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January 22, 2026

Dr. Bret Koplow
Director
Center for Tobacco Products (CTP)
United States Food and Drug Administration
Rockville, MD 20852

Re: Docket No. **FDA-2025-N-0835**

Dear Dr. Koplow,

The R Street Institute (R Street) respectfully submits the following comments in response to the request for public comments on the modified risk tobacco product (MRTP) application for ZYN products submitted by Swedish Match U.S.A., Inc. R Street is a nonprofit, nonpartisan public policy organization focused on advancing free markets and limited, effective government. Our Integrated Harm Reduction work is based on the belief that health policy rooted in harm reduction can significantly reduce the adverse outcomes of harmful behaviors and alleviate the burdens of healthcare costs. Decades of research show that abstinence-only methods are ineffective at a population level for risky behaviors. Policies that criminalize behaviors like smoking lead to unintended negative consequences.

We are writing this letter in strong support of the Modified Risk Tobacco Product (MRTP) applications submitted by Swedish Match USA, Inc., for 20 variants of ZYN nicotine pouch products. As announced in the Federal Register on June 18, 2025, these applications seek authorization to market ZYN with modified risk claims, explicitly stating that "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 modification to the package warnings and labeling is well-supported by a growing body of scientific research demonstrating that ZYN presents substantially lower health risks compared to combustible cigarettes.[1] Granting these applications would provide smokers with accurate, evidence-based information, potentially

[1] Pant, S., & Anderer, S. Can Nicotine Pouches Help People Quit Smoking?. JAMA. https://jamanetwork.com/journals/jama/fullarticle/2843607

encouraging a switch to less harmful alternatives and advancing public health goals under the Family Smoking Prevention and Tobacco Control Act.

The FDA's MRTP pathway allows companies to market tobacco products with reduced-risk claims if rigorous scientific evidence shows that the product, as actually used by consumers, significantly reduces harm to individual users and benefits population health.[2] In the case of ZYN, a tobacco-derived nicotine pouch that contains no tobacco leaf and is used orally without combustion or spitting, the evidence is compelling. Unlike cigarettes, ZYN delivers nicotine through absorption in the mouth, eliminating exposure to tar, carbon monoxide, and numerous carcinogens associated with smoke. This fundamental difference in delivery mechanism underpins the lower risk profile of ZYN and justifies modifying the current warnings, which may not accurately reflect its relative risks and could deter potential switchers.

Central to the MRTP application is research on harmful and potentially harmful constituents (HPHCs) in ZYN compared to traditional tobacco products. Studies have consistently shown that ZYN contains significantly lower levels of toxicants than cigarettes and even other smokeless tobacco products. For instance, an analysis of HPHCs in novel nicotine pouches revealed that ZYN products have the lowest concentrations of harmful substances like chromium, arsenic, and nitrosamines when compared to snus and moist snuff.[3] This reduction in toxicant levels translates to a lower toxicological risk for users, as confirmed by evaluations indicating that ZYN's overall harm is markedly less than that of cigarettes due to the absence of combustion-related byproducts.[4] Such findings support the need to modify package warnings to include affirmative reduced-risk statements, as current generic warnings (e.g., "This product is addictive" or implications of equivalent harm) do not distinguish ZYN's profile from more dangerous products like cigarettes.

Epidemiological and clinical data further bolster this case. Long-term studies on similar oral nicotine products, such as Swedish snus, have demonstrated reduced incidences of tobacco-related diseases among users who switch from smoking. For example, users of snus exhibit lower risks of lung cancer, cardiovascular disease, and chronic obstructive pulmonary disease (COPD) compared to smokers, attributable to the lack of inhaled smoke.[5] Applying this to ZYN, which has even lower HPHC levels than traditional snus, suggests analogous benefits. Independent

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[2] U.S. Food and Drug Administration. (2025, Nov. 06). Modified Risk Tobacco Products. https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products

[3] Back, S., Masser, A.E., Rutqvist, L.E. et al. Harmful and potentially harmful constituents (HPHCs) in two novel nicotine pouch products in comparison with regular smokeless tobacco products and pharmaceutical nicotine replacement therapy products (NRTs). BMC Chemistry 17, 9 (2023). https://link.springer.com/article/10.1186/s13065-023-00918-1#citeas

[4] Harvard T.H. Chan School of Public Health. (2024, April 16). Zyn pouches safer than smoking, but still pose risks. https://hsph.harvard.edu/news/zyn-pouches-safer-than-smoking-but-still-pose-risks/

[5] Clarke, Elizabeth, et al. "Snus: a compelling harm reduction alternative to cigarettes." Harm reduction journal 16.1 (2019): 62. https://link.springer.com/article/10.1186/s12954-019-0335-1

reviews affirm that nicotine pouches like ZYN present significantly lower health risks than smoking, primarily because they avoid the cancer-causing chemicals and toxins in cigarette smoke.[6] Moreover, a comprehensive assessment of nicotine exposure in pouches highlights their position on the harm continuum, positioning them closer to nicotine replacement therapies (NRTs) than to combustible tobacco.[7] These insights underscore the scientific justification for modifying warnings to convey that complete switching to ZYN reduces specific disease risks, thereby empowering consumers with information that could encourage harm-reduction behaviors.

Abuse liability and addiction potential are critical considerations in MRTP evaluations, and here too, the research supports ZYN's favorable profile. Randomized crossover studies have shown that oral nicotine pouches similar to ZYN have an abuse liability lower than cigarettes and comparable to NRT gums, indicating a reduced potential for misuse.[8] Evaluations of nicotine concentration effects further indicate that while ZYN delivers nicotine effectively, its appeal and pharmacokinetics do not exceed those of approved cessation aids, mitigating concerns about gateway use or heightened addiction risks.[9] Importantly, the FDA's own January 2025 PMTA authorization for ZYN, found low youth usage despite market growth, suggesting that modified risk claims would not unduly attract non-users.[10] Modifying package warnings to include reduced-risk information would thus align with evidence that such claims can lower perceived harm relative to cigarettes without increasing overall initiation.[11]

From a public health perspective, authorizing these modifications could accelerate the transition away from smoking, the leading cause of preventable death in the United States. The proposed claim directly addresses key smoking-related diseases, backed by evidence that switching to non-

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[6] Philip Morris International. (2025a, February 13). U.S. regulatory landscape for smoke-free products. PMI Science. https://www.pmiscience.com/en/smoke-free/tobacco-regulation/us-regulation-tobacco-nicotine-products; Philip Morris International. (2025b). Growing scientific and regulatory consensus on smoke-free products. https://www.pmi.com/sustainability/growing-scientific-and-regulatory-consensus-on-smoke-free-products

[7] Foundation for a Smoke-Free World. (2025, January 23). FDA issues first marketing authorization for oral nicotine pouches. The Continuum of Risk. https://www.thecontinuumofrisk.com/2025/01/fda-issues-first-marketing-authorization-for-oral-nicotine-pouches/

[8] Kanobe, Milly N., et al. "Randomized crossover clinical studies to assess abuse liability and nicotine pharmacokinetics of Velo Oral Nicotine pouches." Frontiers in Pharmacology 16 (2025): 1547073. https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2025.1547073/full

[9] Keller-Hamilton, Brittney, et al. "Evaluating the effects of nicotine concentration on the appeal and nicotine delivery of oral nicotine pouches among rural and Appalachian adults who smoke cigarettes: A randomized cross-over study." Addiction 119.3 (2024): 464-475. https://onlinelibrary.wiley.com/doi/full/10.1111/add.16355

[10] U.S. Food and Drug Administration. (2025a, January 17). FDA authorizes marketing of PMI's nicotine pouches. PMI Science. https://www.pmiscience.com/en/news-events/news/fda-authorizes-marketing-of-pmi-s-nicotine-pouches/

[11] Vogel, Erin A., et al. "Effects of flavour and modified risk claims on nicotine pouch perceptions and use intentions among young adults who use inhalable nicotine and tobacco products: a randomised controlled trial." Tobacco control 34.3 (2025): 315-322. https://tobaccocontrol.bmj.com/content/34/3/315.abstract.

combustible products reduces exposure to toxicants and carcinogens.[12] For instance, heated tobacco products (a related category) have been shown to lower toxicant exposure with moderate certainty, a principle extendable to pouches like ZYN.[13] Retaining unmodified warnings risks perpetuating misconceptions that all nicotine products carry equivalent harms, discouraging smokers from switching. In contrast, evidence-based labeling, as sought in the application, could inform the estimated 28 million U.S. adult smokers about viable alternatives, potentially saving lives and reducing healthcare burdens.

It is also worth noting that ZYN's authorization under the PMTA pathway in January 2025 already confirmed that its marketing is appropriate for the protection of public health, with lower HPHC levels than cigarettes and most smokeless products.[14] Building on this, the MRTP applications incorporate additional data on consumer perceptions, actual use patterns, and long-term health outcomes, all of which support the proposed claims. Studies on flavored pouches and modified risk messaging indicate increased appeal among young adults who use inhalable products, but with reduced harm perceptions only relative to cigarettes, not an absolute endorsement of safety.[15] This balanced approach ensures that modifications to warnings promote informed choices without misleading vulnerable populations.

Summary of Recommendations

The R Street Institute profoundly appreciates the opportunity to comment on the review of the ZYN MRTP application and hopes these comments help support the renewal of the MRTP application and motivate the CTP to review and amend tobacco product warnings so that they are specific to the product category. To be clear, the fewer people who smoke, the better. The CTP should focus on providing consumers with the clearest information in the swiftest manner possible to encourage behavioral change in their personal health choices. Tobacco harm reduction is the most efficient approach to tackling smoking disparities as compared to product prohibition and the potential adverse outcomes associated with trying to regulate human behavior. The research embedded in Swedish Match's MRTP applications for ZYN robustly demonstrates that these products pose lower risks than cigarettes for the specified diseases, warranting modifications to package warnings to include the proposed reduced-risk claim. By granting these applications, the FDA would align labeling with scientific evidence, foster harm

[12] Philip Morris International. (2025b). Growing scientific and regulatory consensus on smoke-free products. https://www.pmi.com/sustainability/growing-scientific-and-regulatory-consensus-on-smoke-free-products

[13] Ibid.

[14] U.S. Food and Drug Administration. (2025b, January 16). FDA authorizes marketing of 20 ZYN nicotine pouch products after extensive scientific review. https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-20-zyn-nicotine-pouch-products-after-extensive-scientific-review

[15] Vogel, Erin A., et al. "Effects of flavour and modified risk claims on nicotine pouch perceptions and use intentions among young adults who use inhalable nicotine and tobacco products: a randomised controlled trial." Tobacco control 34.3 (2025): 315-322. https://tobaccocontrol.bmj.com/content/34/3/315.abstract

reduction, and contribute to declining smoking rates. R Street urges the agency to expedite the review and approval of these applications in the interest of public health.

Thank you for considering this letter as part of the public comment process.

Respectfully submitted,

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