



April 23, 2024

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Sent via e-mail

Re: PMTAs for Nicotine Pouch Products

Dear Dr. King:

We write to express our deepening concern about the threat to young people from the marketing of nicotine pouch products in the United States by some of the largest tobacco companies in the world. According to publicly available information, these products are the subject of premarket tobacco product applications (PMTAs) under review by the Food and Drug Administration (FDA). They include Zyn (PMI/Swedish Match), On! (Altria), Velo (BAT/Reynolds) and Rogue (Swisher). In evaluating these PMTAs, it is essential that FDA take into account recent developments in the U.S. marketplace indicating that nicotine pouches are growing in popularity among youth, fueled by the same kind of social media marketing that gave rise to JUUL and an epidemic of e-cigarette use among young people. As explained below, the evidence of risk to youth from flavored nicotine pouches is sufficient to apply to those products the same standard FDA has applied to flavored e-cigarettes. In our view, application of such a standard should support denial of PMTAs to all flavored nicotine pouches. Until FDA's review is complete, enforcement discretion should be revoked and the products removed from the marketplace to mitigate the risk to youth in the short-term.

In evaluating whether flavored e-cigarettes meet the statutory standard of being “appropriate for the protection of the public health” (APPH), FDA has appropriately weighed the risks to youth against the potential benefit to adults who smoke from complete switching from cigarettes.¹ Because of the substantial risk of flavored e-cigarettes with respect to youth appeal,

¹ It is important to note that there is an alternative pathway available through the Center for Drug Evaluation and Research (CDER) for products claimed to be safe and effective for tobacco or smoking cessation. This may be the more appropriate route for certain products, given CDER's

uptake and use, FDA has required PMTA applicants to provide specific evidence of a countervailing benefit of helping people who smoke to stop smoking cigarettes, from a randomized controlled trial, longitudinal cohort study or similarly reliable and robust evidence.

Like JUUL, nicotine pouches can deliver highly addictive levels of nicotine. Because the pouches are placed inside the mouth between the lip and gum, they can be concealed during use in school and other public places, even more so than JUUL because the user emits no vapor. The pouches also are sold with flavors – a feature that has been key to the appeal of JUUL and other e-cigarettes to young people. Zyn, for example, comes in 8 different flavors, including peppermint, menthol, citrus, coffee and cinnamon. Thus, the nicotine pouch product itself shares many of the characteristics that made JUUL and its imitators so appealing to youth.

Moreover, the sophisticated use of social media to promote nicotine pouches, including through influencers with large followings, has been a global phenomenon for several years. Indeed, in October, 2021, a global coalition of over 100 tobacco control, public health and consumer protection organizations, wrote to the CEOs of Facebook/Instagram, Tik Tok and Twitter (now X) about “an alarming increase in tobacco companies using social media platforms to advertise nicotine pouches to young people” and calling on them to prohibit the marketing of such non-pharmaceutical oral nicotine products. The undersigned organizations submitted the letter to then-CTP Director Zeller, advising that “[n]o marketing order should be granted for these products without full FDA consideration of the risk that similar marketing will be directed at young people in the U.S. and without safeguards to ensure that such marketing will not occur.”² A recent report by the Campaign for Tobacco-Free Kids, *#SponsoredbyBigTobacco: Tobacco & Nicotine Marketing on Social Media*,³ documents the continued and ubiquitous social media marketing of tobacco products to young people by two of the world’s largest tobacco companies, British American Tobacco (BAT) and Philip Morris International (Philip Morris). The report found that, between January, 2018 and October, 2023, BAT’s social media marketing of its Velo nicotine pouch product reached an estimated 252 million people in 32 countries, including the United States, with 39% of the audience under the age of 25, including over 10 million teens worldwide. Examples of the global social media marketing of Velo, using youthful “influencers” portraying the products as part of an active, enjoyable lifestyle, can be found at <https://www.tobaccofreekids.org/media/2021/nicotine-pouch-marketing-examples>.

Recent data indicates a sharp increase in the sales of nicotine pouches in the United States, with a six-fold increase from 2019 to 2022.⁴ Zyn leads in U.S. market share, with over

greater authority to restrict how and where products are marketed and sold to reduce the risk to youth.

² https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2021_11_29_Letter-to-FDA-re-world-marketing-of-pouch-products.pdf

³ https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/social-media-marketing-tactics/2023_12_08_SponsoredByBigTobacco.pdf

⁴ Anuja Majmundar, et al., *Nicotine Pouch Sales Trends in the US by Volume and Nicotine Concentration Levels From 2019 to 2022*, JAMA Network Open 2022;5(11):e2242235 (Nov. 15, 2022), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2798449>.

58%.⁵ During this period, nicotine pouches with 6 mg, 4 mg and 3 mg nicotine concentration were most commonly sold, but sales of products with 8 mg concentration level increased more rapidly than products with lower concentration levels.⁶ Research indicates that nicotine pouches can deliver nicotine at levels similar to cigarettes.⁷

Most troubling are the early indications that the social media promotion of these products,⁸ particularly Zyn, is penetrating the U.S. market, sparking increasing interest and usage among young Americans. The use by nicotine pouch companies of “engaging ads with youthful images” has been compared to the advertising tactics of the e-cigarette industry.⁹ The *New York Times* cited the experience of an 18-year-old Kansas high school student:

Greyson Imm, an 18-year-old high school student in Prairie Village, Kan., said he was 17 when Zyn videos started appearing on his TikTok feed. The videos multiplied through the spring, when they appeared almost daily. “Nobody had heard about Zyn until very early 2023,” he said. Now, a “lot of high schoolers have been using Zyn. It’s really taken off, at least in our community.”¹⁰

He went on to explain the appeal of Zyn to high school students, based on his own Instagram poll of students: “Through his interviews, Mr. Imm found that some students, particularly those first hooked on nicotine from vaping, are attracted to Zyn’s high nicotine content and near-invisible delivery method, which is so surreptitious it can be easily consumed during class.” His poll found that 23 percent of the students who responded used oral nicotine products during school.¹¹

⁵ *Id.*

⁶ *Id.*

⁷ WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1047).

<https://iris.who.int/bitstream/handle/10665/372463/9789240079410-eng.pdf>.

⁸ Nicotine pouches are also being promoted through other means long used to market tobacco products to youth, including musical and sporting events. See R. Craver, “ITG Brands turns to nicotine pouches as NASCAR marketing pitch,” *Winston-Salem Journal*, January 28, 2024.

https://journalnow.com/news/local/business/itg-brands-turns-to-nicotine-pouches-as-nascar-marketing-pitch/article_9a2a0a32-b88d-11ee-8e54-9f5fb14e99ae.html#:~:text=ITG%20Brands%20turns%20to%20nicotine%20pouches%20as%20NASCAR%20marketing%20pitch,-Richard%20Craver&text=ITG%20Brands%20is%20poised%20to,of%20a%20%247.1%20billion%20purchase.

⁹ Minal Patel, et al., *Patterns of oral nicotine pouch use among U.S. adolescents and young adults*, *Preventive Medicine Reports* 34:102239 (Aug. 2023),

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10203764/>.

¹⁰ E. Dreyfuss, “Our kids are living in a different digital world,” *New York Times*, January 12, 2024. <https://www.nytimes.com/2024/01/12/opinion/children-nicotine-zyn-social-media.html>

¹¹ *Id.*

The National Youth Tobacco Survey has shown increasing numbers of high school youth reporting current use of nicotine pouches since questions about the product were added to the survey in 2021. In 2023, 1.5% of high school and middle school youth reported currently using nicotine pouches, representing 400,000 students, which is double the number from 2021. More youth reported using flavored nicotine pouches (340,000) than traditional smokeless tobacco products (330,000). Mint (50.8%) is by far the most popular flavor among youth who use nicotine pouches, followed by menthol (23.9%) and fruit (20.5%).¹² As we have learned from the JUUL experience, however, national survey data can lag behind local reports. Particularly since FDA is taking no enforcement action against these products while their applications are pending (an apparent exercise of enforcement discretion with which we disagree), the agency must complete its review in a timely manner.

What we are seeing with nicotine pouches is reminiscent of the early emergence of JUUL in the marketplace, supported by flavors and extensive youth-appealing promotion on social media, followed by a dramatic rise in youth usage. After several years of low but rapidly rising rates of use among youth, by the Fall/Winter of 2017, there were initial reports from media, educators and young people indicating growing use of JUUL in high schools and middle schools. In September of 2018, then-Commissioner Gottlieb declared there was “an epidemic of e-cigarette use among teenagers”¹³ and in November of that year, the National Youth Tobacco Survey showed that use of e-cigarettes by high school students had increased by an astounding 78% in a single year, with a 48% rise in use by middle school students.¹⁴ Then-Commissioner Gottlieb later acknowledged that FDA was caught by surprise: “[w]hat I did not predict was that, in 2018, youth use of e-cigarettes . . . would become an epidemic.”¹⁵

FDA’s recent announcement of enforcement actions against retailers involving sales of Zyn products acknowledges the need for concern about nicotine pouches: “FDA has received

¹² Jan Birdsey et al. *Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023*, Morbidity and Mortality Weekly Report (MMWR) 2023; 72(44):1173-1182 (Nov. 3, 2023), <https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm>; Supplementary Table 2 at <https://stacks.cdc.gov/view/cdc/134701>; Supplementary Table 3 at <https://stacks.cdc.gov/view/cdc/134702>.

¹³ Statement from FDA Commissioner Scott Gottlieb, M.D. on new steps to address epidemic of youth e-cigarette use (Sept. 11, 2018). <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use#:~:text=It's%20simply%20not%20tolerable.,Prevention%20Plan%20earlier%20this%20year>

¹⁴ See Press Release, FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D. on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes* (Nov. 15, 2018).

<https://web.archive.org/web/20190108204905/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>

¹⁵ *Id.*

reports about the potential increased popularity of these products among youth, and the products also are a popular topic on social media among youth and social media influencers.”¹⁶

FDA must not allow Zyn and other nicotine pouch products to become the new JUUL. The warning signs are apparent: a significant and growing presence on social media; a dramatic increase in U.S. sales; survey and anecdotal evidence of growing use by young people – all with respect to a product with characteristics similar to those that made JUUL so appealing to youth, including flavors. The adverse public health consequences of youth uptake of yet another addictive nicotine product are beyond dispute. As FDA repeatedly has found in denying marketing orders for flavored e-cigarettes, “youth and young adult brains are more vulnerable to nicotine’s effects than the adult brain due to ongoing neural development.”¹⁷ Nicotine exposure during adolescence “can induce short and long-term deficits in attention, learning, and memory.”¹⁸ As the Surgeon General has found, “[t]he use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe.”¹⁹

FDA must consider “the increased or decreased likelihood that existing users of tobacco products will stop using such products” as part of its PMTA review. The risks of nicotine pouches to young people are sufficiently real that only the strongest evidence of a benefit in helping those who smoke to stop smoking can outweigh the risks to youth. There is inadequate publicly available data demonstrating that these products have resulted in or encouraged complete switching among adults who smoke. Meanwhile, as described above, there is new evidence that young people are exposed to these products via social media. And just as smokeless tobacco has been advertised in the past, some companies are again marketing their pouches as a way to satisfy nicotine addiction in places and under circumstances where smoking is prohibited or impractical, thus actually functioning to sustain smoking, not curb it.²⁰ One recent study found that “[d]espite explicit or implied reduced harm claims . . . many youth and young adults who smoke cigarettes are using these products concurrently.”²¹ If FDA appropriately takes into account the risks to young people from these products, they cannot be found appropriate for the protection of the public health.

¹⁶ Press Release, FDA, *FDA Issues Warning Letters and Files Civil Money Penalty Complaints Against Retailers for Underage Sales of ZYN Nicotine Pouches* (April 4, 2024), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-warning-letters-and-files-civil-money-penalty-complaints-against-retailers-underage-sales>.

¹⁷ Technical Project Lead (TPL) Review of PMTAs, at 8, <https://www.fda.gov/media/152504/download?attachment>

¹⁸ *Id.*

¹⁹ U.S. Department of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, at 5 (2016), <https://www.ncbi.nlm.nih.gov/books/NBK538680/>.

²⁰ Zongshuan Duan et al., *Nicotine pouch marketing strategies in the USA: an analysis of Zyn, On! and Velo*, Tobacco Control, Published Online First: 11 July 2022, doi: 10.1136/tc-2022-057360, https://www.researchgate.net/publication/361892726_Nicotine_pouch_marketing_strategies_in_the_USA_an_analysis_of_Zyn_On_and_Velo.

²¹ Patel, note 9.

Due to FDA's exercise of enforcement discretion, nicotine pouches have been on the market without the marketing authorization required by the Family Smoking Prevention and Tobacco Control Act for over seven years – ever since the 2016 Deeming Rule subjected these products to FDA regulation. It is time for FDA to revoke the enforcement discretion these products have been granted. FDA must also conclude its public health review of these products, applying the same evidentiary standard for flavored nicotine pouches as it has applied to flavored e-cigarettes and deny PMTAs for flavored nicotine pouches.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Parents Against Vaping e-cigarettes (PAVe)

Truth Initiative