

Food and Drug Administration
Silver Spring, MD 20993

In The Matter of Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments [Docket No. FDA-2025-N-0835]

The American Consumer Institute is an independent 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in selected legislative and rulemaking proceedings in information technology, health care, insurance, and other matters.

We write in support of the Food and Drug Administration's (FDA's) decision to authorize 20 ZYN Nicotine Pouch products.¹ Smoking kills nearly half a million Americans every year.² Harm reduction products such as nicotine pouches have the potential to help smokers quit while drastically decreasing the risks posed by tobacco use. The result is healthier lives for current smokers and lower spending on smoking-related diseases by patients and safety-net programs such as Medicare and Medicaid. By approving these products, the FDA expands the choices available to smokers seeking to quit by ensuring access to less harmful alternatives.

ZYN's Nicotine Pouch products are the first of their kind to receive authorization after successfully completing the Premarket Tobacco Product Application (PMTA) process. The FDA's authorization correctly recognizes the dramatically lower risks of nicotine pouches compared to cigarettes. These products have tested negative for mutagenicity, genotoxicity, and cytotoxicity.³ They also have fewer harmful or potentially harmful constituents—and at much lower levels—than combustible cigarettes.⁴ Zyn pouches have lower toxin levels than cigarettes, as the products contain no tobacco leaf. While nicotine is addictive, it is not the cause of smoking related diseases. Smoking related diseases are caused by the harmful chemicals in tobacco—especially combusted products.

¹ "FDA Authorizes Marketing of 20 ZYN Nicotine Pouch Products after Extensive Scientific Review," United States Food and Drug Administration, January 16, 2025, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-20-zyn-nicotine-pouch-products-after-extensive-scientific-review?utm_campaign=ctp-mrtp&utm_content=pressrelease&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

² "Burden of Cigarette Use in the U.S.," Center for Disease Control, Reviewed October 8, 2024, <https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html>.

³ Brian Keyser, Robert Leverette, et al., "In vitro toxicological evaluation of pouched portioned oral nicotine products," *Frontiers in Toxicology*, Volume 6, November 27, 2024. <https://www.frontiersin.org/journals/toxicology/articles/10.3389/ftox.2024.1452274/full>

⁴ Nargiz Travis, Kenneth Warner, et al., "The Potential Impact of Oral Nicotine Pouches on Public Health: A Scoping Review," *Nicotine and Tobacco Research*, Volume 27, March 24, 2025. <https://pubmed.ncbi.nlm.nih.gov/38880491/>.

A study of smokers using oral nicotine pouches to quit showed significant reductions in exposure to harmful chemicals, in some cases exposure to toxins for those using the pouches is similar to study participants who quit tobacco products entirely.⁵

Although nicotine pouch use remains relatively low among the general population,⁶ evidence suggests that their primary role has been in harm reduction and smoking cessation. Short-term studies show statistically significant reductions in daily cigarette consumption.⁷ Other research indicates that nicotine pouch users tend to be people who already use tobacco products, with current and daily use most common among adults who recently quit another tobacco product.⁸ This pattern of adoption strongly suggests pouches are functioning as a cessation aid for many smokers.⁹

Authorizing these pouches provides adult smokers with more regulated, quality-controlled options to leave cigarettes behind. Sweden has already demonstrated the population-wide benefits of low-risk oral nicotine products, with smoking related cancer rates falling after widespread snus adoption.¹⁰ ZYN nicotine pouches are likely even safer than snus products available in Sweden and the U.S. since they contain no tobacco at all.

The FDA's action on ZYN is an important step, but it should mark the beginning—not the end—of broader approvals for harm-reduction products. Hundreds of thousands of smokers will continue to be left behind if only a narrow subset of lower-risk products makes it through the PMTA process. Different smokers need different tools to quit; some will respond best to nicotine pouches, others to e-cigarettes, heated-tobacco products, or other noncombustible alternatives. Public health is best served when a wide range of rigorously tested, lower-risk alternatives are available to smokers.

⁵ Jesse Rensh, Jeffery Edmiston, et al., "A Randomized, Controlled Study to Assess Changes in Biomarkers of Exposures Among Adults Who Smoke That Switch to Oral Nicotine Pouch Products Relative to Continuing Smoking or Stopping All Tobacco Use," *Journal of Clinical Pharmacology*, Volume 63, October, 2023, <https://pubmed.ncbi.nlm.nih.gov/37322571/>.

⁶ "Nicotine Pouches," Center for Disease Control, January 31, 2025, <https://www.cdc.gov/tobacco/nicotine-pouches/index.html>.

⁷ Lisa Fucito, Stephen Baldassarri, et al., "The Effects of Oral Nicotine Pouches on Cigarette Smoking Behavior and Tobacco Harm Exposure: A Randomized Pilot Trial in Adults," *Tobacco Control*, June 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC12377922/>.

⁸ Cristine D. Delnevo, Marisa Tomaino, and Mary Hrywna, "Patterns of Nicotine Pouch Use Among Adults in the US, 2022-2023," *JAMA Network Open*, Volume 8, Number 9, September 8, 2025, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2838608?guestAccessKey=a05536a1-6192-4094-a9c5-3c02cd60df69&utm_source=for_the_media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfi&utm_term=090825.

⁹ Greg Bruno, "Nicotine Pouches May Offer Path to Reduced Tobacco Harm," *Rutgers School of Public Health*, September 9, 2025, <https://sph.rutgers.edu/news/nicotine-pouches-may-offer-path-reduced-tobacco-harm>.

¹⁰ "Why No One Smokes In Sweden," *Bloomberg*, January 19, 2024, <https://www.bloomberg.com/news/videos/2024-01-19/why-no-one-smokes-in-sweden>.

Before this authorization the FDA had authorized only 42 harm-reduction products for smokers.¹¹ Increasing the number to 62 is a meaningful improvement, but still a very limited set of options compared with the 900 cigarettes the agency authorized in just five years.¹² Providing smokers with more alternatives is essential to accelerating the voluntary shift away from combustible cigarettes and reducing the burden of smoking-related disease.

Cigarettes remain the leading cause of preventable death in the United States, but nicotine pouches eliminate the tobacco and combustion that drive the vast majority of smoking-related harm. The authorization of 20 ZYN nicotine pouch products provides a clear public-health benefit by expanding the availability of smoke-free alternatives that expose users to dramatically fewer toxic chemicals. We urge the FDA to continue this progress and authorize additional tobacco harm reduction products across a variety of categories.

Respectfully,

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¹¹ "Premarket Tobacco Product Marketing Granted Orders," United States Food and Drug Administration, March 28, 2024, <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders>.

¹² "FDA Approves More Than 1200 Combustibles and 900 New Cigarettes," *Vapor Technology Association*, March 2023, <https://vaportechnology.org/wp-content/uploads/2023/04/VTA-Report-%E2%80%93-FDA-Approves-Combustibles.pdf>.

