U.S. FOOD AND DRUG ADMINISTRATION

Tobacco Products Scientific Advisory Committee

Background Materials

Swedish Match USA, Inc.

ZYN Products

MR0000268.PD1 – PD20

January 22, 2026

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1. Executive Summary

In April 2024, Swedish Match USA, Inc. ("we", "our", and "us")[1] submitted Modified Risk Tobacco Product Applications (MRTPAs) for all 20 authorized ZYN 3 mg and 6 mg products with the following proposed reduced risk claim under section 911(g)(1) of the Food Drug & Cosmetic (FD&C) Act:

> *"Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."*

This proposed claim is identical to the claim authorized by FDA for eight General Snus products[2], except for the product name. The primary reasons for FDA's authorization of General Snus MRTPAs were as follows:

- Low levels of harmful and potentially harmful chemicals (HPHCs)
- Low prevalence of youth use
- Over three decades of Swedish epidemiological data demonstrating a decline in tobacco-related disease (e.g., lung cancer, cardiovascular disease [CVD]) with decreased smoking and increased uptake of snus over time ("the Swedish Experience").[3]

FDA recognized the HPHC quantities in the eight authorized General Snus products are significantly lower than those found in cigarette smoke. In conjunction, as cigarette smoking was replaced by snus product use in Sweden since the 1980's, the country has seen significant declines in smoking-related disease, including those listed in the reduced risk claim authorized for the eight General Snus products. Therefore, FDA reasoned that, if smokers in the United States (U.S.) completely switched from smoking to use of General Snus products, their risk of these diseases would likely be reduced.

We believe the conclusions from FDA review of the General Snus MRTPAs are applicable to the ZYN products. ZYN products demonstrate the following similarities with General Snus products:

- Product composition, design, and manufacturing processes
- User populations, patterns, and behaviors
- Nicotine delivery profile
- Low levels of HPHCs

With respect to low levels of HPHCs, the overall HPHC profile for ZYN products is improved compared to the overall HPHC profile of General Snus products.

[1] Swedish Match USA, Inc., the Applicant of the MRTPAs under review (MR0000268.PD1–PD20), is an indirect subsidiary of Philip Morris International Inc. (PMI).

[2] Modified Risk Granted Orders Letter from FDA CTP to Swedish Match USA, Inc. (STN MR0000020-22, MR0000024-25, MR0000027-29) for General Snus MRTPAs (2019). Accessed Searchable Tobacco Products Database November 10, 2025.

[3] Epidemiological data demonstrating long-term reduction of tobacco-related disease in Sweden

The data discussed below demonstrate that ZYN products are used similarly to General Snus products but expose users to lower levels of HPHCs. As FDA stated in their ZYN PMTA Technical Project Lead (TPL) review, *"In terms of benefit, HPHC levels in the [ZYN] products are generally lower than General Snus, a product for which FDA has issued marketing orders."*

Additionally, while the non-clinical and clinical data scientifically substantiate that the proposed claim language is applicable to ZYN products, extensive behavioral data discussed further below, demonstrate that users comprehend the language of the claim, and adults perceive the risks of contracting tobacco-related diseases listed in the claim as lower when they use ZYN products compared to their continued use of cigarettes. The General Snus post-market study, conducted after the initial MRTP authorization for General Snus products[2], demonstrates high levels of consumer understanding of the MRTP claim language and that to receive the reduction in disease risks, they must switch completely away from cigarettes. Similarly, evaluation of the claim with ZYN products showed that adults exposed to the claim language understood their risks of developing the health conditions in the claim are lower relative to cigarettes if they switch to ZYN products, but that ZYN product use is not without risk entirely.

2. Product and Claim Overview

ZYN products, which have been marketed in the United States since 2014, are white pouched products containing tobacco-derived nicotine and have very low moisture content. These products are similar in product design to the Pre-Market Tobacco Product Application (PMTA)- and MRTPA-authorized[2,4,5] pouched General Snus products. The products are also used in a similar fashion (i.e., held between the lip and gum) by the same populations (i.e., adult consumers of nicotine and tobacco products). One critical design difference between these products is that ZYN products do not contain any tobacco leaf or stems (See Figure 1 below), leading to lower HPHC quantities in ZYN products compared to General Snus products.

Figure 1. Pictures of General Snus products packaged in can (far left) and as a pouch (left middle) and ZYN products (right middle) and packaged in can (far right).

[4] Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review for General Snus PMTAs (2015). Accessed Searchable Tobacco Products Database November 10, 2025.
[5] Modified Risk Granted Orders Risk Modification from FDA CTP to Swedish Match U.S.A. Inc. (Multiple STNs) for General Snus MRTPA renewal (2024). Accessed Searchable Tobacco Products Database November 10, 2025.

In January 2025, FDA authorized the marketing of 20 ZYN products, available in two nicotine concentrations and 10 different varieties[6] (See Table 1 and Figure 2). All 20 products use identical pouch materials and contain the same ingredients, except for flavor-specific ingredients. All ingredients, including flavor-specific ingredients, underwent quantitative risk assessments and were found to be below the levels of concern, data which were assessed by FDA as part of the PMTA marketing order decision.

Figure 2. The 20 authorized ZYN varieties under the PMTA pathway.[6] All varieties are pictured with the required nicotine warnings.

Table 1. ZYN products subject of the MRTPAs.

Submission Tracking Number (STN)	Product Name	Nicotine Strength
MR0000268.PD1	ZYN Cool Mint	6 mg
MR0000268.PD2	ZYN Peppermint	3 mg
MR0000268.PD3	ZYN Peppermint	6 mg
MR0000268.PD4	ZYN Spearmint	3 mg
MR0000268.PD5	ZYN Spearmint	6 mg
MR0000268.PD6	ZYN Wintergreen	3 mg
MR0000268.PD7	ZYN Wintergreen	6 mg
MR0000268.PD8	ZYN Citrus	3 mg
MR0000268.PD9	ZYN Citrus	6 mg
MR0000268.PD10	ZYN Coffee	3 mg
MR0000268.PD11	ZYN Coffee	6 mg
MR0000268.PD12	ZYN Cinnamon	3 mg
MR0000268.PD13	ZYN Cinnamon	6 mg
MR0000268.PD14	ZYN Smooth	3 mg
MR0000268.PD15	ZYN Smooth	6 mg
MR0000268.PD16	ZYN Chill	3 mg
MR0000268.PD17	ZYN Chill	6 mg
MR0000268.PD18	ZYN Menthol	3 mg
MR0000268.PD19	ZYN Menthol	6 mg
MR0000268.PD20	ZYN Cool Mint	3 mg

[6] PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted for ZYN PMTAs (2025). Accessed Searchable Tobacco Products Database November 10, 2025.

In April 2024, we submitted MRTPAs for all 20 ZYN products to be marketed with the following proposed reduced risk claim under section 911(g)(1) of the FD&C Act:

> *"Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."*

This proposed reduced risk claim for ZYN products is identical to the claim FDA authorized in 2019[2] and reauthorized in 2024[5] for use in marketing the eight General Snus products, except in product name. The primary reasons FDA initially authorized this claim for use in marketing the General Snus products included:

- Low HPHC quantities
- Low youth use
- The "Swedish Experience" data[3]

The data provided in the ZYN MRTPAs, along with more recently published data, show that similar logic applies to these products and support authorization of ZYN products with the proposed reduced risk claim. The user topographies between ZYN and General Snus products are similar, but ZYN products have substantially lower HPHC levels compared to General Snus products. Because of this, in their review of the ZYN PMTAs, FDA found it reasonable for us to assert that the health effects of General Snus products likely represent the upper limit of likely long-term effects for ZYN products.[6] Given the similarities between General Snus and ZYN products, the "Swedish Experience" epidemiological data can reasonably be bridged to ZYN products; displacement of smoking by ZYN products would be expected to achieve similar or even greater public health benefits than observed in Sweden with snus products. Therefore, based on similar product design and user topography, in conjunction with the reduced toxicological profile of ZYN products, it is reasonable to conclude that the risks of contracting the six health conditions in the claim (mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis) will be lower with ZYN product use compared to cigarette use and are similar, if not lower, compared to use of General Snus products.

The claim language has been evaluated in both pre- and post-market studies for General Snus products, demonstrating it to be well-understood by consumers in terms of the need to completely switch to experience the reduction in risk relative to cigarettes. An additional claim study was conducted exposing consumers to the claim language in the context of ZYN products and testing their risk perceptions. These results show similarities to the results for both pre- and post-market General Snus claim research studies. Further discussion of these studies is provided in the Consumer Understanding and Perceptions section below.

3. Non-Clinical and Clinical Individual Health Data

ZYN products generally have and consistently deliver even lower levels of HPHCs than found in cigarette smoke (see Figure 3). Forty-five HPHCs were measured in the 20 ZYN products. Across all 20 ZYN products, only seven HPHCs were above the limit of quantification (LOQ), including nicotine. Moreover, the majority of these were lower than in the authorized General Snus products (see Figure 4). Importantly, HPHCs such as tobacco-specific nitrosamines (TSNAs) and polycyclic aromatic hydrocarbons (PAH, e.g., benzo[a]pyrene), which are potential carcinogens, were below LOQ in all ZYN products. The overall lower HPHCs is attributed to the fact that General Snus products contain tobacco leaf, while ZYN products do not. Quantitative risk assessments were performed for all HPHCs that were above LOQ, confirming that levels were well below established limits of concern. These data were assessed by FDA as part of the PMTA authorization.

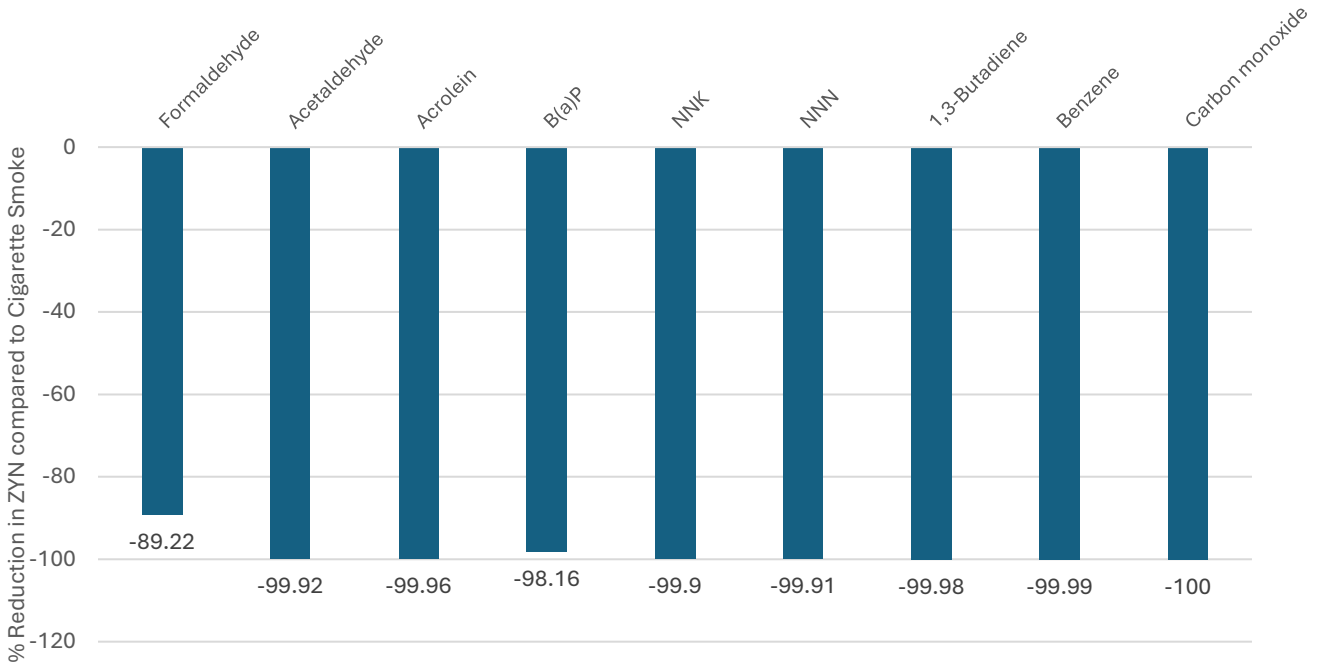

Figure 3. Reductions in HPHCs from ZYN products compared to cigarettes (WHO-9 List).

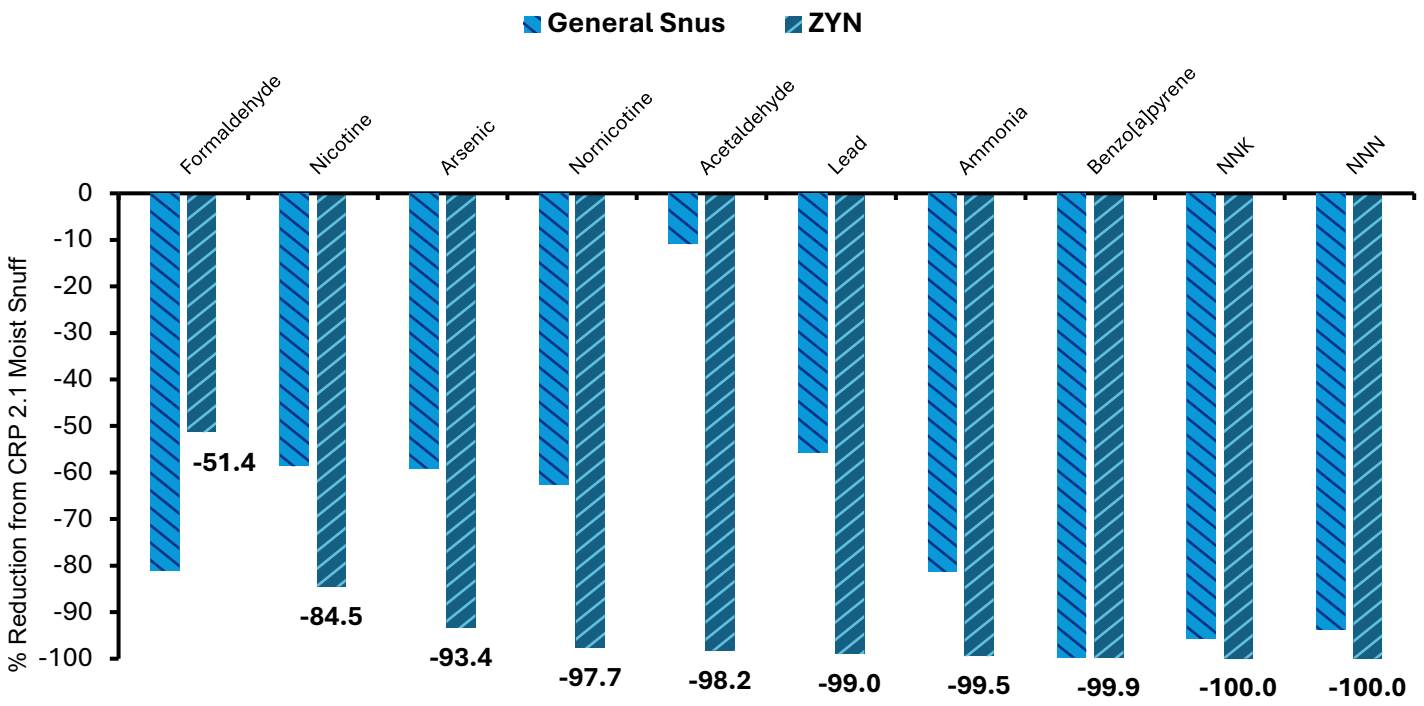

Figure 4. Reductions in HPHCs for General Snus products (Light Blue) and ZYN products (Dark Blue) compared to CRP 2.1 (moist snuff) reference product.

Additionally, because these products are used orally rather than inhaled like cigarettes, concerns about secondary formation of HPHCs and respiratory toxicity do not exist for these products like they do for cigarettes. After reviewing the HPHC data provided in the PMTAs, the ZYN PMTA TPL review stated:

> *"The toxicology review concludes that adults who smoke who switch completely to the new products are expected to experience reduced risk of cancer, respiratory toxicity, and cardiovascular toxicity."*

Notably, these conclusions were reached based primarily on HPHC and toxicological assay data. But, to show how the low HPHCs from the products translate to low levels delivered to users and further support the bridging between snus and ZYN products, we conducted a cross-sectional biomarker study comparing levels of biomarkers of exposure (BoEs) and biomarkers of potential harm (BoPHs) in plasma and urine of non-users of any nicotine or tobacco product compared with those of exclusive users of nicotine pouches, snus, and cigarettes in Sweden. These data were collected to further support the reduction in HPHCs for users of nicotine pouches compared to users of snus or cigarettes. All nicotine pouches used in the study were Swedish Match products and held to the same manufacturing standards. Results of the cross-sectional biomarker study showed that nicotine plasma levels are comparable across all nicotine user groups (see Figure 5) and differ significantly from non-users, levels of BoEs for TSNAs and PAHs are significantly lower in the nicotine pouch user group compared to the other user groups, and the levels were similar to levels found in non-users. Additional data shows that BoPHs for heart disease[7] are significantly lower for nicotine pouch users compared to the cigarette user group, and

[7] Soluble intercellular adhesion molecule-1 (sICAM-1) and growth differentiation factor 15 (GDF-15)

similar to the levels for non-users. These additional biomarker study data provide more evidence, which further supports FDA's conclusions from the ZYN PMTA authorizations, that switching from cigarettes to these products would reduce users' health risks.

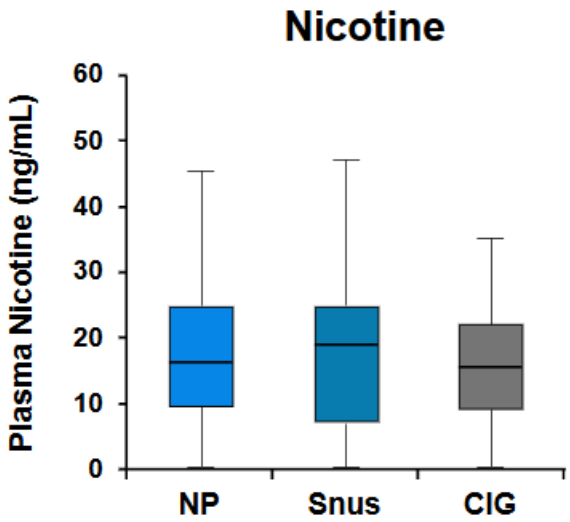

Figure 5. Nicotine levels in users of nicotine pouches (NP), snus, or cigarettes (CIG).

In the ZYN PMTAs, we provided data from several clinical studies assessing PK, nicotine extraction, pharmacodynamics (PD), and the subjective effects associated with abuse liability. Generally, the measures assessed for PD (e.g., pulse rate changes over time) and subjective effects (e.g., "head buzz") were comparable between ZYN and General Snus products in these studies. Across these studies, PK was assessed and compared for ZYN, General Snus, and a commonly used moist snuff product. Plasma nicotine levels in cigarette users spike within 5–7 minutes, which is the typical duration of a cigarette, and then declines rapidly. In contrast, oral products show different PK profiles. For both 3 mg and 6 mg ZYN products, onset, peak, duration, and decline are similar to General Snus and moist snuff. Peak levels are lower for 3 mg ZYN products and higher for 6 mg ZYN products compared to General Snus products, but both are lower than moist snuff products. FDA's PMTA review concluded ZYN products have lower abuse liability than cigarettes and are comparable to other smokeless tobacco products.

Studies evaluating the long-term health risks associated with nicotine pouches have not yet been published. However, extensive literature has been published investigating the long-term risks of developing tobacco-related diseases from cigarette smoking and snus use and comparisons thereof. The epidemiology review of the ZYN PMTAs concluded that it was reasonable to bridge to the published studies on long-term health effects of snus based on similarities in user topography between ZYN and General Snus.[6]

Figure 6 shows the estimated risk of contracting the tobacco-related diseases listed in the claim for snus users compared to cigarette users, based on published literature. Snus use is associated with a lower risk for these conditions compared to cigarette use. In the ZYN PMTAs, we asserted that, given similar user

topographies between ZYN products and General Snus products and ZYN's substantially lower HPHCs, the health effects of General Snus products likely represent the upper limit of likely long-term effects for ZYN products; FDA reviewers found this rationale reasonable, and the TPL concurred with these findings. Therefore, based on similar use patterns and ZYN's reduced toxicological profile, it is reasonable to conclude that the risks of the six health conditions in the claim (mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis) will be lower for ZYN products compared to cigarettes, similar to General Snus products.

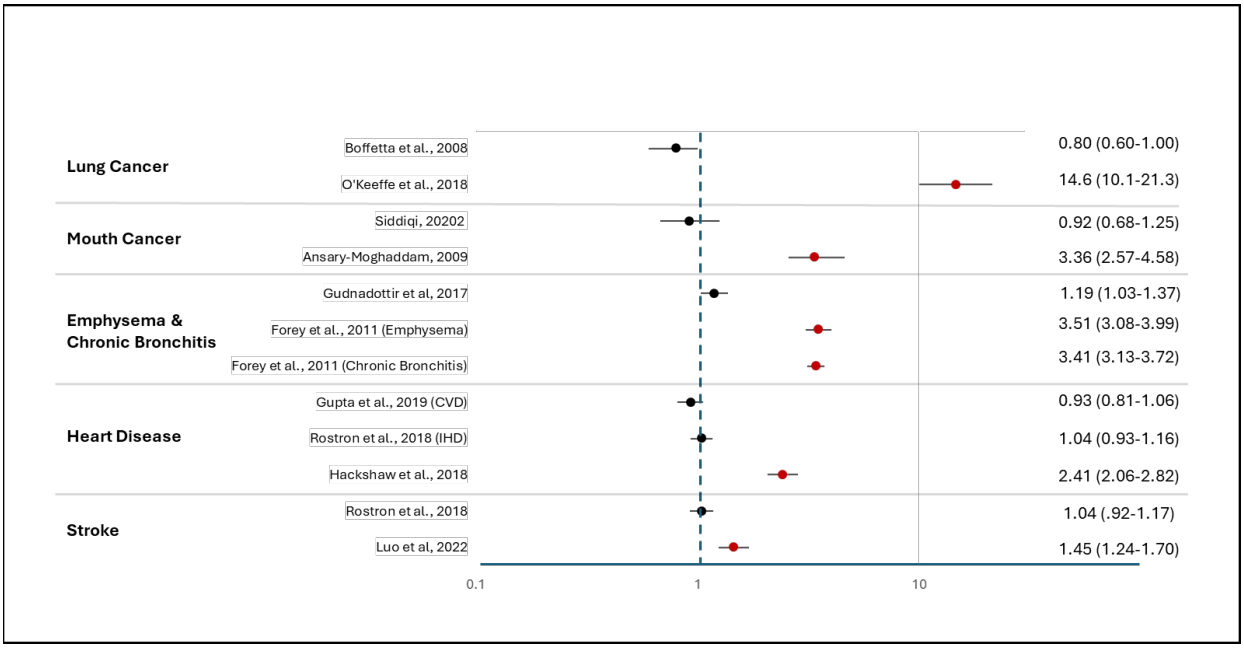

Figure 6. Forest Plot of risks associated with snus and cigarette use for the development of health conditions in the MRTP claim. Black dots represent associated risk of snus use and development of listed disease; red dots represent associated risk of cigarette use and development of listed disease. The further right a dot is, the higher the risk.

Overall, our non-clinical and clinical data, in combination with the published literature on health risks, demonstrates the proposed claim is scientifically substantiated for ZYN products. In their decision to authorize the ZYN PMTAs, FDA evaluated all of our non-clinical and clinical data discussed here, except for the cross-sectional biomarker study data, which only provides additional evidence that further supports the proposed reduced risk claim is scientifically substantiated for ZYN products. It is clear that users who switch from cigarettes to ZYN products are likely to experience a reduction in disease risks, with supporting data discussed below.

4. Swedish Experience Data

Building on the nonclinical and clinical data demonstrating reduced disease risk associated with using ZYN products compared to using cigarettes, it is important to contextualize these findings within real-world outcomes. The "Swedish Experience" provides precedent for tobacco harm reduction, showing how widespread substitution of cigarettes with smokeless tobacco products, such as snus, has driven declines in smoking prevalence and smoking-related diseases over several decades. Given similar use

patterns and improved toxicological profile of ZYN products compared to snus products, bridging these epidemiological findings from Sweden to the U.S. population offers a scientifically and regulatorily validated framework.

Unlike many other countries, Sweden has made products like snus, nicotine pouches, and e-cigarettes accessible, affordable, and acceptable to adults seeking alternatives to smoking.[8,9] As a result, Sweden's smoking rate dropped from 16.5% in 2004 to 5.4% in 2024[10], while the EU average remained at 23%.[11] Due to this approach to tobacco harm reduction and the associated drop-in smoking rates, Sweden is expected to become the first country in Europe to become "smoke-free" to which is defined as less than 5% of the adult population smoking tobacco. This dramatic reduction in smoking translated into significant public health benefits: Sweden's incidence of cancer is 41% lower than the rest of Europe, and tobacco-related mortality is 39.6% lower than the EU average.[11]

Part of the FDA-accepted bridging argument of the "Swedish Experience" data to General Snus during the initial authorization[2] was based on the low HPHCs from General Snus products, significantly lower than those for cigarettes. Specifically, FDA noted the very low levels of TSNAs in the General Snus products as contributing to the reduced risk of mouth cancer for users that switch completely to General Snus products even from other oral tobacco products, not just cigarettes.[2]

The "Swedish Experience" data demonstrate the substantial reduction in rates of tobacco-related disease (e.g., lung cancer, CVD) over several decades after the snus category was widely adopted in Sweden in the 1980's as smoking rates decreased. The data were shown to represent the expected long-term health effects in the U.S. population if consumers fully switched from a more harmful product, such as cigarettes, to a reduced-harm product like General Snus. The low HPHC levels indicate a reduced cancer and heart disease risk over time compared to cigarettes. Given the similarities in design and use between General Snus and ZYN products, the epidemiological data from Sweden with snus use can be bridged to the ZYN products. Therefore, the data suggests that ZYN products could have achieved similar or even greater public health benefits if introduced in Sweden instead of General Snus products.

[8] Amos, A., Arnott, D., Aveyard, P., Bauld, L., Bogdanovica, I., Britton, J., ... & West, R. (2016, April). Nicotine without smoke: Tobacco harm reduction. Royal College of Physicians.

[9] Kozlowski, L. T., & Abrams, D. B. (2016). Obsolete tobacco control themes can be hazardous to public health: the need for updating views on absolute product risks and harm reduction. BMC public health, 16(1), 432.

[10] Swedish National Health Service Statistical Database on Use of Tobacco and Nicotine Products, https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/andtg/tobacco/use-of-tobacco-and-nicotine-products/ (Accessed December 2025).

[11] Smoke Free Sweden. (2023). The Swedish experience: A roadmap to a smoke-free society. https://smokefreesweden.org/wp-content/themes/smokefreesweden/assets/pdf/reports/Report%20The%20Swedish%20Experience%20EN.pdf

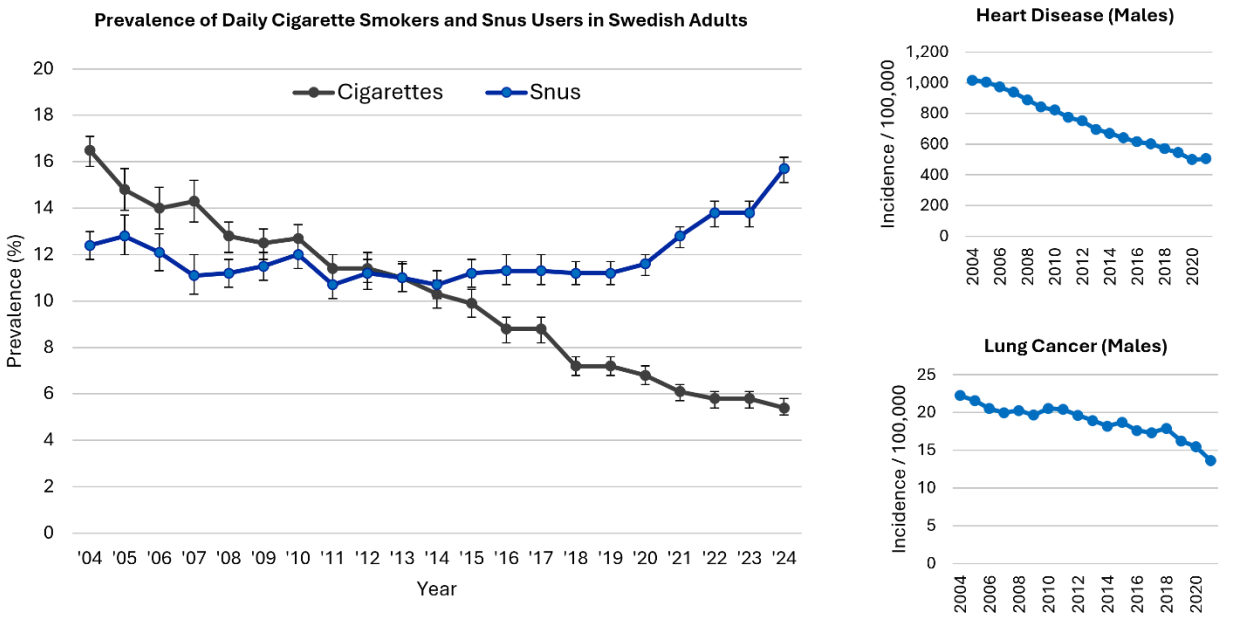

Figure 7. Prevalence of daily cigarette and snus use in Swedish adults 18-64 after 2004 (left), incidence of heart disease (Top Right) and lung cancer (Bottom Right) in Swedish males.[10,12]

ZYN products have only been marketed since 2014, so analogous long-term health data does not yet exist for these products. However, ZYN products are very similar in design and use compared to the authorized General Snus products, but with an improved toxicological profile compared to snus and cigarettes. Additionally, while assessing the ZYN PMTAs, FDA acknowledged the health effects observed for snus are likely to represent the upper limit of health risks for ZYN products[6]. Therefore, this data shows what is possible in the U.S. if consumers completely switch away from cigarettes, as many have in Sweden over the last few decades. Further supporting this, we contracted development of a PHIM based on U.S. marketing of nicotine pouches under different scenarios.[13] While the U.S. and Sweden are different markets, the PHIM developed for the U.S. market estimates that, even under the most limited and pessimistic assumptions, uptake of nicotine pouches with an associated decline in cigarette use could result in 600,000 U.S. lives saved from tobacco-related deaths by 2050.

5. Populations of Use and Use Behaviors

The intended user population for ZYN products, similar to General Snus products, is legal-age adults who use tobacco or nicotine products, and the proposed claim is intended to reach a specific subset of that population – adults who smoke cigarettes. Our PMTAs provided FDA with extensive data showing that some adults who smoke and have started using ZYN products have reduced their cigarette use over time,

[12] Data was not reported for 2017, 2019, or 2023 in this database. For these years, data was imputed such that the value reported for the previous year was repeated for these years with missing data (i.e., data for 2016 was used for 2017; 2018 for 2019; 2022 for 2023).

[13] Lee, P.N., Fry, J.S. & Ljung, T. Estimating the public health impact had tobacco-free nicotine pouches been introduced into the US in 2000. *BMC Public Health* **22**, 1025 (2022). https://doi.org/10.1186/s12889-022-13441-0.

with some completely quitting cigarettes or all tobacco and nicotine products. Of those that continue to smoke cigarettes after starting to use ZYN products, the majority (80.7%) reduced their cigarette consumption, and over half (57.2%) reduced their cigarettes per day by at least 50%. But it is not just our data that shows these trends. A recent publication[14] investigated who uses nicotine pouches, based on analysis of data from the 2022–2023 Tobacco Use Supplement to the Current Population Survey (TUS-CPS). According to the publication[14], ever, current, and daily use of nicotine pouches is very low among tobacco-naïve[15]adults. Additionally, the majority of adults who use nicotine pouches have a history of smokeless tobacco product or cigarette use, and most adults who use nicotine pouches have quit using another tobacco product in favor of using nicotine pouches. The study also suggests that this product category could provide a population-level benefit to those interested in quitting other tobacco products, like cigarettes.

This study aligns with the data and evidence provided in the PMTAs from our ZYN Likelihood of Use study, which showed former and non-users of nicotine and tobacco products do not find ZYN products appealing and do not intend to use the products. Additionally, the ZYN Patterns of Use study, which investigated use patterns among product users, demonstrated that a significant proportion of smokers who use ZYN products reduced their cigarette consumption (i.e., frequency of use and average daily amount) over the course of the study (from 42% reporting smoking prior to using ZYN, down to 8.1% reporting smoking by week 10). Users of moist snuff who began using ZYN products also decreased their usage of moist snuff over the same time period. Almost a quarter (24%) of dual users (i.e., users of ZYN products and any other tobacco product) switched completely to ZYN products, and a small portion of users (3.2%) in the study were able to quit all tobacco and nicotine products by the end of the study.

These data are further supported by the results of the ZYN User Profile Study, which investigated user patterns and behaviors among light[16], medium[17], and heavy[18] users of ZYN products. Across all users in the study, over 80% reduced their overall cigarette consumption since starting to use ZYN products, and more than half reduced their overall cigarette consumption by greater than 50% per day. There was a potential association between more intense use of ZYN products (i.e., more pouches per day) and reducing overall cigarette consumption by at least 50%. Of heavy users, 75.4% reported reductions in their cigarette use by more than 50% since starting to use ZYN products, whereas 61.4% of medium users and 35.0% of light users reported the same metric. Heavy ZYN users who reported to be everyday smokers also used less cigarettes per day (9.6 cigarettes) compared to everyday smokers in the medium (11.7 cigarettes) and light (12.8 cigarettes) ZYN user groups. The data also shows most ZYN users have a

[14] Delnevo CD, Tomaino M, Hrywna M, Bover Manderski MT. (2025). Patterns of nicotine pouch use among adults in the U.S., 2022-2023. JAMA Network Open, 8(9), e2531155. https://doi.org/10.1001/jamanetworkopen.2025.31155.

[15] Naïve tobacco users defined as responding "No" to ever using cigarettes, e-cigarettes, cigars, smokeless tobacco, hookah, pipe, or heated tobacco.

[16] Light users are defined as everyday users who used 1–3 pouches everyday over the past 30 days or someday users who used < 120 pouches total in the past 30 days and did not use 10 pouches or more on any day.

[17] Medium users are defined as everyday users who used 4–9 pouches every day in past 30 days or someday users who used 120–270 pouches in total in the past 30 days and did not use 10 pouches or more on any day.

[18] Heavy users are defined as everyday users who used 10+ pouches every day in past 30 days or someday users who used 10+ pouches on somedays regardless of number of days used in the past 30 days.

history of using smokeless tobacco products and/or cigarettes prior to their use of ZYN (see Figure 8). Since most ZYN users started with cigarettes, the MRTP claim should effectively reach the intended audience and likely increase switching rates.

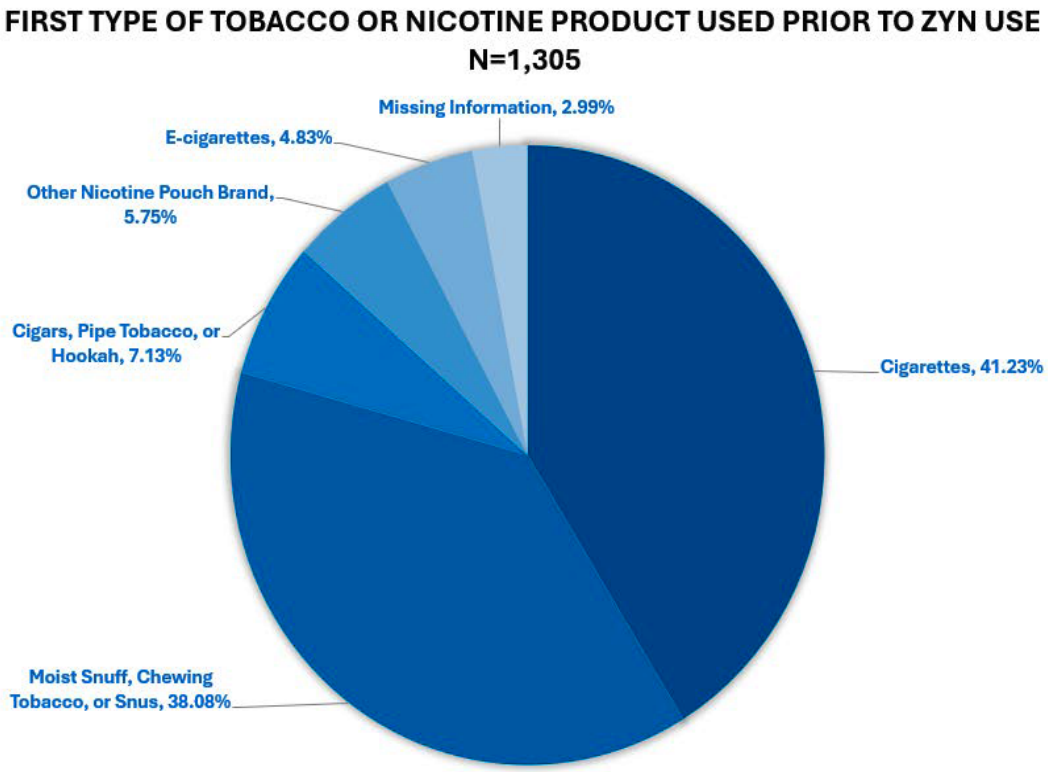

Figure 8. First type of tobacco or nicotine product used prior to ZYN product use. Source – ZYN User Profile Study

Overall, data from both our own studies and literature demonstrate ZYN products are primarily used by the intended audience: current adult users of other tobacco and nicotine products, and specifically, adult users of cigarettes. Data also shows adult nonusers (e.g., never users, former users) are very unlikely to use these products. User behavior data from our studies indicate that while a proportion of adults are able to reduce their overall cigarette consumption over that study time periods, some users in studies who reported using other tobacco products prior to ZYN use are able to switch completely to ZYN products from the other tobacco products over the course of the study. These data show users of tobacco and nicotine products are willing to switch completely to ZYN products, allowing them to experience the reductions in health risks described above, while demonstrating minimal risk to nonusers. With authorization of the proposed claim, we aim to help even more adult users of cigarettes experience potential reductions in disease risks by switching completely away from cigarettes.

6. Consumer Understanding and Perceptions

Initial consumer perceptions of risk related to ZYN products were assessed in the ZYN Likelihood of Use and ZYN Patterns of Use studies provided in the PMTAs. Across both studies, respondents conveyed an

understanding of the continuum of risk when considering use of any tobacco or nicotine product versus ZYN products, and versus cigarettes. Across all health conditions evaluated in these two studies (adult tooth loss, mouth cancer, gum disease, and serious health problems), most respondents perceived low-to-minimal absolute risk to human health for never using tobacco and nicotine products, low-to-moderate absolute risks to human health for using ZYN products exclusively, and moderate-to-very high absolute risks for smoking cigarettes. We also conducted a tobacco products perceptions and intentions to use (TPPI) study with the proposed claim. We assessed whether exposure to the claim impacted intentions to use ZYN products as well as absolute and relative risk perceptions in different user groups, including current users of cigarettes, current smokeless tobacco users, non-established users of tobacco and nicotine products ages 21–24, non-established users of tobacco and nicotine products of all ages (21+), and former users of tobacco and nicotine products other than cigarettes or smokeless tobacco.

Results show exposure to ZYN marketing materials with the proposed claim generally does not impact likelihood to initiate or reinitiate tobacco or nicotine product use in nonusers (i.e., never established and former users), though these groups did perceive lower health risks associated with ZYN products compared to cigarettes. Additionally, exposure to the proposed claim did not significantly alter the intention to quit cigarettes among current daily users of cigarettes; however, exposure to the claim did raise awareness about the potentially lower risks of developing the six critical health conditions in the claim (i.e., mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis) when using ZYN products compared to continued smoking. Exposure to the claim in the test group led to slightly lower perceived risk for developing the six health conditions after using ZYN products compared to the control group (i.e., subjects exposed to marketing materials without the claim). Overall, all subjects perceived low-to-moderate or moderate risks of developing each of the six health conditions mentioned in the claim after using ZYN products, with the highest perceived risks associated with cigarette use and the lowest perceived risks associated with nicotine replacement therapy (NRT) or cessation. Additionally, subjects exposed to the claim generally perceived lower risks of developing all six conditions after use of ZYN products relative to cigarettes. Overall, these results clearly demonstrate that subjects understood ZYN products are not risk-free and the risk of developing the health conditions in the claim after using ZYN products is significantly lower compared to the risk after using cigarettes.

A post-market study completed for General Snus products assessed whether consumers understood that complete switching is needed to lower disease risks by asking consumers how many cigarettes they could smoke to have a lower risk of the health conditions in the claim. Over all four waves of that study, more than 80% of consumers correctly picked “zero cigarettes”, demonstrating a high rate of comprehension that consumers understand “instead of” means complete switching. While this question was not assessed again during the ZYN study with claim, the similarities between products have been demonstrated, and recognized by FDA. Additionally, the authorized reduced risk claim for General Snus used in this study is the same as the proposed reduced risk for ZYN, except in product name. Therefore, users of ZYN, a product similar to General Snus in manner and populations of use but with a lower toxicological risk profile, are similarly likely to understand that “instead of” refers to the need to completely switch away from cigarettes to ZYN to experience the likely lower long-term health risks.

7. Low Youth Use of Nicotine Pouches (Nationally Representative Survey Data)

Data from several nationally representative surveys assessing youth use of tobacco and nicotine products show the estimated prevalence of current (i.e., past 30-day) nicotine pouch use among youth through 2024 remains at or below 1.8%. The National Youth Tobacco Survey (NYTS) added nicotine pouches to their annual questionnaire in 2021, and the estimated prevalence of current use through 2024 shows consistently low current youth use of nicotine pouches across all four years (1.0–1.8%). In comparison, current use of e-cigarettes among youth (5.9–9.4% over the same time period) shows that it remains the most popular tobacco product among youth. Additionally, estimates for current nicotine pouch use among youth are comparable to those observed for smokeless tobacco, which includes snus, across the same four-year time period (0.96%–1.5%).[19,20,21,22] Estimates from the Altria Client Services' Underage Tobacco Use Study (UTUS), a repeated cross-sectional survey that collects data on underage tobacco use on a quarterly basis, were similar to those reported by NYTS. Past 30-day nicotine pouch use estimates remained low throughout 2020–2024 study periods, at approximately 1.2% overall. The most recent available wave of the Monitoring the Future (MTF) data (2024) shows the prevalence of past 30-day use of nicotine pouches remains low at 1.8% among middle and high school students overall.[23] Of the other tobacco-related products tracked in MTF, prevalence estimates for past 30-day use of nicotine pouches was comparable to those for past 30-day cigarette (1.6%) and smokeless tobacco (2.4%) use, but notably lower than past 30-day e-cigarette use (10.1%). In comparison, MTF data from 2017 was provided in the MRTPA for Copenhagen® Snuff Fine Cut, an FDA-authorized MRTP, showing use prevalence of smokeless tobacco products at 3.5% among middle and high school students. Youth use rates of nicotine pouches are half of those for smokeless tobacco products in the studies provided to support authorization of the MRTPA for Copenhagen® Snuff Fine Cut. Finally, the Population Assessment of Tobacco and Health (PATH) survey data from waves 7 (2022) and 7.5 (2023) show past 30-day use of nicotine pouches among youth remains below 0.5%.

Overall, nationally representative U.S. survey data from multiple sources demonstrate low youth use of the nicotine pouch product category, which includes ZYN. Further, estimates of nicotine pouch use among youth are comparable to those for smokeless tobacco product use.

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[19] Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(No. SS-5):1–29. DOI: http://dx.doi.org/10.15585/mmwr.ss7105a1external icon.

[20] Park-Lee E, Ren C, Cooper M, Cornelius M, Jamal A, Cullen KA. Tobacco Product Use Among Middle and High School Students — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1429–1435. DOI: http://dx.doi.org/10.15585/mmwr.mm7145a1.

[21] 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.

[22] Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924. DOI: http://dx.doi.org/10.15585/mmwr.mm7341a2

[23] Miech, R. A., Johnston, L. D., Patrick, M. E., O'Malley, P. M. (2025). Monitoring the Future national survey results on drug use, 1975–2024: Overview and detailed results for secondary school students. Monitoring the Future Monograph Series. Ann Arbor, MI: Institute for Social Research, University of Michigan.

8. Responsible Marketing and Controls

Nationally representative survey data demonstrate consistently low youth use of nicotine pouches across multiple years and surveys. We are committed to guarding against underage access to these products, while continuing to provide adults (21+) with better alternatives to smoking and traditional tobacco. No one below the legal age should use nicotine in any form, and we commit to that clearly in our Marketing Code.

Our responsible marketing practices cover labeling, advertising, marketing, promotion, and other consumer-directed activities, and are directed to adult (21+) current tobacco and nicotine users. Our goal is to responsibly communicate accurate, truthful, and non-misleading information about our smoke-free products to legal age (21+) tobacco and nicotine users.

Specifically, our responsible marketing practices include, but are not limited to the following:

- Access to the product website (ZYN.com) is restricted to only those confirmed to be at least 21 years old, through our third-party age verification partners who match consumer information with government databases to confirm individuals' identity and age;
- We only use models who are aged 35 and over;
- Our branded social media pages are only on platforms that enable age-restricted controls;
- Brand-specific events or activations we engage in are age-restricted;
- We do not pay social media influencers to endorse our products.

Pursuant to the ZYN Marketing Granted Orders (MGOs)[24], we submitted 30-day notifications of all labeling, advertising, and marketing related to ZYN products for the first six months of authorization. Additionally, we will submit Annual Reports every year for these products (starting in January 2026) to provide an overall assessment of how the marketing of these products continues to be appropriate for the protection of public health, including marketing impressions data allowing us to track the age of consumers who view our materials across multiple channels.

The proposed claim would be marketed in accordance with our own policy and practices, which align with current FDA and legal requirements. The modified risk claim would be directed to current adult smokers. If authorized as a modified risk tobacco product, marketing materials with the claim would continue to be subject to ongoing FDA oversight and reporting requirements.

[24] MGO_Ltr_SMUSA_PM593-PM612_Zyn_MM_DD_2024_Redacted for ZYN PMTAs (2025). Accessed Searchable Tobacco Products Database November 10, 2025.

9. Conclusions

Available data and analyses demonstrate ZYN products meet the standard under section 911(g)(1) of the FD&C Act, and therefore, can be sold or distributed with the proposed reduced risk claim. ZYN products, as actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and
- Benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

The proposed claim is identical to the authorized claim for General Snus products, except for the product name. The primary reasons for the authorization of the claim for General Snus included: low levels of HPHCs, low youth use, and the "Swedish experience" epidemiological data demonstrating long-term reduction of tobacco-related disease in Sweden. The data discussed herein scientifically substantiates that this proposed reduced risk claim is also applicable for ZYN for the same reasons. As the ZYN PMTA TPL review states:

"The toxicology review concludes that adults who smoke who switch completely to the new products are expected to experience reduced risk of cancer, respiratory toxicity, and cardiovascular toxicity."

FDA authorization of ZYN products with the proposed reduced risk claim will provide nearly 30 million U.S. adults who continue to smoke with the opportunity to be informed and to choose a product that can reduce their risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis, if they switch away from cigarettes.