



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE

Alister F. Martin, MD, MPP
Commissioner

March 4, 2026

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Via Electronic Submission

<http://www.regulations.gov>

Gotham Center
42-09 28th St.
Long Island City, NY 11101

Re: Food and Drug Administration Docket No. Fda-2025-N-0835 for Modified Risk Tobacco Product Application for Zyn Oral Pouch Products Containing Nicotine

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (Health Department or NYC Health Department) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding the Modified Risk Granted Orders application filed by Swedish Match for Zyn oral pouch products containing nicotine.

The NYC Health Department urges the FDA against approving an exposure Modification Order under § 911(g)(1)(A) of the Federal Food, Drug, and Cosmetic Act.

Zyn products are distinct from the previously authorized Swedish Match USA Inc.'s MRTPs because of their appeal to youth.

Swedish Match's application relies on similarity to General snus, a Swedish Match product previously granted an exposure modification order. However, although their manufacturing processes are similar, the marketing, availability and popularity among youth and young adults are different for Zyn products.

The current application applies to Zyn products in coffee, citrus and cinnamon flavors in addition to spearmint, cool mint, peppermint and wintergreen. The only flavor available in General snus is mint. The range of flavors and lack of noticeable tobacco in Zyn creates a much greater appeal for people who have never previously used tobacco products. While the application includes clinical and population health data reports that might support the request, they have been redacted to such a degree that basic findings are not available for public review.



Zyn pouches appear poised to follow the trajectory of e-cigarettes, with rapid adoption by youth who would otherwise not have used commercial nicotine products and are now likely to be customers for life.

Zyn will not 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 as required by section 911(g)(1) of the FD&C Act.

Youth and Adults Who Have Never Smoked May Start with Zyn, Especially Given Zyn Marketing in the US to Date

While intensive efforts by the public health community have reduced e-cigarette use among youth between 2020 and 2024, nicotine pouch use in the past 30 days doubled during the same time frame.¹ Combining youth and young adults, data show that nicotine pouch use has grown even faster, nearly quadrupling between 2022 and 2025.² This trend does not reflect a group of people transitioning from combustible tobacco products to nicotine pouches. In fact, recent research demonstrates an increase in dual use, along with e-cigarettes, among youth and young adults.³

Swedish Match, like all tobacco companies, needs a stream of new customers. Research suggests that young adults pay less attention to warning labels and report greater intent to use tobacco products when there are modified risk messages.^{4,5} Combining those messages with ads that disassociate nicotine pouches from other tobacco products, emphasize that it is “tobacco-free,” and base their appeal on convenience and lifestyle factors may further promote use among a generation with record-low rates of cigarette smoking.^{6,7,8,9} Likewise, media channels favored by Swedish Match for marketing Zyn from 2019-2021, including entertainment and sports, are similar to tactics used to attract previous generations of youth to use combustible tobacco products in previous generations.¹⁰

Although youth are usually aware of the harms of smoking, they often have misconceptions about the harms of using other tobacco and nicotine products. Nicotine can change the chemistry of the adolescent brain; it may affect learning ability and worsen memory and concentration. Youth are particularly vulnerable to nicotine dependence, which can occur even with occasional use. Nicotine withdrawal symptoms include anxiety, irritability and depressed mood, so nicotine dependence may compound stress and mental health symptoms. Nicotine may also affect the way the adolescent brain processes other drugs, such as alcohol, cannabis and cocaine.¹¹ Early studies suggest that nicotine pouches may present oral health and other risks as well.^{12,13,14,15,16}

Benefits to adults who smoke have not been proven

Zyn is not comparable to nicotine replacement therapy (NRT). Zyn products contain flavorings and other additives that have not been proven safe for consumption, nor has efficacy for tobacco treatment been established. NRT medications have been thoroughly evaluated, and their ingredients and manufacturing process are closely monitored.¹⁷ Due to FDA's traditional "safe and effective"



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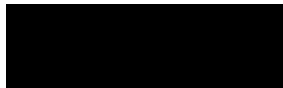
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standard for evaluating medical products not applying to tobacco products, Zyn has not been assessed under that standard. Further, Zyn has authorization to be sold in a 6mg form, 50% to 200% more nicotine than the available doses of short-acting NRT (4mg and 2mg), likely promoting higher levels of dependence, fostering long-term use, and increasing exposure to any health risks. Marketing Zyn with the proposed 'modified risk' message may be misunderstood to mean that Zyn is an FDA approved tobacco treatment medication, when the company has not applied for such a designation. Plans to test oral nicotine products compared to nicotine replacement therapy exist, but the results are not in.¹⁸ There are too many unknowns currently to conclude that the product offers a public health benefit¹⁹ Not only would such a conclusion be premature, but it increases risk of nicotine addiction to millions of young Americans.

Conclusion

For these reasons, and because there is insufficient evidence to indicate it has reduced harm to individuals or at the population level, the **Modified Risk Granted Orders should not be granted**. In addition, the FDA should provide aggressive oversight and enforcement of Zyn marketing and actively monitor prevalence of use—particularly among youth—to determine whether additional marketing restrictions are warranted. Thank you for allowing public comments on this critically important issue.

Sincerely,



Alister F. Martin, MD, MPP
Commissioner
New York City Department of Health and Mental Hygiene

¹ Han D, Harlow AF, Miech RA, et al. Nicotine Pouch and E-Cigarette Use and Co-Use Among US Youths in 2023 and 2024. *JAMA Netw Open*. 2025;8(4):e256739. doi:10.1001/jamanetworkopen.2025.6739

² CDC Foundation. (2025). Monitoring Tobacco Product Use Among Youth and Young Adults in the U.S. TEEN+ Data Brief, Issue 2.

³ Do EK, Koris K, McKay TL, Watkins JA, Panigrahi G, Hair EC, Tobacco and nicotine product use patterns and trends among United States youth and young adults (2021–2024), *Preventive Medicine Reports*, 2025, 103284, ISSN 2211-3355, <https://doi.org/10.1016/j.pmedr.2025.103284>.

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- ⁵ Mays D, Johnson AC, Glasser A, Mercincavage M, Strasser AA. Effects of IQOS health warnings and modified risk claims among young adult cigarette smokers and non-smokers. *Tob Control*. 2023;32(4):505-508. doi:10.1136/tobaccocontrol-2021-056810
- ⁶ Keller-Hamilton, B., Curran, H., Stevens, E. M., Zettler, P. J., Mays, D., & Ferketich, A. K. (2023). Effects of "Tobacco Free" Language in Warning Labels on Perceptions of Electronic Cigarettes and Nicotine Pouches among Young Adult Men: A Randomized Trial. *Substance use & misuse*, 58(10), 1302–1306. <https://doi.org/10.1080/10826084.2023.2215308>
- ⁷ Keller-Hamilton, B., Curran, H., Stevens, E. M., Zettler, P. J., Mays, D., & Ferketich, A. K. (2023). Effects of "Tobacco Free" Language in Warning Labels on Perceptions of Electronic Cigarettes and Nicotine Pouches among Young Adult Men: A Randomized Trial. *Substance use & misuse*, 58(10), 1302–1306. <https://doi.org/10.1080/10826084.2023.2215308>
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