0 (3.3–7.5)	3.0 (2.4–3.6)	800,000
Other oral nicotine products ^{††}	2.7 (2.1–3.4)	3.2 (2.6–4.1)	4.9 (2.8–8.5)	—	1.7 (1.1–2.6)	3.2 (2.4–4.1)	3.5 (2.7–4.6)	4.2 (2.4–7.2)	3.0 (2.5–3.5)	800,000
Nicotine pouches	1.7 (1.2–2.4)	3.0 (2.2–4.1)	—	—	—	3.0 (2.3–3.9)	2.0 (1.2–3.2)	—	2.3 (1.8–3.0)	580,000
Pipe tobacco	1.5 (1.1–2.0)	1.9 (1.4–2.5)	—	—	—	1.8 (1.3–2.5)	2.0 (1.5–2.7)	2.3 (1.3–3.9)	1.7 (1.4–2.0)	440,000
Heated tobacco products	1.5 (1.1–2.0)	1.5 (1.0–2.1)	—	—	1.7 (1.0–2.9)	1.4 (0.9–2.0)	1.8 (1.3–2.4)	1.6 (0.9–3.0)	1.5 (1.1–2.0)	370,000
Any combustible tobacco product ^{§§}	10.9 (9.3–12.8)	11.6 (10.1–13.2)	11.1 (7.0–17.1)	4.4 (2.4–7.8)	11.2 (8.5–14.7)	11.6 (9.7–13.7)	12.0 (10.4–13.8)	14.4 (11.0–18.5)	11.2 (9.9–12.7)	3,090,000
Multiple tobacco products ^{¶¶}	10.1 (8.7–11.8)	9.6 (8.4–10.9)	11.0 (7.2–16.3)	3.6 (2.1–6.0)	7.3 (5.5–9.7)	10.8 (9.1–12.8)	10.3 (8.9–11.8)	13.3 (10.1–17.3)	9.8 (8.7–11.1)	2,750,000
High school students (grades 9–12)										
Any tobacco product [¶]	30.1 (26.9–33.5)	25.9 (23.5–28.5)	29.0 (19.1–41.5)	—	21.8 (18.8–25.2)	31.4 (28.0–34.9)	27.3 (24.8–29.8)	35.1 (27.3–43.7)	27.9 (25.8–30.2)	4,390,000
E-cigarettes	26.0 (23.2–29.0)	19.5 (17.6–21.5)	20.3 (12.5–31.2)	—	14.7 (11.7–18.2)	26.0 (23.0–29.2)	22.3 (20.0–24.9)	27.5 (20.9–35.3)	22.6 (20.9–24.5)	3,550,000
Cigarettes	8.8 (7.3–10.6)	8.3 (7.0–9.7)	—	—	3.0 (1.8–5.0)	10.5 (9.0–12.1)	8.8 (6.9–11.1)	10.5 (6.8–15.7)	8.5 (7.7–9.5)	1,310,000
Cigars ^{††}	4.8 (3.6–6.4)	7.9 (6.3–9.9)	—	—	4.8 (3.2–7.1)	7.8 (6.1–10.0)	5.4 (4.4–6.6)	9.6 (6.4–14.0)	6.4 (5.3–7.7)	980,000
Hookahs	4.0 (2.7–5.9)	3.5 (2.3–5.4)	—	—	—	3.6 (2.5–5.3)	3.9 (2.7–5.5)	3.3 (1.9–5.8)	3.7 (2.8–5.1)	560,000
Smokeless tobacco (composite) ^{††}	2.2 (1.5–3.2)	4.3 (3.3–5.7)	—	—	—	3.8 (2.8–5.1)	2.9 (2.1–4.0)	6.9 (4.1–11.4)	3.3 (2.6–4.1)	500,000
Other oral nicotine products ^{††}	2.8 (2.0–4.0)	4.0 (3.1–5.3)	—	—	1.6 (0.9–2.7)	4.1 (3.0–5.4)	3.8 (3.0–4.8)	—	3.5 (2.8–4.2)	520,000
Nicotine pouches	2.0 (1.4–2.9)	4.1 (3.0–5.6)	—	—	—	4.5 (3.5–5.7)	1.8 (1.1–2.8)	—	3.1 (2.4–4.0)	430,000
Pipe tobacco	1.7 (1.2–2.5)	2.4 (1.8–3.2)	—	—	—	2.7 (2.0–3.5)	2.2 (1.5–3.2)	3.3 (2.0–5.5)	2.1 (1.7–2.5)	310,000
Heated tobacco products	1.7 (1.2–2.5)	1.6 (1.0–2.4)	—	—	—	1.8 (1.2–2.8)	1.5 (0.9–2.3)	—	1.6 (1.2–2.3)	230,000
Any combustible tobacco product ^{§§}	13.6 (11.3–16.2)	14.9 (13.0–16.9)	—	—	10.7 (8.2–14.0)	16.4 (14.1–19.1)	13.8 (11.7–16.3)	17.5 (12.6–23.7)	14.2 (12.6–16.1)	2,190,000
Multiple tobacco products ^{¶¶}	12.8 (10.5–15.4)	12.6 (11.1–14.2)	14.2 (8.0–24.0)	4.6 (2.5–8.3)	7.1 (4.9–10.1)	15.4 (13.1–18.1)	11.7 (10.0–13.6)	17.1 (12.2–23.3)	12.7 (11.1–14.4)	1,990,000

See table footnotes on the next page.

TABLE 1. (Continued) Percentage of middle and high school students who reported ever using tobacco products,* by product, overall and by school level, sex, and race and ethnicity — National Youth Tobacco Survey, United States, 2023

Tobacco product	% (95% CI)									Total estimated weighted no. [§]
	Sex		Race and ethnicity [†]						Total	
	Female	Male	AI/AN, NH	Asian, NH	Black or African American, NH	White, NH	Hispanic or Latino	Multiracial, NH		
Middle school students (grades 6–8)										
Any tobacco product [¶]	15.4 (12.9–18.3)	13.8 (11.3–16.6)	15.3 (9.7–23.2)	—	17.8 (12.9–24.0)	12.3 (10.0–14.9)	18.7 (16.5–21.1)	17.6 (13.0–23.6)	14.7 (12.5–17.1)	1,780,000
E-cigarettes	11.0 (9.1–13.3)	8.2 (6.9–9.8)	—	—	10.6 (8.5–13.1)	8.4 (6.8–10.3)	12.3 (10.5–14.4)	11.3 (6.3–19.5)	9.7 (8.3–11.3)	1,170,000
Cigarettes	4.6 (3.6–5.9)	4.0 (2.7–5.9)	—	—	5.5 (3.9–7.8)	3.5 (2.5–5.1)	5.3 (3.8–7.2)	—	4.3 (3.3–5.5)	510,000
Cigars ^{††}	2.4 (1.6–3.6)	2.9 (2.0–4.2)	—	—	4.6 (2.8–7.4)	1.7 (1.1–2.6)	3.5 (2.3–5.3)	—	2.6 (1.9–3.7)	310,000
Hookahs	—	1.7 (1.2–2.3)	—	—	—	0.9 (0.5–1.6)	2.9 (2.1–4.0)	—	2.1 (1.4–3.2)	240,000
Smokeless tobacco (composite) ^{††}	2.3 (1.6–3.1)	2.7 (1.8–4.0)	—	—	—	2.9 (1.9–4.4)	2.5 (1.6–3.9)	—	2.4 (1.8–3.3)	290,000
Other oral nicotine products ^{††}	2.4 (1.8–3.2)	2.1 (1.6–2.7)	—	—	—	2.0 (1.4–2.9)	2.9 (1.8–4.4)	2.9 (1.6–5.2)	2.2 (1.8–2.7)	260,000
Nicotine pouches	—	—	—	—	—	1.0 (0.6–1.8)	—	—	—	—
Pipe tobacco	1.1 (0.6–2.0)	1.1 (0.6–2.0)	—	—	—	—	1.7 (1.2–2.4)	—	1.1 (0.7–1.6)	120,000
Heated tobacco products	1.2 (0.7–1.9)	—	—	—	—	0.8 (0.5–1.5)	2.1 (1.6–2.8)	—	1.2 (0.8–1.8)	130,000
Any combustible tobacco product ^{§§}	7.5 (5.7–10.0)	7.2 (5.1–9.9)	6.6 (3.6–11.7)	—	11.9 (7.0–19.4)	5.3 (3.8–7.3)	9.3 (7.3–11.7)	9.8 (6.4–14.8)	7.3 (5.6–9.4)	870,000
Multiple tobacco products ^{¶¶}	6.7 (5.3–8.6)	5.5 (4.2–7.2)	—	—	7.6 (4.7–12.2)	4.7 (3.5–6.2)	8.0 (6.0–10.6)	7.9 (5.3–11.6)	6.1 (4.9–7.5)	740,000

Abbreviations: AI/AN = American Indian or Alaska Native; NH = non-Hispanic.

* Ever use is defined as ever having used the product, even once or twice. Because of missing data on the ever use questions, denominators for each tobacco product might be different. For each question, response options were “yes” or “no.”

† Hispanic or Latino persons could be of any race. Estimates among NH Native Hawaiian or other Pacific Islander students, overall and by school level, were statistically unreliable for all measures and are not presented in this table.

§ Estimated weighted total number of ever tobacco product users was rounded down to the nearest 10,000 persons. Overall estimates were reported based on 22,069 U.S. middle and high school students. School level was determined by reported grade level: high school (grades 9–12; n = 10,879) and middle school (grades 6–8; n = 11,067). The sum of subgroup estimates might not sum to overall population estimates because of rounding or exclusion of students who did not report sex, race and ethnicity, or grade level.

¶ Any tobacco product use is defined as ever use of one or more of the following tobacco products: e-cigarettes, cigars, cigarettes, smokeless tobacco (composite), hookahs, nicotine pouches, heated tobacco products, pipe tobacco, bidis (small brown cigarettes wrapped in a leaf), or other oral nicotine products.

** Dashes indicate that data were statistically unreliable because of an unweighted denominator <50 or a relative SE >30%.

†† Cigars were defined as cigars, cigarillos, or little cigars. Smokeless tobacco (composite) was defined as chewing tobacco, snuff, dip, or snus. Other oral nicotine products were defined as lozenges, discs, tablets, gums, dissolvable tobacco products, and other products. In 2023, dissolvable tobacco products were reclassified from smokeless tobacco to other oral nicotine products.

§§ Any combustible tobacco product use was defined as ever use of one or more of the following tobacco products: cigarettes, cigars, hookahs, pipe tobacco, or bidis.

¶¶ Multiple tobacco product use was defined as ever use of two or more of the following tobacco products: e-cigarettes, cigars, cigarettes, smokeless tobacco (composite), hookahs, nicotine pouches, heated tobacco products, pipe tobacco, bidis, or other oral nicotine products.

significant change in current use of any composite measure or individual tobacco product was observed.

Discussion

Current use of any tobacco product by high school students declined by an estimated 540,000 students, from 2.51 million in 2022 (3) to 1.97 million in 2023. In 2023, 22.2% of middle and high school students (representing 6.21 million) reported

ever using any tobacco product, and 10.0% of students (representing 2.80 million) reported current use of any tobacco product. Similar to 2022 (3), ever use of any tobacco product was lowest among non-Hispanic Asian students and did not differ significantly across most racial and ethnic groups.

E-cigarettes have been the most commonly used tobacco product among U.S. youths since 2014 (4). Youth e-cigarette use is a critical public health concern, because approximately

TABLE 2. Percentage of middle and high school students who reported current (past 30-day) tobacco product use, by product,* overall and by school level, sex, and race and ethnicity — National Youth Tobacco Survey, United States, 2023

Tobacco product	% (95% CI)								Total estimated weighted no. [§]
	Sex		Race and ethnicity [†]					Total	
	Female	Male	AI/AN, NH	Black or African American, NH	White, NH	Hispanic or Latino	Multiracial, NH		
Overall									
Any tobacco product [¶]	11.2 (9.5–13.1)	8.9 (7.7–10.3)	8.0 (4.7–13.2)	9.3 (7.5–11.3)	9.5 (7.7–11.6)	11.7 (10.1–13.4)	12.6 (8.8–17.7)	10.0 (8.9–11.2)	2,800,000
E-cigarettes	9.3 (8.1–10.8)	6.1 (5.0–7.4)	5.9 (3.4–10.0)	5.6 (4.5–7.1)	7.7 (6.3–9.4)	8.5 (7.4–9.8)	10.2 (6.8–15.1)	7.7 (6.8–8.6)	2,130,000
Cigarettes	1.4 (1.0–1.9)	1.8 (1.4–2.4)	— ^{**}	—	1.6 (1.1–2.3)	2.1 (1.5–3.1)	1.6 (1.0–2.8)	1.6 (1.2–2.1)	430,000
Cigars	1.3 (0.9–2.0)	1.8 (1.4–2.3)	—	2.3 (1.4–3.8)	1.0 (0.7–1.4)	2.2 (1.7–2.8)	—	1.6 (1.2–2.0)	420,000
Nicotine pouches	0.8 (0.5–1.3)	2.1 (1.5–3.0)	—	—	1.4 (0.9–2.2)	1.9 (1.1–3.3)	—	1.5 (1.0–2.1)	400,000
Smokeless tobacco (composite) ^{††}	—	1.6 (1.1–2.3)	—	—	1.2 (0.7–1.8)	1.6 (1.1–2.4)	—	1.2 (0.9–1.7)	330,000
Other oral nicotine products	1.1 (0.9–1.4)	1.2 (0.9–1.7)	0.5 (0.3–0.8)	—	1.2 (0.9–1.5)	1.5 (1.1–2.0)	—	1.2 (1.0–1.4)	310,000
Hookahs	1.3 (0.8–2.1)	0.9 (0.6–1.3)	—	—	0.7 (0.4–1.1)	1.3 (1.0–1.7)	1.3 (0.7–2.4)	1.1 (0.8–1.5)	290,000
Heated tobacco products	0.7 (0.5–1.0)	1.2 (0.8–1.9)	—	1.0 (0.5–1.7)	0.7 (0.4–1.2)	1.5 (1.0–2.2)	—	1.0 (0.7–1.3)	260,000
Pipe tobacco	0.5 (0.3–0.7)	0.6 (0.4–0.9)	—	—	0.5 (0.3–0.8)	0.9 (0.5–1.4)	—	0.5 (0.4–0.7)	130,000
Any combustible tobacco product ^{§§}	3.3 (2.6–4.1)	3.5 (2.9–4.2)	2.7 (1.5–4.9)	4.7 (3.1–7.0)	2.7 (2.2–3.5)	3.9 (3.1–4.8)	3.7 (2.4–5.5)	3.4 (2.9–4.0)	920,000
Multiple tobacco products ^{¶¶}	3.4 (2.7–4.2)	3.4 (2.7–4.2)	2.0 (1.1–3.5)	3.2 (1.8–5.5)	3.1 (2.4–4.0)	3.9 (3.4–4.5)	4.1 (2.6–6.5)	3.4 (2.9–3.9)	940,000
High school students (grades 9–12)									
Any tobacco product [¶]	14.1 (11.6–17.0)	11.2 (9.4–13.1)	—	9.8 (7.7–12.5)	13.6 (11.2–16.5)	12.4 (10.6–14.4)	17.2 (11.3–25.3)	12.6 (11.1–14.3)	1,970,000
E-cigarettes	12.2 (10.3–14.5)	8.0 (6.3–10.0)	—	5.6 (4.2–7.4)	11.3 (9.2–13.7)	9.7 (8.0–11.8)	14.2 (9.0–21.8)	10.0 (8.8–11.4)	1,560,000
Cigarettes	1.5 (1.0–2.2)	2.3 (1.8–2.9)	—	—	2.2 (1.4–3.4)	2.2 (1.6–3.0)	—	1.9 (1.5–2.4)	290,000
Cigars	1.4 (0.8–2.3)	2.3 (1.7–3.0)	—	1.9 (1.2–3.0)	1.4 (0.9–2.2)	2.3 (1.6–3.3)	—	1.8 (1.4–2.4)	280,000
Nicotine pouches	—	2.6 (1.9–3.6)	—	—	2.2 (1.4–3.4)	1.6 (0.9–2.7)	—	1.7 (1.2–2.5)	260,000
Smokeless tobacco (composite) ^{††}	—	2.1 (1.4–3.0)	—	—	1.7 (1.1–2.6)	1.7 (1.1–2.7)	—	1.5 (1.1–2.2)	230,000
Other oral nicotine products	0.9 (0.7–1.3)	1.5 (1.0–2.2)	—	—	1.3 (1.0–1.8)	1.6 (1.1–2.2)	—	1.2 (1.0–1.6)	180,000
Hookahs	1.4 (0.8–2.4)	0.9 (0.6–1.5)	—	—	—	1.0 (0.6–1.6)	—	1.1 (0.8–1.6)	170,000
Heated tobacco products	0.7 (0.4–1.2)	1.4 (0.8–2.5)	—	—	—	1.6 (0.9–2.7)	—	1.0 (0.7–1.6)	150,000
Pipe tobacco	0.5 (0.3–0.9)	0.7 (0.4–1.2)	—	—	0.6 (0.4–1.0)	—	—	0.6 (0.4–0.9)	90,000
Any combustible tobacco product ^{§§}	3.6 (2.7–4.7)	4.3 (3.6–5.2)	—	4.5 (3.2–6.2)	3.8 (3.0–5.0)	3.8 (2.8–5.0)	5.3 (3.3–8.6)	3.9 (3.4–4.6)	600,000
Multiple tobacco products ^{¶¶}	3.5 (2.7–4.7)	4.3 (3.4–5.5)	—	—	4.3 (3.2–5.7)	3.9 (3.0–5.1)	6.1 (3.6–10.2)	3.9 (3.3–4.7)	610,000

See table footnotes on the next page.

one half of students ever using e-cigarettes reported using them currently, indicating that many young persons who try e-cigarettes remain e-cigarette users. In 2023, 10.0% of high school students and 4.6% of middle school students used e-cigarettes during the past 30 days. From 2022 (3) to 2023, a significant decline in current e-cigarette use occurred among high school students (from 14.1% to 10.0%), while no statistically

significant change occurred among middle school students (from 3.3% in 2022 to 4.6% in 2023). The decline since 2022 in high school student e-cigarette use is likely attributable to multiple factors, such as ongoing efforts at the national, state, and local levels to implement tobacco control strategies, including Food and Drug Administration (FDA) regulatory actions. Continued surveillance is needed to determine the trajectory of

TABLE 2. (Continued) Percentage of middle and high school students who reported current (past 30-day) tobacco product use, by product,* overall and by school level, sex, and race and ethnicity — National Youth Tobacco Survey, United States, 2023

Tobacco product	% (95% CI)							Total	Total estimated weighted no. [§]
	Sex		Race and ethnicity [†]						
	Female	Male	AI/AN, NH	Black or African American, NH	White, NH	Hispanic or Latino	Multiracial, NH		
Middle school students (grades 6–8)									
Any tobacco product [¶]	7.5 (5.9–9.4)	5.7 (4.1–8.0)	—	8.5 (5.8–12.4)	4.1 (3.2–5.2)	10.3 (7.5–14.0)	6.0 (3.4–10.5)	6.6 (5.1–8.5)	800,000
E-cigarettes	5.6 (4.5–7.1)	3.5 (2.5–4.8)	—	5.7 (3.9–8.2)	3.1 (2.2–4.2)	6.6 (5.3–8.2)	—	4.6 (3.6–5.8)	550,000
Cigarettes	1.1 (0.7–1.9)	—	—	—	0.8 (0.4–1.4)	—	—	1.1 (0.6–1.9)	120,000
Cigars	1.2 (0.7–2.2)	1.0 (0.6–1.8)	—	—	—	1.8 (1.1–3.1)	—	1.1 (0.7–1.8)	130,000
Nicotine pouches	—	—	—	—	0.5 (0.3–0.8)	—	—	—	—
Smokeless tobacco (composite) ^{††}	0.6 (0.4–1.0)	—	—	—	—	—	—	0.7 (0.5–1.2)	80,000
Other oral nicotine products	1.3 (0.9–1.8)	0.8 (0.6–1.3)	—	—	1.0 (0.6–1.6)	1.3 (0.8–2.0)	—	1.1 (0.8–1.4)	120,000
Hookahs	—	0.8 (0.5–1.5)	—	—	0.4 (0.2–0.7)	1.8 (1.1–2.9)	—	1.0 (0.6–1.8)	120,000
Heated tobacco products	0.8 (0.4–1.3)	—	—	—	—	1.3 (0.8–2.3)	—	0.8 (0.5–1.4)	90,000
Pipe tobacco	—	—	—	—	—	—	—	0.4 (0.2–0.6)	40,000
Any combustible tobacco product ^{§§}	2.8 (1.8–4.4)	2.3 (1.4–3.6)	—	—	1.3 (0.9–1.9)	3.7 (2.4–5.6)	—	2.5 (1.7–3.8)	300,000
Multiple tobacco products ^{¶¶}	3.1 (2.2–4.4)	2.0 (1.3–3.0)	—	—	1.5 (1.0–2.2)	3.5 (2.5–4.9)	—	2.5 (1.8–3.5)	300,000

Abbreviations: AI/AN = American Indian or Alaska Native; NH = non-Hispanic.

* Current use is defined as use on ≥ 1 days during the past 30 days for each product. Because of missing data on past 30-day use questions, denominators for each tobacco product might be different.

[†] Hispanic or Latino persons could be of any race. Estimates among NH Asian and NH Native Hawaiian or other Pacific Islander students, overall and by school level, were statistically unreliable for all measures and are not presented in this table.

[§] Estimated weighted total number of current tobacco product users was rounded down to the nearest 10,000 persons. Overall estimates were reported based on 22,069 U.S. middle and high school students. School level was determined by reported grade level: high school (grades 9–12; $n = 10,879$) and middle school (grades 6–8; $n = 11,067$). The sum of subgroup estimates might not sum to overall population estimates because of rounding or exclusion of students who did not report sex, race and ethnicity, or grade level.

[¶] Any tobacco product use is defined as current use of one or more of the following tobacco products on ≥ 1 days during the past 30 days: e-cigarettes, cigars, cigarettes, smokeless tobacco (composite), hookahs, nicotine pouches, heated tobacco products, pipe tobacco, bidis (small brown cigarettes wrapped in a leaf), or other oral nicotine products.

** Dashes indicate that data were statistically unreliable because of an unweighted denominator < 50 or a relative SE $> 30\%$.

^{††} Cigars were defined as cigars, cigarillos, or little cigars. Smokeless tobacco (composite) was defined as chewing tobacco, snuff, dip, or snus. Other oral nicotine products were defined as lozenges, discs, tablets, gums, dissolvable tobacco products, and other products. In 2023, dissolvable tobacco products were reclassified from smokeless tobacco to other oral nicotine products.

^{§§} Any combustible tobacco product use was defined as current use of one or more of the following tobacco products: cigarettes, cigars, hookahs, pipe tobacco, or bidis.

^{¶¶} Multiple tobacco product use was defined as current use of two or more of the following tobacco products: e-cigarettes, cigars, cigarettes, smokeless tobacco (composite), hookahs, nicotine pouches, heated tobacco products, pipe tobacco, bidis, or other oral nicotine products.

middle school e-cigarette use. Despite the decline in e-cigarette use among high school students, close to 40% of high school students using e-cigarettes reported frequent use, and 29.9% reported daily use. Furthermore, 550,000 middle school students currently used e-cigarettes, including 20.7% reporting frequent use. Similar patterns were observed in 2022 for both middle school and high school students. These findings are concerning, because adolescents have reported symptoms of nicotine dependence when using tobacco products only 1–3 days per month (1). Efforts aimed at reducing nicotine dependence among adolescents by preventing initiation of tobacco products is important (5).

Among students who reported current e-cigarette use, disposables were the most commonly used device type. Disposable e-cigarettes have been gaining market share; they are relatively inexpensive, have a high nicotine content, and are available in flavors appealing to youths (e.g., fruit and candy) (6). In January 2020, FDA announced that it would prioritize enforcement against prefilled e-cigarettes in flavors other than tobacco and menthol (7). In 2023, NYTS for the first time assessed tobacco-flavored product use, use of flavors that included the word “ice” or “iced” in their name, and use of concept flavors. These results, combined with results of other flavored tobacco

TABLE 3. Percentage of middle and high school students reporting current (past 30-day) e-cigarette use,* overall by selected characteristics and school level — National Youth Tobacco Survey, United States, 2023

Characteristic	Overall		High school		Middle school	
	Estimated weighted no. [†]	% (95% CI)	Estimated weighted no. [†]	% (95% CI)	Estimated weighted no. [†]	% (95% CI)
Among all students	2,130,000	7.7 (6.8–8.6)	1,560,000	10.0 (8.8–11.4)	550,000	4.6 (3.6–5.8)
Among current e-cigarette users						
Frequency of use during past 30 days						
1–5 days	980,000	46.1 (39.8–52.7)	630,000	40.7 (33.1–48.7)	340,000	62.0 (55.7–67.9)
6–19 days	400,000	19.1 (15.0–24.1)	300,000	19.7 (14.1–26.8)	90,000	17.3 (12.2–24.0)
20–30 days	740,000	34.7 (28.4–41.7)	620,000	39.7 (31.3–48.6)	110,000	20.7 (14.6–28.6)
Daily e-cigarette use[§]	530,000	25.2 (19.2–32.3)	460,000	29.9 (22.1–39.1)	60,000	11.4 (7.5–17.0)
Device type most often used[¶]						
Disposables	1,240,000	60.7 (53.3–67.6)	1,000,000	65.2 (56.3–73.1)	240,000	47.9 (39.5–56.5)
Prefilled or refillable pods or cartridges	330,000	16.1 (12.2–21.0)	240,000	16.0 (11.1–22.5)	80,000	16.7 (11.4–23.8)
Tanks or mod system	120,000	5.9 (4.4–7.8)	90,000	6.0 (4.3–8.4)	20,000	4.4 (2.5–7.5)
Don't know the type	350,000	17.3 (12.7–23.1)	190,000	12.8 (8.7–18.4)	150,000	31.1 (22.2–41.5)
Any brand**						
Elf Bar	1,160,000	56.7 (50.6–62.6)	900,000	59.1 (52.9–65.1)	260,000	50.0 (37.5–62.5)
Esco Bars	440,000	21.6 (16.2–28.3)	370,000	24.9 (18.1–33.1)	60,000	12.0 (6.9–20.2)
Vuse	420,000	20.7 (16.4–25.9)	330,000	22.2 (16.9–28.6)	80,000	16.3 (10.8–23.8)
JUUL	330,000	16.5 (12.9–20.9)	240,000	16.3 (11.8–22.1)	80,000	16.8 (11.4–24.1)
Mr. Fog	280,000	13.6 (7.9–22.4)	230,000	15.1 (8.2–26.3)	— ^{††}	—
SMOK (including NOVO)	230,000	11.3 (6.3–19.5)	—	—	30,000	6.7 (3.9–11.1)
Breeze	230,000	11.6 (7.6–17.4)	200,000	13.2 (8.0–21.2)	30,000	6.6 (4.1–10.5)
Kangvape (including Onee Stick)	180,000	8.8 (6.6–11.7)	130,000	8.7 (6.5–11.6)	—	—
Fume	180,000	9.0 (6.4–12.6)	140,000	9.2 (6.0–13.9)	40,000	8.2 (4.7–14.0)
NJOY	150,000	7.5 (5.5–10.3)	120,000	8.1 (5.6–11.7)	20,000	5.4 (3.1–9.2)
blu	120,000	6.0 (4.4–8.3)	70,000	5.2 (3.4–7.8)	40,000	8.1 (5.0–12.9)
HQD	110,000	5.5 (3.4–8.5)	80,000	5.7 (3.3–9.7)	—	—
Logic	80,000	3.9 (2.5–6.1)	50,000	3.7 (2.3–5.8)	—	—
Suorin (including Air Bar)	70,000	3.8 (2.5–5.6)	50,000	3.8 (2.3–6.3)	—	—
Lost Mary ^{§§}	50,000	2.6 (1.4–4.8)	40,000	3.3 (1.8–5.9)	—	—
Some other brand not listed	350,000	17.3 (11.6–24.9)	290,000	19.5 (12.4–29.2)	50,000	10.9 (6.0–19.0)
Not sure or don't know the brand	490,000	23.9 (19.3–29.2)	300,000	19.8 (15.6–24.9)	180,000	35.4 (24.3–48.3)
Usual brand^{¶¶}						
Elf Bar	630,000	31.1 (26.2–36.4)	460,000	30.2 (24.8–36.2)	170,000	33.9 (24.6–44.7)
Vuse	170,000	8.7 (5.8–12.9)	150,000	10.0 (6.4–15.3)	—	—
Esco Bars	120,000	6.0 (3.4–10.4)	110,000	7.7 (4.3–13.5)	—	—
JUUL	70,000	3.4 (1.9–6.1)	—	—	—	—
Mr. Fog	—	—	—	—	—	—
SMOK (including NOVO)	—	—	—	—	—	—
Breeze	—	—	—	—	—	—
Kangvape (including Onee Stick)	—	—	—	—	—	—
Fume	—	—	—	—	—	—
NJOY	—	—	—	—	—	—
blu	—	—	—	—	—	—
HQD	—	—	—	—	—	—
Logic	—	—	—	—	—	—
Suorin (including Air Bar)	—	—	—	—	—	—
Lost Mary	—	—	—	—	—	—
No usual brand	90,000	4.4 (2.8–7.0)	70,000	4.7 (2.8–7.5)	—	—
Some other brand not listed	270,000	13.2 (7.8–21.5)	230,000	15.4 (8.6–25.9)	—	—
Not sure or don't know the brand	400,000	19.8 (16.0–24.1)	240,000	16.0 (12.5–20.4)	150,000	30.5 (22.1–40.4)
Flavored e-cigarette use***						
Any flavor other than tobacco-flavored or unflavored	1,900,000	89.4 (86.2–91.9)	1,410,000	90.3 (86.6–93.1)	480,000	87.1 (79.9–92.0)
Exclusive use of tobacco-flavored or unflavored	110,000	5.6 (3.9–7.9)	80,000	5.4 (3.4–8.4)	30,000	6.2 (3.4–11.0)
Unspecified	100,000	5.0 (3.5–7.2)	60,000	4.3 (2.8–6.6)	—	—

See table footnotes on the next page.

TABLE 3. (Continued) Percentage of middle and high school students reporting current (past 30-day) e-cigarette use,* overall by selected characteristics and school level — National Youth Tobacco Survey, United States, 2023

Characteristic	Overall		High school		Middle school	
	Estimated weighted no. [†]	% (95% CI)	Estimated weighted no. [†]	% (95% CI)	Estimated weighted no. [†]	% (95% CI)
Flavor type used among current e-cigarette users^{†††}						
Fruit	1,280,000	63.4 (59.8–66.9)	930,000	62.6 (57.9–67.0)	340,000	66.3 (59.5–72.5)
Candy, desserts, or other sweets	700,000	35.0 (29.1–41.5)	510,000	34.4 (27.5–42.1)	190,000	37.0 (28.6–46.4)
Mint	560,000	27.8 (22.0–34.4)	470,000	31.6 (24.2–40.1)	80,000	16.5 (11.6–22.9)
Menthol	400,000	20.1 (15.5–25.8)	340,000	23.3 (17.6–30.1)	50,000	10.4 (7.2–14.8)
Unflavored	230,000	11.6 (8.8–15.1)	160,000	10.9 (7.8–15.0)	60,000	13.2 (8.7–19.5)
Non-alcoholic drinks ^{§§§}	220,000	11.3 (6.4–19.1)	—	—	30,000	7.4 (4.1–13.0)
Alcoholic drinks ^{§§§}	170,000	8.4 (5.5–12.7)	130,000	9.0 (5.5–14.4)	—	—
Tobacco-flavored	120,000	6.4 (4.5–9.0)	70,000	5.3 (3.7–7.4)	—	—
Clove or spice ^{§§§}	120,000	6.0 (4.3–8.2)	70,000	5.1 (3.3–7.7)	40,000	7.9 (4.6–13.1)
Chocolate	90,000	4.9 (3.4–7.1)	50,000	3.4 (1.9–6.2)	40,000	8.0 (4.3–14.3)
Some other flavor	120,000	6.0 (4.2–8.5)	60,000	4.6 (3.0–7.0)	50,000	10.0 (5.9–16.4)
Use of any flavors that included the word “ice” or “iced” (such as “blueberry ice” or “strawberry ice”)^{††††}						
Yes	1,100,000	57.9 (52.5–63.1)	800,000	57.0 (51.3–62.6)	290,000	61.0 (52.8–68.5)
No	560,000	29.5 (24.8–34.8)	440,000	31.6 (26.1–37.7)	110,000	24.1 (18.2–31.1)
Don't know	230,000	12.6 (9.8–16.0)	160,000	11.4 (8.3–15.5)	70,000	15.0 (10.2–21.5)
Use of any concept flavors with a name that did not describe a specific flavor (such as “solar,” “purple,” “jazz,” “island bash,” or “fusion”)^{****}						
Yes	300,000	16.1 (13.5–19.0)	210,000	15.4 (12.2–19.3)	80,000	17.7 (12.3–24.7)
No	1,110,000	58.5 (52.5–64.3)	850,000	60.9 (52.8–68.4)	250,000	52.8 (45.5–60.0)
Don't know	480,000	25.4 (21.6–29.7)	330,000	23.7 (19.0–29.2)	140,000	29.5 (22.6–37.5)

* Current (past 30-day) use of e-cigarettes was determined by asking, “During the past 30 days, on how many days did you use e-cigarettes?” Current use was defined as use on ≥1 days during the past 30 days.

† Estimated total number of users was rounded down to the nearest 10,000 persons. The sum of subgroup estimates might not sum to overall population estimates because of rounding or exclusion of students who did not report grade level (n = 102), device type (n = 53), any brand (n = 54), usual brand (n = 61), flavor types used (n = 84), use of flavor including the word “ice” or “iced” (n = 136), or use of flavors without specific flavor descriptor (n = 143).

§ Daily e-cigarette use was defined as use on all 30 of the past 30 days.

† Device type was determined by the question, “Which of the following best describes the type of e-cigarette you have used in the past 30 days? If you have used more than one type, please think about the one you use most often.”

** All current e-cigarette users were asked, “During the past 30 days, what e-cigarette brands did you use? (Select one or more).” Those who selected “some other brand(s) not listed here” could provide a write-in response. Write-in responses corresponding to an original response option were recoded.

†† Data were statistically unreliable because of an unweighted denominator <50 or a relative SE >30%.

§§ Lost Mary was not included in the list of prespecified response options, but it was the most commonly provided write-in response for “some other brand(s) not listed here.”

††† If a single brand was selected for the question, “During the past 30 days, what e-cigarette brands did you use (Select one or more),” it was reported as the respondent’s usual brand. Those who selected one or more brands were asked, “During the past 30 days, what brand of e-cigarettes did you usually use? (Choose only one answer).” Those who selected “some other brand(s) not listed here” could provide a write-in response. Write-in responses corresponding to an original response option were recoded.

*** All current e-cigarette users were asked, “In the past 30 days when you used e-cigarettes, what flavors did you use? (Select one or more)?” Those who provided no valid responses were defined as “Unspecified” flavored users.

†††† Flavor type was determined by response to the question, “In the past 30 days when you used e-cigarettes, what flavors did you use? (Select one or more).” Those who selected “some other flavor not listed here” could provide a write-in response; write-in responses corresponding to an original response option were recoded.

§§§ These flavor options provided examples: “Alcoholic drinks (such as wine, margarita, or other cocktails);” “Non-alcoholic drinks (such as coffee, soda, lemonade, or other beverage);” and “Spice (such as cinnamon, vanilla, or clove).”

†††† Current e-cigarette users were asked, “Did any of the flavors you used in the past 30 days have names or descriptions that included the word ‘ice’ or ‘iced’ (for example, blueberry ice or strawberry ice)?” Those who reported using only unflavored e-cigarettes (n = 60) did not receive the question.

**** Current e-cigarette users were asked, “Did any of the flavors that you used in the past 30 days have a name that did not describe a specific flavor, such as ‘solar,’ ‘purple,’ ‘jazz,’ ‘island bash,’ and ‘fusion,’ or some other word or phrase?” Those who reported using only “unflavored” e-cigarettes (n = 60) did not receive the question.

product use research, continue to demonstrate the high appeal of flavored tobacco products among young persons.

Multiple factors continue to influence tobacco product use and initiation among middle and high school students, including availability of flavored products, marketing, and misperceptions regarding harm. Continued surveillance provides an understanding of the prevalence and frequency of tobacco

product use, the popularity of specific brands and flavors, and how product use behaviors change over time as the tobacco product marketplace continues to diversify.

Limitations

The findings in this report are subject to at least three limitations. First, data were obtained by self-report, which can result in social desirability and recall biases, although previous

Summary**What is already known about this topic?**

Use of tobacco products in any form by youths is unsafe.

What is added by this report?

In 2023, 10.0% of middle and high school students reported current tobacco product use. From 2022 to 2023, current e-cigarette use among high school students declined from 14.1% to 10.0%. E-cigarettes remained the most commonly used tobacco product among youths. Among middle school and high school students who currently use e-cigarettes, 25.2% used e-cigarettes daily, and 89.4% used flavored e-cigarettes.

What are the implications for public health?

Tobacco use declined among high school students; however, sustained public health monitoring with implementation of evidence-based tobacco control strategies, including effective youth interventions, media campaigns, Food and Drug Administration regulations, and other proven tobacco prevention policies might further reduce youth tobacco product use.

research suggests that self-reported measures of tobacco use among persons aged 12–21 years correlate with biomarkers of tobacco use (8). Second, these findings might not be generalizable to youths who are home-schooled, have dropped out of school, are in detention centers, or are enrolled in alternative schools. Finally, the response rate for the 2023 NYTS was lower than that for the 2022 NYTS (30.5% in 2023 versus 45.2% in 2022). The lower response rate can increase the potential for bias and result in higher SEs for some estimates; higher SEs can reduce the power to detect a significant difference, if there is one, when doing year to year comparisons, especially for certain population groups. Adjustments were made to the survey weights to reduce the potential for nonresponse bias. Therefore, 2023 NYTS estimates may be compared with 2022 NYTS estimates for the same population groups.

Implications for Public Health Practice

In 2023, 10.0% (representing 2.80 million) of U.S. middle and high school students reported current tobacco product use. A significant decline in current e-cigarette use occurred among high school students from 2022 to 2023 (from 14.1% to 10.0%). Given the negative health consequences of tobacco use (2) and the unique harms associated with adolescent nicotine exposure (1), prevention of tobacco use by youths is imperative. Thus, a continued comprehensive approach to

tobacco use prevention is needed to further reduce tobacco use among youths, based on knowledge about youth product use behaviors. Further, longstanding and proven tobacco prevention policies, such as price increases, comprehensive smoke-free policies (that include e-cigarettes), counter-marketing campaigns, and health care intervention, will continue to reduce youth initiation and tobacco use (5).

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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1.1 Product Promotional Material and Marketing Plan

A Premarket Tobacco Product Application (PMTA) must contain a description of the applicant's plans for labeling, advertising, marketing, promotion, and other consumer-directed activities regarding the new tobacco product developed by the time of filing. Such marketing plans must contain descriptions of actions that would be taken by the applicant, on behalf of the applicant, or at the applicant's direction for at least the first year the product would be marketed after receiving an order. If an applicant does not intend to use any advertising, marketing, promotion, or other communication activities directed at consumers, or has not developed marketing plans by the time of submission, the PMTA must contain a statement to that effect. As part of the description of the marketing plan, the PMTA must specify items such as the intended target audience(s), media and distribution channels, particular tactics, total dollar amount(s) of media buys and marketing and promotional activities (where applicable), and timing for the activities, including, but not limited to, information describing items listed in 21 Code of Federal Regulations (CFR) Section 1114.7 (f)(2) of the PMTA Rule (FDA, 2021).

The following outlines the marketing plan for the ZYN Product Line. (b) (4)

As ZYN was the first nicotine pouch brand launched in the U.S. market, it was extremely important that ZYN was brought to market responsibly. The brand's Commitment to Responsibility is:

(b) (4)

1.1.1 Labeling

All ZYN product labeling carries the following warning at 30% of the two primary panels: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." While eventually required by the Food and Drug Administration (FDA), this warning was included on the ZYN packaging (b) (4)

Product-specific labels are discussed in Section 1.9 of respective PMTAs.

1.1.2 Advertising, Marketing, Promotion, and Other Consumer-Directed Activities

In-Store Communication: At retail locations where ZYN will be sold, branded fixtures may be used to display products in a non-self-serve location. Representative examples of the merchandiser and shelf talker are shown in **Figure 1.1.1** and **Figure 1.1.2**, respectively. Additional signage may also be used to communicate that the product is available for sale at that location and to display pricing.

Figure 1.1.1 Representative Example of Merchandiser



Figure 1.1.2 Representative Example of Shelf Talker



Website: The ZYN.com website (see representative example in **Figure 1.1.3**) is an age-gated site where consumers can get information about ZYN, purchase ZYN and locate retailers that sell the ZYN product.

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

MENU

United States

ZYN

STORES

ACCOUNT

WELCOME TO ZYN.COM

Discover fresh nicotine satisfaction, with ZYN Nicotine Pouches.

LOG IN

Email

Password

LOG IN

ch

Remember me

Forgot password?

REGISTER

New to ZYN? Register today.

REGISTER

ZYN IS FOR ADULT TOBACCO AND NICOTINE CONSUMERS 21+ ONLY

We take the issue of underage usage extremely seriously, which is why we require all new visitors to go through a strict age verification process before entering our website.

Not intended for use by minors, women who are pregnant or breastfeeding, or persons with or at risk of heart disease or high blood pressure. If you have a serious health condition, please consult a healthcare professional before use. Keep out of reach of children. Use as directed.

If you do not currently use tobacco or nicotine, ZYN is not for you. If you use tobacco or nicotine and would like to quit, please visit [BeTobaccoFree.gov](#)

Digital Marketing: ZYN utilizes digital marketing to reach age-verified, adult (ages 21+) consumers who have demonstrated interest in tobacco or nicotine products. (b) (4)

Instead, ZYN's goal is to ensure there is adequate age verification measures in place. When establishing partnerships with digital marketing agencies, ZYN stipulates that the only intended audience is adults (ages 21+) who are current nicotine or tobacco users. ZYN has gone to great lengths to avoid reaching an unintended audience and closely monitors all consumer inquiries. For more information on age verification, see [Section 1.1.2.1](#). Representative examples of such activities are banner advertisements (**Figure 1.1.4**).

Figure 1.1.4 Digital Advertisement Banner Representative Examples



Social Media: We will only use social media platforms that can restrict access by age. ZYN has both Facebook and Instagram pages. Only consumers who are ages 21+ and voluntarily elect to visit or follow the Facebook and Instagram pages will be exposed to the content. Representative examples of Facebook and Instagram social media posts are shown in **Figure 1.1.5** and **Figure 1.1.6**.

Figure 1.1.5 Social Media (Facebook) Post Representative Examples



Figure 1.1.6 Social Media (Instagram) Post Representative Examples

**WARNING: This product contains nicotine.
Nicotine is an addictive chemical.**

**WARNING: This product contains nicotine.
Nicotine is an addictive chemical.**

zyn_usa ...

zyn_usa The moment is only what you make of it.
#FindYourZYN

#ZYN #FindYourZYN #Freedom #nicotinepouches
#ZYNnicotinepouches #handsfree

13w

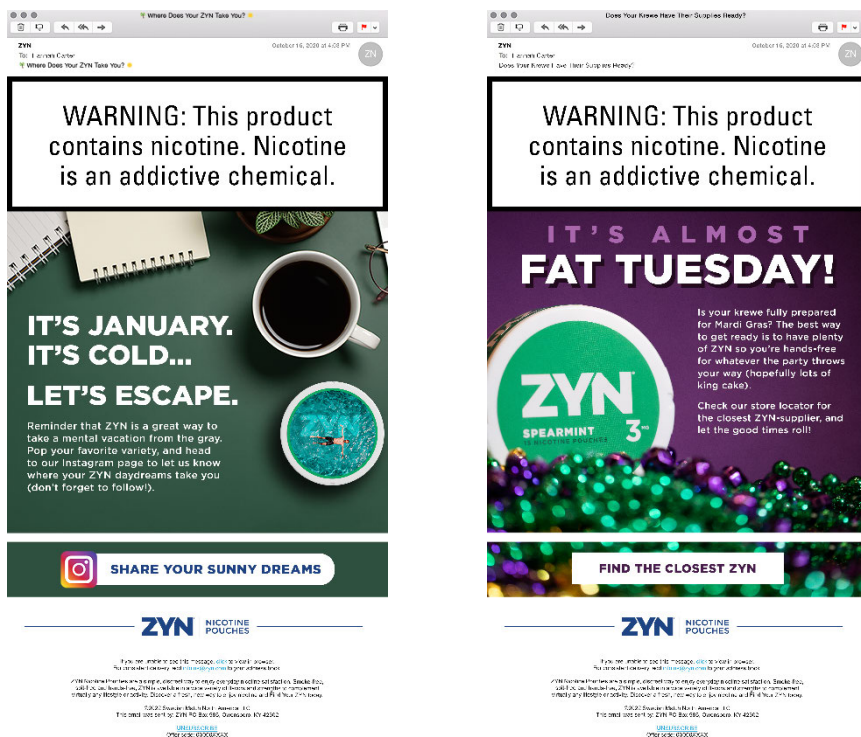
zyn_usa ...

zyn_usa Like new socks across a polished floor,
ZYN is all about that #smoothlife
#ZYN #FindYourZYN #Freedom
#nicotinepouches #ZYNnicotinepouches
#handsfree

7w

Customer Relationship Marketing (CRM): ZYN will communicate with age-verified consumers who have registered on ZYN.com and have opted in to receive brand communications through email. Opted-in consumers will receive a monthly email plus additional emails triggered by the consumers interaction with consumer programs hosted on ZYN's age-gated website. For example, consumers who enroll in ZYN Rewards will receive emails pertinent to the ZYN Rewards program. Each email sent will have an unsubscribe feature should the consumer choose to opt out. Two representative examples of email communication are shown in **Figure 1.1.7**.

Figure 1.1.7 Representative Examples of Consumer Emails



If you are unable to see this message, [click](#) to view in browser.
For consistent delivery, add info.us@zyn.com to your address book.

ZYN Nicotine Pouches are a simple, discreet way to enjoy everyday nicotine satisfaction. Smoke-free, spit-free and hands-free, ZYN is available in a wide variety of flavors and strengths to complement virtually any lifestyle or activity. Discover a fresh, new way to enjoy nicotine and Find Your ZYN today.

©2022 Swedish Match North America LLC
This email was sent by: ZYN PO Box 986, Owensboro, KY 42302

[UNSUBSCRIBE](#)
Offer code: 00000XXX

1.1.2.1 Use of Competent and Reliable Data Sources, Tools, Technologies, and Methodologies to Establish, Maintain, and Monitor Highly Targeted Marketing Plans and Media Buys

ZYN will employ technology to ensure its messaging reaches only the intended audience of adult (ages 21+) tobacco or nicotine users.

Website: For a consumer to gain access to the ZYN.com website, their identity and age must be verified by a third-party vendor before a user can navigate past the landing page. Upon visiting the website, the consumer is immediately directed to a registration page to gather information from the visitor. This information is securely used by the third-party vendor (b) (4) who uses voter registration, driver's license, and credit bureau information to match the provided information with a known identity by using known addresses, names, and birthdate. If the identity is not verified or is below the age of 21, access to the website is denied. While thousands of potential ZYN customers have been lost to our restrictive website registrations and email opt-ins, Swedish Match believes it is the brand safe and responsible thing to do.

Digital Marketing: ZYN will use a trusted global media agency to serve advertisements only to adult (ages 21+) tobacco or nicotine users. The media agency will integrate all ZYN advertising efforts with a partner (b) (4) to provide independent, third-party, traffic-auditing, and blocking services. (b) (4)

This secondary layer of filtering is specifically blocking ads from being served, even to targeted tobacco or nicotine audiences ages 21+, while the user is on any website that would not be considered brand safe.

Social Media: ZYN uses Facebook's and Instagram's age-gating tools to only grant access to the ZYN Facebook and Instagram pages to consumers who are registered as adults, ages 21+.

CRM: For a consumer to receive CRM communication from ZYN, they must have registered on the ZYN.com website and have their age identified as being an adult, age 21+, by the methods mentioned under **Website**. In addition, the consumer must opt in to receive marketing communication from the brand. A consumer who has not registered on the ZYN.com website will not receive a marketing communication from the brand.

Consumer Engagement: For a consumer to gain access to a ZYN activation, (b) (4)

1.1.2.2 Target Adult Audiences by Age Range(s) (Including Young Adult Audiences, Ages 21 to 24) and Other Demographic or Psychographic Characteristics

The target adult audience of ZYN is a consumer who currently uses a tobacco or nicotine product and is over the age of 21.

Consumer research indicates that the nicotine pouch consumer is similar, but not identical, to the moist snuff consumer. Both have very similar profiles in terms of marital status, household income, and family make up. However, differences of the two consumer groups include nicotine pouch consumers having a higher incidence of females, a higher income level, and a slightly lower median age than moist snuff consumers. Also of note, there was a correlation between consumption and quitting behavior – this despite the fact that the product is not marketed as such. The more times a tobacco consumer has tried to quit in the past, the more interest they had in the product. Finally, it was also determined that nicotine pouches have minimal appeal to consumers who currently do not use tobacco or nicotine products.

In addition to formal consumer research, the company has received an overwhelming number of unsolicited product reviews and testimonials for ZYN. These testimonials largely praise the product for helping the consumer to stop or reduce traditional TNP use and, in some cases, allowing them to quit nicotine altogether (again, ZYN is not marketed as a cessation product). With the consumer's consent, these stories are occasionally shared through age-verified marketing platforms with other consumers.

1.1.2.3 Insight Into the Target Audience the Applicant Is Using to Inform Its Marketing Plans, Including Its Strategic Approach, Key Messages and Themes, Creative Direction, and Potential Marketing Tactics or Channels

The main insight that drives marketing communication is that many adult tobacco consumers prefer a discreet nicotine experience. This results in key messaging that ZYN is smoke free and spit free. Representative examples of messaging at retail locations where ZYN will be sold include a counter mat (**Figure 1.1.8**) and a 3-sided pole cover (**Figure 1.1.9**).

Figure 1.1.8 Counter Mat Representative Examples

**WARNING: This product contains nicotine.
Nicotine is an addictive chemical.**

ZYN | NICOTINE POUCHES

AVAILABLE IN 10 VARIETIES AND 2 STRENGTHS

3mg for clean nicotine satisfaction | **6mg** for even more nicotine enjoyment

SMOKE-FREE

SPIT-FREE

HANDS-FREE

FIND YOUR ZYN at **ZYN.com**

ZYN rewards

BUY ZYN. COLLECT POINTS. EARN REWARDS.

The ZYN Rewards Store offers 70+ premium items.

Start earning at:
ZYN.com/Rewards

See also for terms and conditions. ZYN.
©2022 Swedish Match North America LLC.

**WARNING: This product contains nicotine.
Nicotine is an addictive chemical.**

ZYN | NICOTINE POUCHES

AVAILABLE IN 2 UNFLAVORED VARIETIES AND 2 STRENGTHS

3mg for clean nicotine satisfaction | **6mg** for even more nicotine enjoyment

SMOKE-FREE

SPIT-FREE

HANDS-FREE

FIND YOUR ZYN at **ZYN.com**

ZYN rewards

BUY ZYN. COLLECT POINTS. EARN REWARDS.

The ZYN Rewards Store offers 70+ premium items.

Start earning at:
ZYN.com/Rewards

See also for terms and conditions. ZYN.
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Figure 1.1.9 3-Sided Pole Cover (Flat & Assembled Views) Representative Example



1.1.2.4 Any Means by Which Youth Access or Youth Exposure to the Products' Labeling, Advertising, Marketing, and Promotion Would Be Limited

ZYN will limit exposure to youth by only conducting marketing efforts in age-verified mediums and by adhering to any and all regulations for warnings at the local, state, and federal levels to help reduce youth appeal of its marketing materials. In addition, ZYN will meet a self-imposed marketing code of conduct for all of the company's products and take the following steps to limit exposure to youth and thus help further mitigate risks to youth:

(b) (4)

If granted a PMTA, Swedish Match would plan to proactively communicate the designation and would respond accordingly to media outlets that would want to engage in articles, interviews, etc. that would be published in a public forum.

In the event of any false or incorrect statements or stories being produced by the media, Swedish Match would make reasonable efforts with the responsible source to correct any errors. (b) (4)

1.1.2.5 Use of Partners, Sponsors, Influencers, Bloggers, or Brand Ambassadors to Advertise or Promote the Products

(b) (4)

1.1.2.6 Use of Consumer Engagements, Including Events at Which the Products Will Be Demonstrated or Sampled

(b) (4)

Figure 1.1.10 (b) (4)

