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**RE: Comments in Docket No. FDA-2025-N-0835 for the Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments, 90 Fed. Reg. 52969 (November 24, 2025)**

The Campaign for Tobacco-Free Kids (“Tobacco-Free Kids”) submits these comments in connection with the January 22, 2026, meeting of the Tobacco Products Scientific Advisory Committee (“TPSAC”) to consider modified risk tobacco product applications submitted by Swedish Match USA, Inc., for the following products: ZYN Cool Mint 3 mg; ZYN Cool Mint 6 mg; ZYN Peppermint 3 mg; ZYN Peppermint 6 mg; ZYN Spearmint 3 mg; ZYN Spearmint 6 mg; ZYN Wintergreen 3 mg; ZYN Wintergreen 6 mg; ZYN Citrus 3 mg; ZYN Citrus 6 mg; ZYN Coffee 3 mg; ZYN Coffee 6 mg; ZYN Cinnamon 3 mg; ZYN Cinnamon 6 mg; ZYN Smooth 3 mg; ZYN Smooth 6 mg; ZYN Chill 3 mg; ZYN Chill 6 mg; ZYN Menthol 3 mg; and ZYN Menthol 6 mg (collectively, “ZYN nicotine pouches”). Through its applications, Swedish Match seeks authorization from the Food and Drug Administration to market these products with the following reduced risk claim: “*Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.*”

## INTRODUCTION

Tobacco-Free Kids **opposes** orders authorizing this claim because Swedish Match has failed to meet the statutory standard for the following reasons:

1. FDA’s past authorizations of a similar claim for General Snus should not determine whether the pending applications for ZYN nicotine pouches are granted because the Tobacco Control Act requires product-specific analyses.

2. Significant differences between ZYN and General Snus – in use rates, relative toxicology and marketing – clearly warrant different consideration.
3. The applicant’s reliance on the Swedish experience is misleading and of limited relevance.
4. The applicant did not submit sufficient data on consumer perception or behavior change related to the proposed modified risk claim and this specific product.

## LEGAL BACKGROUND

The ZYN modified risk applications are governed by section 911 of the Food, Drug and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act).<sup>1</sup> Under the statute, a “modified risk tobacco product” is “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”<sup>2</sup> The Act considers a product “sold or distributed” for such a use if, among other things, “[its] label, labeling, or advertising . . . represents explicitly or implicitly that . . . the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products.”<sup>3</sup> A modified risk tobacco product cannot be introduced into interstate commerce without an order under section 911(g).<sup>4</sup>

Before the FDA can issue such an order, it must find that the “*applicant has demonstrated* that [the] product, *as it is actually used by consumers* will” both:

- (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- (B) 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.<sup>5</sup>

FDA is required to consider the following specific, empirical factors in determining whether this standard has been met:

- (A) the relative health risks to individuals of the tobacco product that is the subject of the application;

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<sup>1</sup> Codified at 21 U.S.C. § 387k.

<sup>2</sup> FD&C Act § 911(b)(1).

<sup>3</sup> FD&C Act § 911(b)(2)(A)(i)(I).

<sup>4</sup> FD&C Act § 911(a).

<sup>5</sup> FD&C Act § 911(g)(1) (emphasis added).

- (B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- (C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application; [and]
- (D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under subchapter V [of the FD&C Act] to treat nicotine dependence.<sup>6</sup>

Thus, it is not enough for an applicant to show that its product is less hazardous than other tobacco products. Nor is it enough for an applicant to show that its proposed claim is no worse for public health than the status quo. For a modified risk application to be granted, the applicant must show that the benefits of risk reduction, considering the likelihood that people who use tobacco products will completely switch to the modified risk product, *outweigh* the risks of increased initiation or diminished cessation. This, in turn, requires FDA to make scientific judgments not only about the physical effect of the product's use, but also about the likely responses of potential consumers (both those who currently use tobacco products and those who do not) to the product's marketing as a modified risk product, *i.e.*, a product marketed with a reduced risk or reduced exposure claim. It is the population-wide impact not only of selling the product, *but rather of selling the product with a particular claim*, that should determine whether the statutory standard in section 911 is met.

## **POINTS FOR THE COMMITTEE'S CONSIDERATION**

### **I. FDA's past authorizations of a similar claim for General Snus should not determine whether the pending applications for Zyn nicotine pouches are granted because the Tobacco Control Act requires product-specific analyses.**

Swedish Match's applications "rely on FDA's conclusions when it granted [modified risk granted orders] for [its] authorized [modified risk tobacco products]," which it identifies as "the following General Snus Products: MR0000020, MR0000021, MR0000022, MR0000024, MR0000025, MR0000027, MR0000028, MR0000029."<sup>7</sup> Swedish Match suggests that FDA's conclusions from those applications "be extrapolated" to the company's pending ZYN applications because ZYN and General Snus "are oral tobacco products intended for use in the same manner," because ZYN products "deliver similar quantities of nicotine but greater

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<sup>6</sup> FD&C Act § 911(g)(4).

<sup>7</sup> PMI, Module 1, Cover Letter at 1.

reduction in HPHCs” than General Snus products, and for other reasons.<sup>8</sup> Such an approach, however, is inconsistent with the statutory framework, which provides for product-specific applications and analyses.

A modified risk tobacco product application, and any subsequent authorization, is specific to an individual product.<sup>9</sup> The authorized claim that Swedish Match’s ZYN applications attempt to rely on is that “[u]sing *General Snus* instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis” (emphasis added). But in authorizing and reauthorizing the modified risk claim for General Snus, FDA did not conclude that an entire category of tobacco products is less risky than cigarettes; its conclusions were (as the authorized claim states) limited to General Snus.

Broader conclusions from individual authorizations cannot be drawn. Each application contains information about an individual product’s “formulation,” its “advertising and labeling,” and “how consumers actually use” it<sup>10</sup>—all of which vary from product to product. Relatedly, FDA’s analysis of each application considers, among other factors, whether those who do not currently use any tobacco products “will start using *the* tobacco product that is the subject of the application” if the claim is authorized<sup>11</sup>—again, something that will vary from product to product. Indeed, the Acting Director of the Center for Tobacco Products recently highlighted the existence of “significant variability within the same category of tobacco products.”<sup>12</sup> FDA may, then, properly find that one product may use a specific claim, while properly denying another product that same claim. It cannot “extrapolate” its conclusions from the General Snus application to other products in the same category. Nor can it “extrapolate” its conclusions to a product in an entirely different class altogether.

TPSAC should therefore reject Swedish Match’s attempt to diminish its statutory burden through reliance on past FDA decisions of different products – particularly where many of the flaws in the company’s past applications resurface here.<sup>13</sup> It should require Swedish Match to

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<sup>8</sup> *Id.*

<sup>9</sup> *See, e.g.*, FD&C Act § 911(d) (permitting the filing of “an” application for “a” modified risk tobacco product and requiring various information about “the” product); § 911(g)(1) (providing for FDA to issue “an” order).

<sup>10</sup> FD&C Act § 911(d)(1), (3), & (6).

<sup>11</sup> FD&C Act § 911(g)(4)(c) (emphasis added).

<sup>12</sup> Keynote Address, Food and Drug Law Institute’s Tobacco and Nicotine Products Regulation and Policy Conference (October 28, 2025).

<sup>13</sup> The applicant’s primary reliance on FDA’s grant of an MRTP for the Swedish Match General Snus products is particularly problematic, given the weaknesses in the General Snus applications, as highlighted by several members of TPSAC during its June 26, 2024, meeting to consider the renewal of FDA’s modified risk orders for the snus products. TPSAC members discussed, for example, (1) Swedish Match’s failure to determine consumer perception following exposure to the modified risk claim for General Snus; (2) Swedish Match’s limitation of its postmarket surveillance studies to current users of General Snus; and (3) the failure of the proposed claim to

submit sufficient evidence demonstrating that the statutory standards have been independently met.

## **II. Significant differences between ZYN and General Snus – in use rates, relative toxicology and marketing – clearly warrant different consideration.**

The applicant claims that ZYN is comparable to General Snus,<sup>14</sup> but there are stark differences between these products, noted below, that make the General Snus modified risk authorization and renewal of questionable relevance to this application. TPSAC and FDA must consider differences in the current environment and context, particularly ZYN’s marketing, and who is actually using these products. ZYN is already popular among youth and young adults, with the marketing reinforcing the seeming ubiquitous presence of ZYN imagery. Adding a modified risk claim could make these products more attractive to this population. Toxicological difference also should be considered, particularly as they bear on the abuse liability of the ZYN products.

### **A. Use rates for nicotine pouches, particularly for young people and particularly for ZYN, distinguish ZYN from General Snus.**

Surveys show that, unlike General Snus, nicotine pouch use—particularly ZYN—has been increasing and is concentrated among adolescents and young adults.

Although nicotine pouch use rates among youth are relatively low now, they are rapidly trending upwards. The 2024 National Youth Tobacco Survey (NYTS) data show that 1.8% of middle and high schoolers (480,000 youth) used nicotine pouches in the past 30 days (current use), **more than double the number from 2021**.<sup>15</sup> Further, data from the Monitoring the Future survey showed that past 30-day nicotine pouch use rates among 12th graders **more than doubled between 2023 and 2025**.<sup>16</sup> This trend mimics the early years of initially slow-growing e-cigarette use among youth, just before the rates rose to epidemic levels within a year. However, national survey data can lag behind local reports, so the number of youth users could well be higher.

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make clear that only complete switching could achieve lower risks. *See generally*, Comments of American Academy of Pediatrics, et al., in Docket No. FDA-2014-N-1051, opposing renewal applications for General Snus (August 14, 2024), [https://assets.tobaccofreekids.org/content/what\\_we\\_do/federal\\_issues/fda/2024\\_08\\_14\\_General-Snus-MRT-renewal-comments.pdf](https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2024_08_14_General-Snus-MRT-renewal-comments.pdf).

<sup>14</sup> PMI, Module 2, Integrated Summary at 2.

<sup>15</sup> Eunice Park-Lee et al., *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024*, 73 MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) 774-778 (September 5, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf>.

<sup>16</sup> Monitoring the Future, *NICOTINE POUCHES: Trends in 30 Day Prevalence of Use in 8th, 10th, and 12th Grade*, accessed December 18, 2025, <https://monitoringthefuture.org/data/bx-by/drug-prevalence/#drug=%22Nicotine+Pouches%22>.

Similarly, national surveys generally show low use rates among adults overall, but higher rates among younger adults.<sup>17</sup> Data from the 2022-2023 Population Assessment of Tobacco and Health (PATH) study show that, although overall adult past 30-day use of nicotine pouches was low, younger adults had higher odds of use compared to the 65+ age group.<sup>18</sup> In addition to finding higher use rates among younger adults, the Monitoring the Future survey found that past-year nicotine pouch use rates among young adults (19-30 years old) doubled between 2023 and 2024.<sup>19</sup>

Moreover, ZYN is *by far the most reported brand used by youth and young adults*. Data from the 2024 NYTS showed that 77.6% of high schoolers who reported currently using nicotine pouches used ZYN.<sup>20</sup> Data from the CDC Foundation’s TEEN+ survey also showed that ZYN is the most commonly used brand among young people (13-20 years old) who used nicotine pouches.<sup>21</sup>

In contrast, national surveys no longer separately report past 30-day snus use, indicating that the use of these products, including General Snus, appears to be low enough that the data cannot be separated out. The Monitoring the Future survey provides past 12-month data on snus use among youth since 2011, which have shown significant declines in rates since then.<sup>22</sup>

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<sup>17</sup> Hongying Daisy Dai et al., *Prevalence of Nicotine Pouch Use Among US Adults*, 332 JAMA 755-757 (September 3, 2024), <https://doi.org/10.1001/jama.2024.10686>.

<sup>18</sup> Amanda M. Palmer et al., *Nicotine Pouch Use in Youths and Adults Who Use Cigarettes, E-Cigarettes, and Smokeless Tobacco*, 8 JAMA Network Open e2511630 (2025), <https://doi.org/10.1001/jamanetworkopen.2025.11630>.

<sup>19</sup> Monitoring the Future, Table/Figure 53, *Trends in 12-Month Prevalence among Respondents of Modal Ages 19 through 65, by Age Group*, accessed December 22, 2025, <https://monitoringthefuture.org/wp-content/uploads/2025/07/mtfpanel2025.pdf>.

<sup>20</sup> Park-Lee, E, *supra* note 15.

<sup>21</sup> CDC Foundation, *Monitoring Tobacco Product Use Among Youth and Young Adults in the U.S. TEEN+ Data Brief*, Issue 2 (2025), <https://tobacomonitoring.org/wp-content/uploads/2025/09/Tobacco-Epidemic-Evaluation-Network-Data-Brief-Issue-2.pdf>.

<sup>22</sup> Although the data showed a statistically significant increase in 12th graders reporting snus use in 2025 as compared to 2024, MTF suggested that trend “may reflect students reporting nicotine pouch use in response to the snus question. The survey wording—‘Use snus (a small packet of tobacco that is put in the mouth)’—could easily be interpreted by students as referring to nicotine pouches.” Monitoring the Future, *SNUS: Trends in 12 Month Prevalence of Use in 8th, 10th, and 12th Grade*, accessed December 22, 2025, <https://monitoringthefuture.org/data/bx-by/drug-prevalence/#drug=%22Snus%22>.

**B. There are substantial toxicological differences between ZYN and General Snus that likely impact usage differences.**

TPSAC should carefully examine chemical differences between ZYN and General Snus, particularly as they may be related to the stark differences in usage.<sup>23</sup> Information provided in the Tobacco Product Lead’s decision summary for the ZYN marketing granted order show differences in the product formulations of General Snus and ZYN, indicating that the toxicological findings for ZYN are not comparable to General Snus.<sup>24</sup>

For example, ZYN pouches use nicotine salts while General Snus products do not, raising significant questions about the generalizability of toxicological findings for General Snus compared to ZYN. Nicotine salts are compounds produced when free-base nicotine is combined with an acid, creating a more potent form of nicotine that is less irritating and can increase abuse liability, particularly among nicotine-naïve populations.<sup>25</sup> The introduction of nicotine salts, most successfully by JUUL, changed the nicotine market by enabling the delivery of an unprecedented level of nicotine to users and set off what some researchers called a “nicotine arms race.”<sup>26</sup> The 2018 Surgeon General advisory warned that nicotine salts made it easier for young people to initiate the use of nicotine with e-cigarettes.<sup>27</sup> Although most of the research on nicotine salts is from e-cigarettes and may present different health risks when used in nicotine pouches (i.e., absorbed through the gum instead of inhaled as aerosol), the use of this compound in nicotine pouches cannot be ignored given its contribution to the youth e-cigarette epidemic when introduced in JUUL.

In addition, ZYN is offered in ten different non-tobacco flavors, as opposed to General Snus’ three non-tobacco flavors. These seven additional flavors not only raise concerns about the appeal to youth, but the flavor additives also may raise different toxicological issues compared to General Snus.

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<sup>23</sup> The information on product formulation or manufacturing in the modified risk application references the Swedish Match Tobacco Product Master Files (TPMF), which is not accessible to the public.

<sup>24</sup> FDA, Technical Project Lead (TPL) Review of PMTAs: PM0000593.PD1-PM0000612.PD1 at 12 (January 13, 2025),

[https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA\\_TPL\\_PM593-PM612\\_Zyn\\_01\\_13\\_2025\\_Redacted.pdf](https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted.pdf) (hereinafter referred to as “ZYN TPL”).

<sup>25</sup> Arit M. Harvanko et al., *Characterization of Nicotine Salts in 23 Electronic Cigarette Refill Liquids*, 22 NICOTINE & TOBACCO RESEARCH 1239-1243 (2019), <https://doi.org/10.1093/ntr/ntz232>.

<sup>26</sup> Robert K. Jackler et al., *Nicotine arms race: JUUL and the high-nicotine product market*, 28 TOBACCO CONTROL 623-628 (2019), <https://doi.org/10.1136/tobaccocontrol-2018-054796>.

<sup>27</sup> Office of the Surgeon General, *Surgeon General’s Advisory on E-Cigarette Use Among Youth* (December 18, 2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

Research shows that flavors in tobacco products are appealing to youth and can increase youth initiation and regular use. The 2024 Surgeon General’s report concluded that “[t]he tobacco industry has designed, engineered, and marketed menthol cigarettes and other tobacco products that deliver multisensory flavor experiences which increase the likelihood of tobacco initiation, addiction, and sustained use.”<sup>28</sup> FDA itself has also acknowledged the important role that flavors play in attracting youth tobacco users. For instance, FDA’s press statement announcing the marketing denial order for Logic Menthol e-cigarettes stated that “[f]or non-tobacco-flavored e-cigarettes, including menthol-flavored e-cigarettes, existing evidence demonstrates a known and substantial risk with regard to youth appeal, uptake and use.”<sup>29</sup>

In the ZYN MGO decision summary, FDA noted: “The new products [ZYN] come in a variety of characterizing flavors, and the literature shows that in general, non-tobacco flavors increase the appeal of tobacco products, particularly for youth, and, as such, increase the risk of youth initiation.”<sup>30</sup> The 2024 NYTS found that the large majority of youth pouch users (86%) use flavored nicotine pouches. Mint (53.3%) was by far the most popular flavor among youth nicotine pouch users, followed by fruit (22.4%) and menthol (19.3%).<sup>31</sup> Combined with the data showing ZYN as the most common brand among youth who use nicotine pouches,<sup>32</sup> this indicates that flavored ZYN are the most popular among youth.

### C. ZYN marketing is vastly different than General Snus marketing.

Unlike General Snus, ZYN’s marketing has elevated the product’s popularity to the point that it is synonymous with certain celebrities, groups, and practices. This expands the population exposed to ZYN much farther than adults who smoke. It also results in product recognition that greatly exceeds that of General Snus. The attached **Appendix** includes a variety of company-sponsored marketing, user-generated social media posts, and other content that show the degree to which ZYN has pervaded our culture. The nature and pervasiveness of the ZYN marketing,

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<sup>28</sup> U.S. Department of Health and Human Services, *Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General*, Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health at 9 (2024), <https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-full-report.pdf>.

<sup>29</sup> FDA, *FDA Denies Marketing of Logic’s Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard* (October 26, 2022), <https://web.archive.org/web/20230629020206/https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-logics-menthol-e-cigarette-products-following-determination-they-do-not-meet>.

<sup>30</sup> ZYN TPL at 7.

<sup>31</sup> Park-Lee, *supra* note 15.

<sup>32</sup> *Id.*

combined with the dramatic recent increases in ZYN usage among youth and young adults, underscores the potential for significantly higher usage among these groups going forward.

ZYN's presence in social media has proliferated in the past few years. TikTok, a platform popular with youth and young adults, is inundated with videos of young people using nicotine pouches, which garner millions of views and shares. These posts are often humorous and portray the products in a positive light, and few posts have the warning messages that ads for nicotine pouches are legally required to include.<sup>33</sup> User-generated posts reinforce the belief that ZYN is everywhere and can encourage use among peers. Posts are visible to almost anyone, and the common use of hashtags make ZYN-related content easy to find. Some popular hashtags included #zynbabwe, #upperdecky, #zynygang, and #zynisnotasin.<sup>34</sup> Research shows that youth and young adults who see tobacco content on social media, particularly posts by celebrities and influencers, have a higher susceptibility to trying tobacco products and higher odds of lifetime use of tobacco products.<sup>35</sup>

Further, endorsements and mentions of ZYN by celebrities and influencers (so-called "ZYNfluencers") have broadened the audience of these nicotine pouches to include young people who don't currently use tobacco and may not understand the addictiveness of these products. For instance, frequent references to ZYN by Tucker Carlson (nicknamed "Tucker Carlzyn") and podcaster Joe Rogan elevated awareness of these products among young conservative men.<sup>36</sup>

ZYN Rewards, ZYN's loyalty program, allows people to redeem points acquired from purchases for iPads, Apple Watches, Dyson hair stylers, and previously, ZYN-branded items like

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<sup>33</sup> Tianze Sun et al., *Sports, Gigs, and TikToks: Multichannel Advertising of Oral Nicotine Pouches*, NICOTINE & TOBACCO RESEARCH (August 27, 2024), <https://doi.org/10.1093/ntr/ntae188>; Scott I. Donaldson et al., *Describing ZYN-Related Content on TikTok: Content Analysis*, NICOTINE & TOBACCO RESEARCH (January 17, 2025), <https://doi.org/10.1093/ntr/ntaf016>; Marco Zenone et al., *The Promotion of Oral Nicotine Pouches for Non-Smoking Cessation Purposes on TikTok*, NICOTINE & TOBACCO RESEARCH (January 29, 2025), <https://doi.org/10.1093/ntr/ntaf024>.

<sup>34</sup> Sun, *supra* note 33; Donaldson, *supra* note 33; Zenone, *supra* note 33.

<sup>35</sup> Scott I. Donaldson et al., *Association Between Exposure to Tobacco Content on Social Media and Tobacco Use: A Systematic Review and Meta-analysis*, 176 JAMA PEDIATRICS 878-885 (2022), <https://doi.org/10.1001/jamapediatrics.2022.2223>; Carmen CW Lim et al., *Swipe to Inhale: Tobacco-Related Content on Social Media and Susceptibility to Tobacco Use*, 67 AMERICAN JOURNAL OF PREVENTIVE MEDICINE 968-972 (2024), <https://doi.org/10.1016/j.amepre.2024.07.020>.

<sup>36</sup> Whizy Kim et al., *Zyn, the nicotine pouch at the center of a brewing culture war, explained*, VOX (January 30, 2024), <https://www.vox.com/health/2024/1/30/24054888/zyn-nicotine-pouch-smokeless-tobacco-snus-snuff-dip-chewing>.

towels.<sup>37</sup> For 3,000 points, ZYN has offered tickets to exclusive concerts for popular musicians like Noah Kahan<sup>38</sup> and Lainey Wilson,<sup>39</sup> and shows with comedians like Nate Bargatze.<sup>40</sup> A post about the Noah Kahan concert on a country music Instagram account evoked comments from non-ZYN users wanting to buy ZYN just to attend the concert.<sup>41</sup>

These types of loyalty or continuity programs can encourage repeat purchases and higher consumption to accumulate enough points to redeem for rewards. Some offer large point incentives to recruit additional registrants, including new users. Indeed, data presented by PMI to investors shows that ZYN rewards members consume more cans of ZYN per week than non-reward members.<sup>42</sup> One study found many social media posts about prizes obtained through these reward programs by young women, a potentially new customer base for these products.<sup>43</sup>

Tobacco companies have a long history of using loyalty programs to encourage consumption, particularly among youth. For instance, in the historic case *United States v. Philip Morris, Inc.*, which found that the major tobacco companies were violating the Racketeer Influenced and Corrupt Organizations Act (RICO Act), Judge Kessler relied on evidence demonstrating that Reynolds discussed offers of promotional items aimed at young people, including Camel-branded Walkman cases, board games, t-shirts, and mugs, and even discounts on Ticketmaster tickets.<sup>44</sup> These programs increase youth excitement for these products by linking their purchase to coveted non-tobacco products or experiences. For example, Studies have documented how rewards programs from cigarette companies, like “Camel Cash” and “Marlboro Miles,” that require people to collect points through purchases and redeem them for

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<sup>37</sup> Jasmine Li, *Forget airline miles—Gen Z and millennials are obsessed with nicotine pouch Zyn’s lucrative rewards program, which includes \$400 Apple watches and \$600 Dyson AirWraps*, FORTUNE (May 11, 2024), <https://fortune.com/2024/05/11/zyn-rewards-nicotine-pouch-prizes-millennial-gen-z/>; Page D. Dobbs et al., *‘Cashing in’ nicotine pouches for prizes*, TOBACCO CONTROL (June 15, 2024), <https://doi.org/10.1136/tc-2024-058691>.

<sup>38</sup> Page Dobbs et al., *Music festivals, exclusive concerts and reward programmes: nicotine pouch promotion on social media*, TOBACCO CONTROL (October 30, 2025), <https://doi.org/10.1136/tc-2025-059579>.

<sup>39</sup> Zyn website, accessed May 29, 2025, <https://us.zyn.com/ZYNRewardsStore/zyn-presents-lainey-wilson/>.

<sup>40</sup> Calvin.givens Instagram post, “Zyn presents Nate Bargatze. ...” (October 12, 2025), [https://www.instagram.com/p/DPtdrlaEeyP/?img\\_index=1](https://www.instagram.com/p/DPtdrlaEeyP/?img_index=1).

<sup>41</sup> Country Hub Instagram post (February 23, 2025), [https://www.instagram.com/countryhub/p/DGbAhq6PUW8/?hl=en&img\\_index=1](https://www.instagram.com/countryhub/p/DGbAhq6PUW8/?hl=en&img_index=1).

<sup>42</sup> PMI, *Introduction to PMI U.S. Management Team*, NYSE Investor Meeting at Slide 13 (September 24, 2024), <https://philipmorrisinternational.gcs-web.com/static-files/3160d05d-1b9d-488b-a691-2dad7e10b1c2>.

<sup>43</sup> Dobbs, *supra* note 37.

<sup>44</sup> *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 637-39 (D.D.C. 2006).

products, are particularly successful in capturing the loyalty of youth, incentivizing them to experiment with cigarettes, progress to regular smoking, and smoke more.<sup>45</sup>

Brand sponsorships at events broadens the product's exposure to a larger audience beyond tobacco users. Swedish Match prominently features ZYN branding, logos, and taglines at sponsored music concerts, and gives away ZYN-branded merchandise, both of which are prohibited for traditional smokeless tobacco products.<sup>46</sup> For instance, social media posts show ZYN-sponsored main stage completely surrounded by branded signs at the 2023 Big Machine Music City Grand Prix.<sup>47</sup>

Tobacco companies' sponsorships of sporting events are another way to expose a wide population to these products and create positive associations with the brands.<sup>48</sup> PMI also recently announced an "expanded" sponsorship of Ferrari to add ZYN branding to cars racing in various Formula 1 Grands Prix races.<sup>49</sup> With Formula 1 touting the growth of its young fanbase<sup>50</sup> and engaging new partnerships with Disney, Lego and Hot Wheels<sup>51</sup> to expand its reach and appeal to kids, it's clear that the audience exposed to ZYN branding on cars will be much younger than before. For example, one news report indicated that "[m]ore than 4 million children aged 8 to 12 now actively follow F1 across the EU and US, an audience that didn't exist five years ago."<sup>52</sup>

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<sup>45</sup> John W. Richards, Jr. et al., *RJ Reynolds' 'Camel Cash': another way to reach kids*, 4 TOBACCO CONTROL 258-260 (1995), <https://doi.org/10.1136/tc.4.3.258>; Ellen Feighery et al., *Seeing, wanting, owning: the relationship between receptivity to tobacco marketing and smoking susceptibility in young people*, 7 TOBACCO CONTROL 123-128 (1998).

<sup>46</sup> See 21 C.F.R. § 1140.34(a).

<sup>47</sup> Big Machine Music City Grand Prix, *Superstar Flo Rida to Headline Saturday Evening Concert on the Zyn Main Stage*, Press Release (April 19, 2023), <https://musiccitygp.com/sound-speed-merge-as-the-big-machine-music-city-grand-prix-reveals-musical-lineup-for-nashvilles-indycar-race-weekend-2/>. Brewco Marketing Group Instagram (March 1, 2024), [https://www.instagram.com/p/C3-kGWVrymQ/?img\\_index=3](https://www.instagram.com/p/C3-kGWVrymQ/?img_index=3).

<sup>48</sup> Sun, *supra* note 33.

<sup>49</sup> PMI, *Philip Morris International Expands its Partnership with Scuderia Ferrari HP, Launching a Bold New Chapter in Their Long-Standing Relationship*, Press Release (December 3, 2025), <https://www.businesswire.com/news/home/20251203479419/en/Philip-Morris-International-Expands-its-Partnership-with-Scuderia-Ferrari-HP-Launching-a-Bold-New-Chapter-in-Their-Long-Standing-Relationship>.

<sup>50</sup> "Formula 1 and Motorsport Network unveil 2025 Global Fan Survey," Formula 1 (July 1, 2025), <https://www.formula1.com/en/latest/article/formula-1-and-motorsport-network-unveil-2025-global-fan-survey.4YqMebNy8BLaapyJfjzDXO>.

<sup>51</sup> Edward Watkinson, *Disney deal shows why F1 finally gets it about young fans*, HITC (October 31, 2025), <https://www.hitc.com/disney-deal-shows-why-f1-finally-gets-it-about-young-fans/>.

<sup>52</sup> *Id.*

All of these efforts increase ZYN’s exposure to the general public, particularly youth, and create the perception that ZYN is “everywhere” and use is common.<sup>53</sup> *The New York Times* was one of the first publications to reveal the often-unseen pervasiveness of social media posts touting ZYN to young people, including from accounts with large numbers of youth followers.<sup>54</sup> Since then, other articles have highlighted ZYN’s popularity among certain segments of the population. These segments include young conservative men, driven primarily by initial endorsement of the product by Tucker Carlson and calls for a “Zynsurrection” from some Republican politicians,<sup>55</sup> and athletes, including professional baseball players and football players.<sup>56</sup>

TPSAC should be leery of PMI’s claims that it will adhere to its marketing standards for ZYN since the company has not followed its own rules for IQOS. For instance, while the company states that it will “not engage with anyone for the purpose of generating social media posts to market our smoke-free products,”<sup>57</sup> social media content creators were invited to attend IQOS-sponsored events in Austin and Fort Lauderdale and subsequently posted about their experiences. An “Austin lifestyle creator” posted from a VIP lounge at the MotoGP (motorcycle Grand Prix) race, stating, “Thanks @iqos.us for having us 😊” and wearing an IQOS-branded lanyard.<sup>58</sup> Similarly, a “digital creator” in Miami posted a video about the IQOS launch concert, showing products and the event space.<sup>59</sup>

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<sup>53</sup> Emily Sundberg, *How Zyn Conquered the American Mouth*, GQ (January 30, 2025), <https://www.gq.com/story/how-zyn-conquered-the-american-mouth>. Ashwin Rodrigues, *Why Are Zyn Nicotine Pouches Suddenly Everywhere?*, GQ (June 22, 2023), <https://www.gq.com/story/zyn-nicotine-pouches-suddenly-everywhere>.

<sup>54</sup> Emily Dreyfuss, *Our kids are living in a different digital world*, THE NEW YORK TIMES (January 12, 2024), <https://www.nytimes.com/2024/01/12/opinion/children-nicotine-zyn-social-media.html>.

<sup>55</sup> Kim, *supra* note 36.

<sup>56</sup> Jake Mintz, *MLB players turning to nicotine pouches amid tobacco bans*, FOX SPORTS (March 3, 2023), <https://www.foxsports.com/stories/mlb/mlb-players-turning-to-nicotine-pouches-amid-tobacco-bans>; Charles Curtis, *The Baker Mayfield and ZYN nicotine pouches controversy, explained*, YAHOO! SPORTS (October 25, 2024), <https://sports.yahoo.com/baker-mayfield-zyn-nicotine-pouches-123039107.html>.

<sup>57</sup> PMI, *Responsible marketing and sales practices*, (May 18, 2021), accessed December 10, 2025, <https://www.pmi.com/sustainability/integrated-report-2020/responsible-marketing-and-sales-practices-progress-2020/>.

<sup>58</sup> Jukiener Instagram post (March 29, 2025), accessed December 10, 2025, [https://www.instagram.com/p/DHzDlNFxHTD/?img\\_index=3](https://www.instagram.com/p/DHzDlNFxHTD/?img_index=3).

<sup>59</sup> Ashleyyodele Instagram post (May 4, 2025), accessed December 10, 2025, <https://www.instagram.com/p/DJP8mj-PfRd/>.

### III. The applicant's reliance on the Swedish experience is misleading and of limited relevance.

The applicant uses FDA's reference to Sweden or the "Swedish experience" in its original modified risk granted order for General Snus to support this ZYN application. However, this description is erroneous and ultimately the comparison to the Swedish experience with snus should not be decisive. Just as TPSAC and FDA found the "Swedish experience" of limited relevance for the U.S. in considering the General Snus applications, this committee should also reject this argument.

#### A. FDA did not accept Swedish Match's claim that consumer behavior in Sweden is applicable to the U.S.

In its ZYN MRTPA, the applicant incorrectly states, "FDA noted the importance of the 'Swedish experience' data in their decision to authorize use of the reduced risk claim in marketing of [General snus]. Even if such longitudinal data does not yet exist for [ZYN], the 'Swedish experience' is relevant to [ZYN] due to the similarities in product design, manner of use, *user behavior, and user populations*" (emphasis added and internal citations omitted).<sup>60</sup> However, this statement misrepresents FDA's discussion about the "Swedish experience" with respect to General Snus. To the contrary, FDA stated:

The applicant proposed that, as MRTPs, its products could have a similar impact in the U.S. as snus has had in Sweden. In particular, the applicant described a historical trend documented in Sweden, often called the "Swedish Experience," a grassroots movement wherein a large proportion of smokers transitioned to exclusive snus use, bringing rates of smoking to historically low levels and resulting in a population with a lower incidence of smoking-related diseases than comparable countries. Thus, the applications relied primarily on behavioral epidemiological data from Sweden and Norway. *Ultimately, FDA's review of this evidence concluded that it had limited applicability to the potential impacts of marketing the MRTPs in the U.S.* FDA pointed to the range of social and cultural differences between the two marketing contexts—including that snus is a traditional Swedish product—*limiting the validity of extrapolating from one to the other.* Moreover, snus was not marketed as a reduced risk product in Sweden, underscoring that

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<sup>60</sup> PMI, Module 2: Integrated Summary, at 6.

adoption of the product was related to other factors. *These limitations were also identified by TSPAC in the 2015 meeting.*<sup>61</sup>

FDA and TPSAC did not then accept Swedish Match’s reliance on the “Swedish experience” with respect to consumer behavior and patterns of use for General Snus, and they certainly should not rely on the experience of snus in Sweden, when, as discussed earlier, reports show that ZYN is already exhibiting far greater popularity in the U.S. than General Snus.<sup>62</sup>

Further reinforcing this position is the lack of any demonstrated public health benefit from General Snus, a product that FDA authorized for sale in the U.S. in 2015 and to use a modified risk claim in 2019. Despite years of marketing, even with the modified risk claim, Swedish Match has not produced any data showing meaningful migration from cigarettes to snus that the company claimed would occur.

**B. Newer data from Sweden raise concerns about snus and nicotine pouches.**

Assertions about the “success” of the “Swedish experience” are overstated and outdated, and do not reflect recent data and patterns of use.

Despite claims about Sweden’s experience with snus and cigarette smoking, there is no reliable evidence that snus will help people quit smoking. The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) conducted a systematic review of studies on snus in Nordic countries and was unable to make any conclusions about associations between using snus and quitting smoking due to a lack of independent studies.<sup>63</sup> A more recent systematic review that included studies from Sweden also found only “weak” evidence for snus helping smokers quit.<sup>64</sup>

The decline in adult smoking rates in Sweden has slowed in the last five years. Meanwhile, use of snus and nicotine pouches has been increasing since 2018, with younger adults having higher rates of use compared to older adults. Long-term trends show that snus use

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<sup>61</sup> FDA, Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act – Technical Project Lead at 39 (October 22, 2019), <https://www.fda.gov/media/131923/download?attachment> (emphasis added).

<sup>62</sup> Sundberg, *supra* note 53; Rodrigues, *supra* note 53; Will Yakowicz, *How Zyn Conquered America*, FORBES (September 26, 2024), <https://www.forbes.com/sites/willyakowicz/2024/09/26/how-zyn-took-over-america/>.

<sup>63</sup> Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), *Associations between the use of snus (moist tobacco) or e-cigs and tobacco smoking: A systematic review*, Summary and main findings (June 15, 2020), <https://www.sbu.se/312e>.

<sup>64</sup> Daniel Stjepanovic et al., *Efficacy of smokeless tobacco for smoking cessation: a systematic review and meta-analysis*, 32 TOBACCO CONTROL 757-768 (2023), <https://doi.org/10.1136/tobaccocontrol-2021-057019>.

remained relatively steady during the time that smoking rates were declining more rapidly and increased in more recent years as the smoking rate declines have slowed.<sup>65</sup>

Among Swedish youth, smoking rates have not changed dramatically since 2016 even though the general trend is downwards. In fact, smoking rates among upper secondary school year 2 students (around 17 years old) *increased* between 2021 and 2024. Meanwhile, use of snus among older adolescents stayed relatively steady until 2016, after which rates began to rise, with even more dramatic increases among girls.<sup>66</sup> Daily and almost daily use of snus is more common than occasional use among youth.<sup>67</sup> Increasing use of both cigarettes and snus among some Swedish youth is concerning and is further evidence that the “Swedish experience” is not a success story.

Given the lack of data (even from Swedish authorities) showing an association between snus and smoking cessation, as well as more recent prevalence trends among adults and youth, TPSAC should reject the notion that marketing ZYN with the same modified risk claim as used for General Snus will benefit the public health in the U.S.

#### **IV. The applicant did not submit sufficient data on consumer perception or behavior change related to the proposed modified risk claim and this specific product.**

The new study that the applicant submitted as part of its modified risk application did not address crucial questions needed to determine if using the proposed claim would benefit the health of the public as a whole.<sup>68</sup> Swedish Match did not adequately show that smokers intended to completely switch to ZYN due to the claim, did not demonstrate that consumers understood the language in the proposed claim to mean complete switching, and left out critical data specific to young populations. This is crucial data because the phrase “instead of cigarettes,” as used in the claim, does not sufficiently explain to consumers that only complete switching could achieve lower risks. Independent studies published since the original General Snus order was granted recommend using clearer messaging about switching completely. For instance, Wackowski, et al. (2021) stated that “it is important that future MRTP communications make clear that harm

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<sup>65</sup> Public Health Agency of Sweden, *Use of tobacco and nicotine products* (December 12, 2024), <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/living-conditions-and-lifestyle/andtg/tobacco/use-of-tobacco-and-nicotine-products/>.

<sup>66</sup> *Id.*

<sup>67</sup> Swedish Association for Alcohol and Drug Education, *Tobacco and nicotine products*, (February 2, 2024), <https://www.can.se/fakta/tobaks-och-nikotinprodukter/> (Google-translated from Swedish).

<sup>68</sup> PMI, Report - ZYN Modified Risk Claims - Perceptions of and Likelihood to Use, Version 1.0 March 21, 2024, *Quantitative Study to Assess Perceptions of and Likelihood of Use of ZYN® with Modified Risk Claims Among US Adults, REPORT SMNA 5240072*.

reduction is conditional on complete product switching, not dual product use.”<sup>69</sup> For these reasons, this application is insufficient and a modified risk order should not be granted.

In addition, the significant redactions made in the publicly available version of the applicant’s Tobacco Product Perceptions and Intentions to Use Study make it impossible for the public to sufficiently assess the results.

**A. The applicant’s perception study did not demonstrate that smokers intend to switch to ZYN based on the claim.**

PMI’s Perceptions of and Likelihood to Use report make contradictory statements about the impact of exposure to the proposed modified risk statement and intentions to switch, a problem exacerbated by the redacted data. At the beginning of the report, one of the conclusions states: “For current smokers, there was no difference in the change in intention to quit smoking pre- post exposure to the ZYN® Nicotine Pouches regardless of exposure group.”<sup>70</sup> Later, however, the report states: “Smokers indicated an increased motivation to quit use of cigarettes, ENDS and smokeless TNP post-exposure (Table 12) compared to pre-exposure (Table 16).”<sup>71</sup> It is important to resolve this discrepancy, especially since the public has not been given the details of the findings.

Because the Tobacco Control Act requires that companies show that using the modified risk claim will cause a positive change<sup>72</sup> – in this case, induce smokers to quit smoking or completely switch away from cigarettes – and not just do no harm, if PMI failed to show an increase in intention to quit after exposure to the proposed claim, then the evidence is not sufficient to support granting this application.

**B. The applicant didn’t assess consumer understanding of complete switching.**

The applicant did not submit any new data showing that consumers understood the proposed claim to mean that complete switching was necessary to achieve the stated benefit. Neither the submitted Tobacco Product Perceptions and Intentions to Use Study nor the referenced Likelihood of Use or Patterns of Use studies from the original PMTA for ZYN addressed this issue. Hence, even if the Patterns of Use study showed that some people who smoke switched completely to ZYN, that change was not a result of the proposed claim, which may demonstrate that a modified risk claim is not itself a factor in inducing people to switch

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<sup>69</sup> Olivia A. Wackowski et al., *Smokers’ Exposure to Perceived Modified Risk Claims for ECigarettes, Snus, and Smokeless Tobacco in the United States*, 23 NICOTINE & TOBACCO RESEARCH 605-608 (2021), <https://doi.org/10.1093/ntr/ntaa159>.

<sup>70</sup> PMI, *supra* note 68, at 10.

<sup>71</sup> PMI, *supra* note 68, at 62.

<sup>72</sup> See FD&C Act § 911(g)(1).

from cigarettes with ZYN. As mentioned earlier, the burden is on the applicant to demonstrate that the claim itself yields a benefit, not just show that the claim would not worsen the status quo.

By using the same wording as the General Snus modified risk claim, the proposed claim for ZYN suffers from the same flaws that were highlighted by TPSAC with respect to General Snus, and thus should not be granted in the form that has been proposed.

**C. Other potentially missing data may warrant the denial of the application.**

TPSAC should investigate whether the applicant has sufficiently provided data on the potential impact of the proposed claim for ZYN on young adults and youth.

The Tobacco Product Perceptions and Intentions to Use Study report stated that the applicant planned to oversample young adults,<sup>73</sup> but the redactions prevent confirmation that it had done so and that it had stratified their results by age. Because use of nicotine pouches – and particularly ZYN – is higher among younger adults, it is important for the applicant to have submitted sufficient data showing an appropriate level of comprehension of the proposed claim and the impact of the proposed claim on this population.

While the applicant referred to national surveys and Altria Client Services' Underage Tobacco Use Study (UTUS) for general data on youth use of nicotine pouches,<sup>74</sup> the company did not appear to submit data specifically showing youth perception of the proposed claim and the potential impact of exposure to this claim on initiation and use. Public health groups have repeatedly stressed the importance of providing these data to inform FDA's decision-making.<sup>75</sup> It

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<sup>73</sup> PMI, *supra* note 68, at 5.

<sup>74</sup> PMI, Module 6.1: Clinical Population Health Studies, at 7.

<sup>75</sup> CTFK, *Comment Letter on Applications for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.*, 13-16 (January 3, 2018), [https://www.tobaccofreekids.org/assets/images/content/2018\\_01\\_03\\_CTFK\\_IQOS\\_comments.pdf](https://www.tobaccofreekids.org/assets/images/content/2018_01_03_CTFK_IQOS_comments.pdf); CTFK, *Comment Letter on Notice of Meeting re Tobacco Product Application Review*, 4-6 (December 7, 2018), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/2018\\_12\\_07\\_CTFK\\_Comments\\_premarket\\_review\\_meeting.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2018_12_07_CTFK_Comments_premarket_review_meeting.pdf); CTFK et al., *Comment Letter on Modified Risk Tobacco Product Applications for IQOS system with Marlboro HeatSticks, IQOS system with Marlboro Smooth Menthol HeatSticks, and IQOS system with Marlboro Fresh Menthol HeatSticks submitted by Philip Morris, S.A.*, 2, 8-14 (February 11, 2019), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2019\\_02\\_11\\_Public\\_Health\\_Groups\\_Comments\\_IQOS\\_MRPTAs.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2019_02_11_Public_Health_Groups_Comments_IQOS_MRPTAs.pdf); CTFK et al., *Comment Letter on Proposed Rule for Premarket Tobacco Product Applications and Recordkeeping Requirements*, 21-25 (December 16, 2019), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/PublicHealthGroupsCommentsonPMTAProposedRule.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/PublicHealthGroupsCommentsonPMTAProposedRule.pdf); CTFK et al., *Principles to Guide FDA Premarket*

is particularly important to provide data on the impact on youth if the proposed claim will be displayed in locations easily visible to youth and children, such as the point-of-sale display shown in the Tobacco Product Perceptions and Intentions to Use Study.<sup>76</sup>

Short of submitting youth perception data, the applicant did not appear to supply adequate information that might explain if and why the young adult data could be “bridged” to demonstrate the impact of the claim on youth. At the very least, this information should have been included.

Finally, it is unclear if the Tobacco Product Perceptions and Intentions to Use Study evaluated current nicotine pouch users (or, specifically, ZYN users) apart from overall tobacco/nicotine product users. FDA, TPSAC, and the public should be provided this information to understand the impact of the proposed claim on this population.

## CONCLUSION

We urge TPSAC to take account of the developments discussed above in considering whether Swedish Match’s application meets the statutory standard, and to recommend that FDA deny the applications.

Respectfully submitted,

Campaign for Tobacco-Free Kids

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*Review of E-Cigarettes and Other Deemed Products*, 3-4 (August 10, 2020), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2020\\_08\\_10\\_Premarket-Principles.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_08_10_Premarket-Principles.pdf); FDA, *February 6, 2019 TPSAC Meeting Transcript*, 69-71 (Feb. 6, 2019), <https://www.fda.gov/media/122002/download>; CTFK et al., *Comment Letter to FDA about the Youth-Oriented Marketing of the IQOS Heated Cigarette Product in Other Countries* (May 14, 2019), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/2019\\_05\\_14\\_youth\\_marketing\\_iqos.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2019_05_14_youth_marketing_iqos.pdf); CTFK et al., *Necessity of Adolescent Risk Perception Data in Modified Risk Tobacco Applications* (February 15, 2019), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2019\\_02\\_15\\_Public-Health-Groups-Adolescent-Risk-Perception.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2019_02_15_Public-Health-Groups-Adolescent-Risk-Perception.pdf); CTFK, *Comments on Public Scientific Workshop on Youth Tobacco Cessation: Science and Treatment Strategies*, 6-7 (May 31, 2019), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2019-05-31\\_FDA-Youth-Cessation-Workshop-Comments.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2019-05-31_FDA-Youth-Cessation-Workshop-Comments.pdf); Bonnie Halpern-Felsher et al., *The Importance of Including Youth Research in Premarket Tobacco Product and Modified Risk Tobacco Product Applications to the Food and Drug Administration*, 67 JOURNAL OF ADOLESCENT HEALTH 331-333 (2020), <https://doi.org/10.1016/j.jadohealth.2020.06.020>.

<sup>76</sup> PMI, *supra* note 68, at 139.

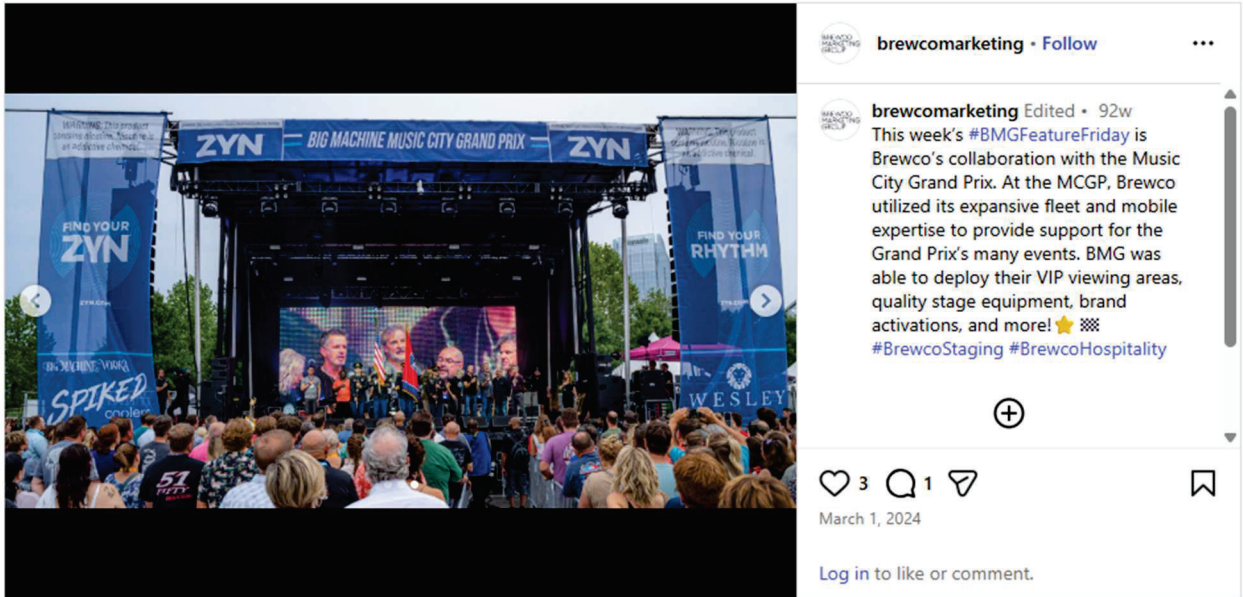
# **Appendix**

## **Examples of ZYN Marketing, the Prevalence of ZYN on Social Media, and Related Content**

# ZYN-sponsored events

## Music City Grand Prix

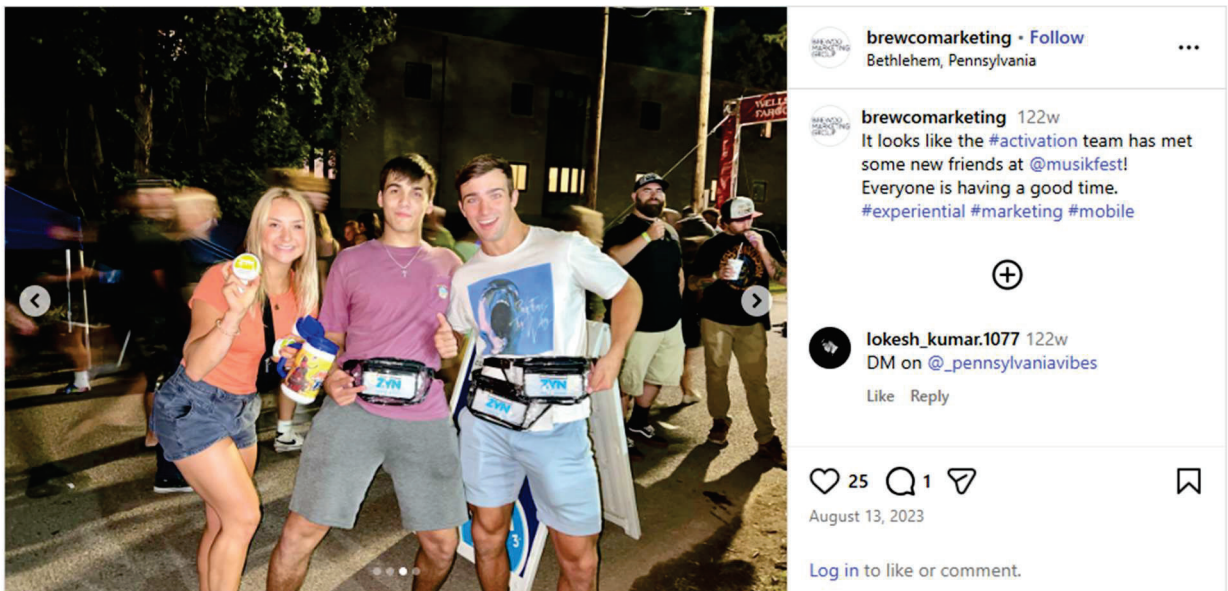
ZYN was prominently displayed on stage at this IndyCar series event in Nashville, Tennessee. Signs encouraged attendees to “Find Your ZYN” and “Find Your RHYTHM.”



Source: [https://www.instagram.com/p/C3-kGWVrymQ/?img\\_index=3](https://www.instagram.com/p/C3-kGWVrymQ/?img_index=3) (Mar. 1, 2024).

## Musikfest

Festivalgoers are photographed receiving ZYN-branded merchandise at this music festival in Bethlehem, Pennsylvania.



Source: [https://www.instagram.com/p/Cv4omADrrAW/?img\\_index=3](https://www.instagram.com/p/Cv4omADrrAW/?img_index=3) (Aug. 13, 2023).

## Calf Fry Music Festival

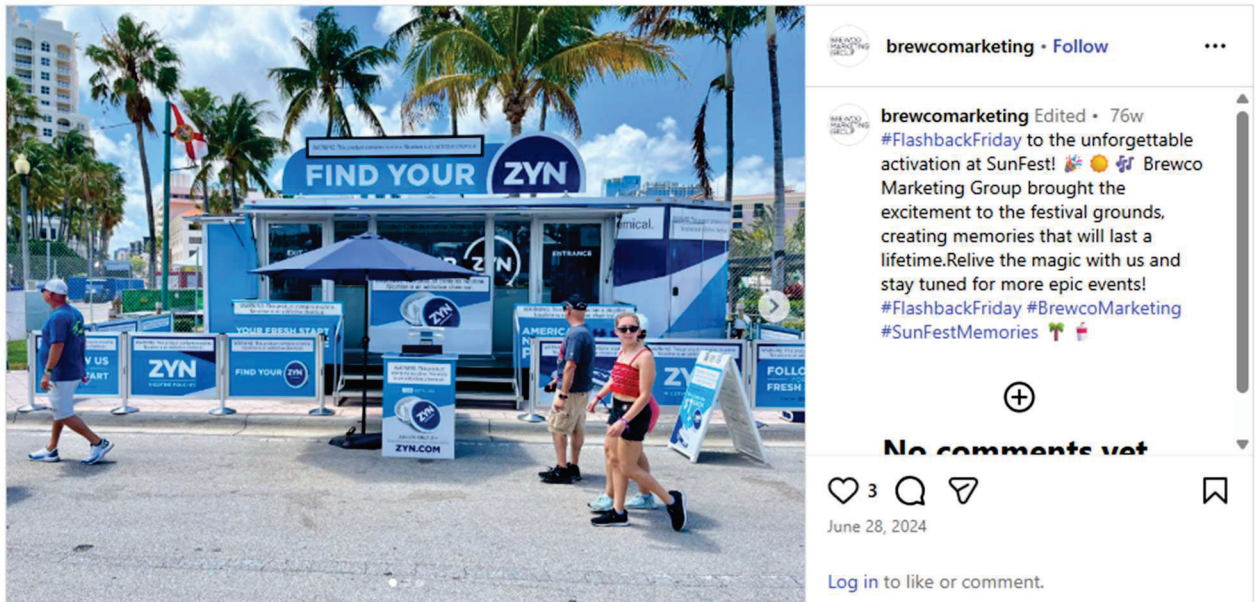
This Stillwater, Oklahoma, music festival celebrated ZYN as their “RETURN” sponsor on social media.



Source: <https://www.instagram.com/calffryok/p/CrRzON9AgBY/> (April 20, 2023).

## SunFest

A ZYN trailer invited festivalgoers to “Find your ZYN” at SunFest, a music and art festival open to all ages in West Palm Beach, Florida.



Source: [https://www.instagram.com/p/C8xaIMIRITm/?img\\_index=1](https://www.instagram.com/p/C8xaIMIRITm/?img_index=1) (June 28, 2024).

# ZYN Rewards, including Exclusive Events, and Sweepstakes

ZYN Rewards encourages users to: “Enjoy ZYN. Collect points. Claim rewards.”



Source: <https://us.zyn.com/ZYNRewardsPOS/> (accessed July 3, 2024).

3,000 ZYN Rewards points purchased two tickets to an exclusive show for ZYN users that headlined country music star **Lainey Wilson**.

A screenshot of the ZYN Rewards store interface. On the left, there are three small thumbnail images of Lainey Wilson. The main image is a large promotional graphic for the event, featuring the ZYN PRESENTS logo and the name 'LAINEY WILSON' in large white letters over a background of a dirt road in a rural landscape. To the right of the image, there is a 'NEW' badge, the event title 'ZYN PRESENTS: LAINEY WILSON', and the text '(2 TICKETS PER ORDER) 3,000 PTS'. Below this, there is a checkbox with the text 'I understand lodging and transportation are NOT included with the purchase of tickets. Tickets are non-refundable and non-transferable. By accepting, I agree to the extended disclaimer outlined below.' At the bottom, there is a quantity selector set to '1' and a blue 'Add to Cart 3,000' button.

Source: <https://us.zyn.com/ZYNRewardsStore/zyn-presents-lainey-wilson/> (May 29, 2025).

3,000 rewards points also bought a pair of tickets to an exclusive **Noah Kahan** show. One comment stated, “Welp.. guess I have to take up a nicotine addiction now.”



Source: [https://www.instagram.com/countryhub/p/DGbAhq6PUW8/?hl=en&img\\_index=1](https://www.instagram.com/countryhub/p/DGbAhq6PUW8/?hl=en&img_index=1) (Feb. 23, 2025).

Reporting on the sold-out Noah Kahan show, one Denver, Colorado, publication commented that: “Those who didn’t already have a crippling nicotine addiction ... needed to get cracking to secure these tickets.”

## Zyn City: Noah Kahan Sells Out an Exclusive Zyn Show in Denver

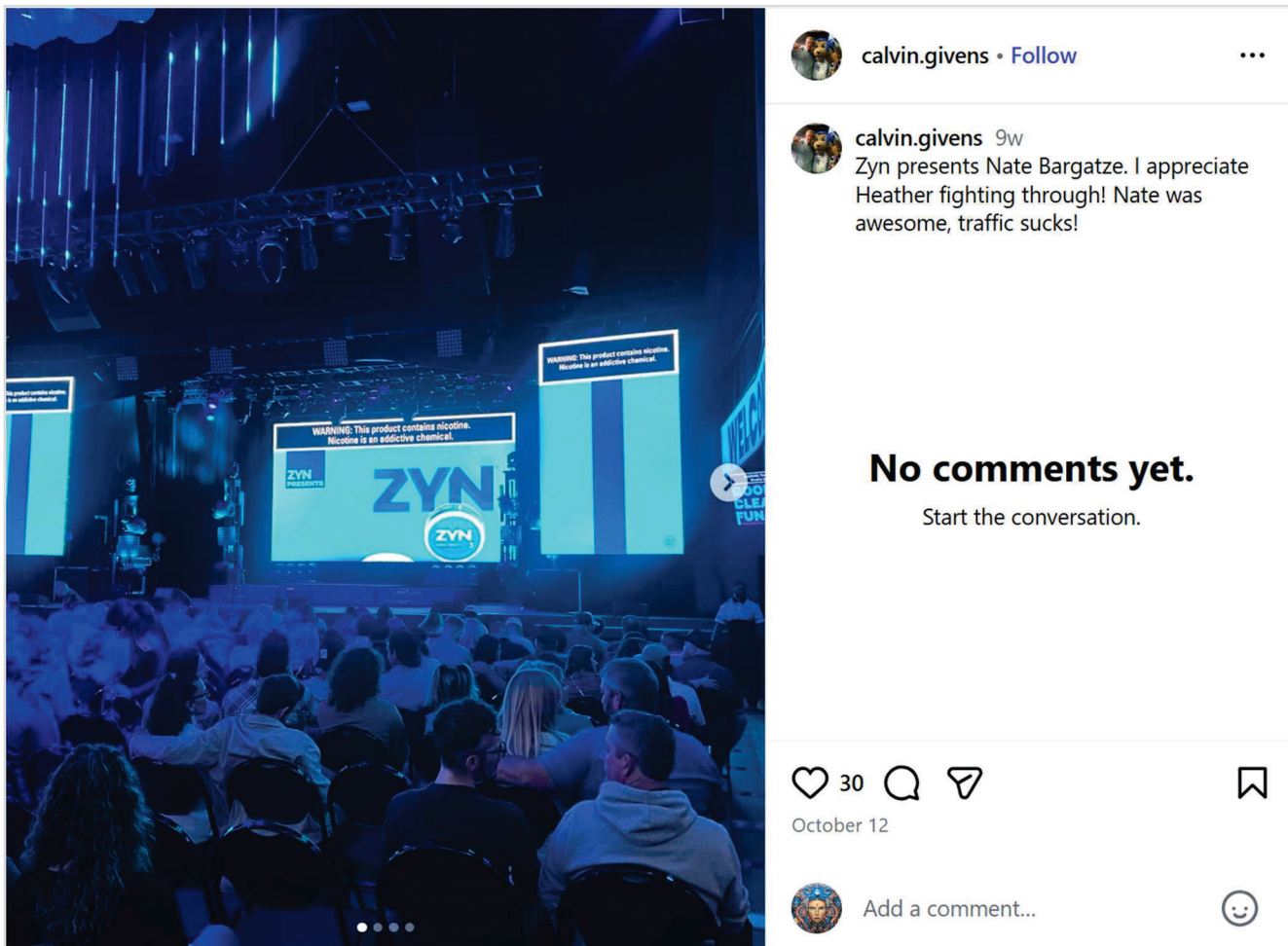
It’s about time we rewarded people with crippling nicotine addiction! Only those who bought at least 200 tins of Zyn were able to access tickets.

By Westword Staff | March 3, 2025

Those who didn't already have a crippling nicotine addiction (or a friend who lent their own rewards points) needed to get cracking to secure these tickets. The tobacco pouches come in a tin with a QR code on the back; once scanned, you'll receive fifteen points. So that's 200 tins of Zyn, or 3,000 pouches. And with Zyn costing upwards of \$10 a tin, that would run you up to \$2,000 to access the Kahan tickets if you've never bought the nicotine product before and decided to start in order to go to the show. You could also **buy them in bulk** for about half the price.

Source: <https://www.westword.com/music/how-to-get-tickets-to-noah-kahan-zyn-concert-in-denver-23839175> (Mar. 3, 2025).

ZYN also held an exclusive show with comedian **Nate Bargatze**. As one Instagram user's post shows, ZYN was prominently featured on stage.



Source: <https://www.instagram.com/p/DPtdrlaEeyP/> (October 12, 2025).

One Reddit user who attended posted to the r/standup message board that “being addicted to nicotine paid off.”

I guess being addicted to nicotine paid off. It was all new material and he crushed. Really enjoyed the show. His openers were great as well.

↑ 554 ↓ · 🗨️ 266

Source:

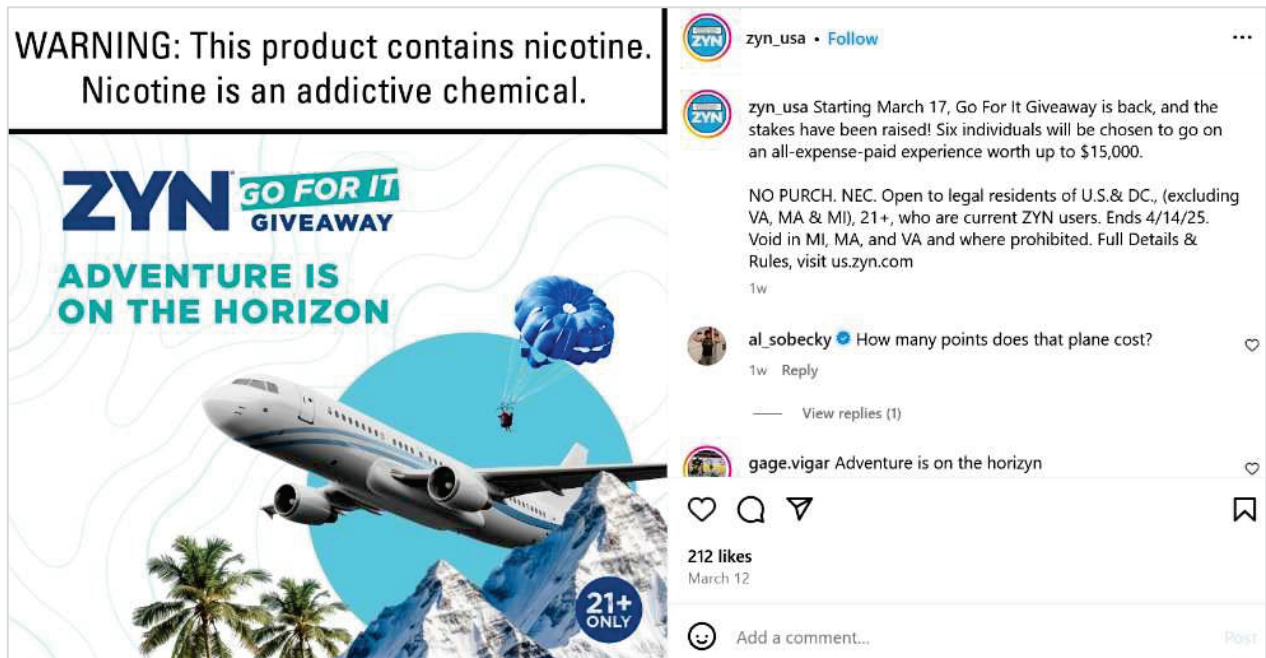
[https://www.reddit.com/r/Standup/comments/1o4p0kn/saw\\_nate\\_bargatze\\_at\\_the\\_zyn\\_exclusive\\_event/](https://www.reddit.com/r/Standup/comments/1o4p0kn/saw_nate_bargatze_at_the_zyn_exclusive_event/) (Dec. 19, 2025).

One banner advertisement online featured a **Bluetooth turntable** that ZYN Rewards members could earn.



Source: <https://apnews.com/article/kentucky-youth-vaping-law-lawsuit-a511ee7052471880ae4aa3205f199d1f> (April 22, 2024).

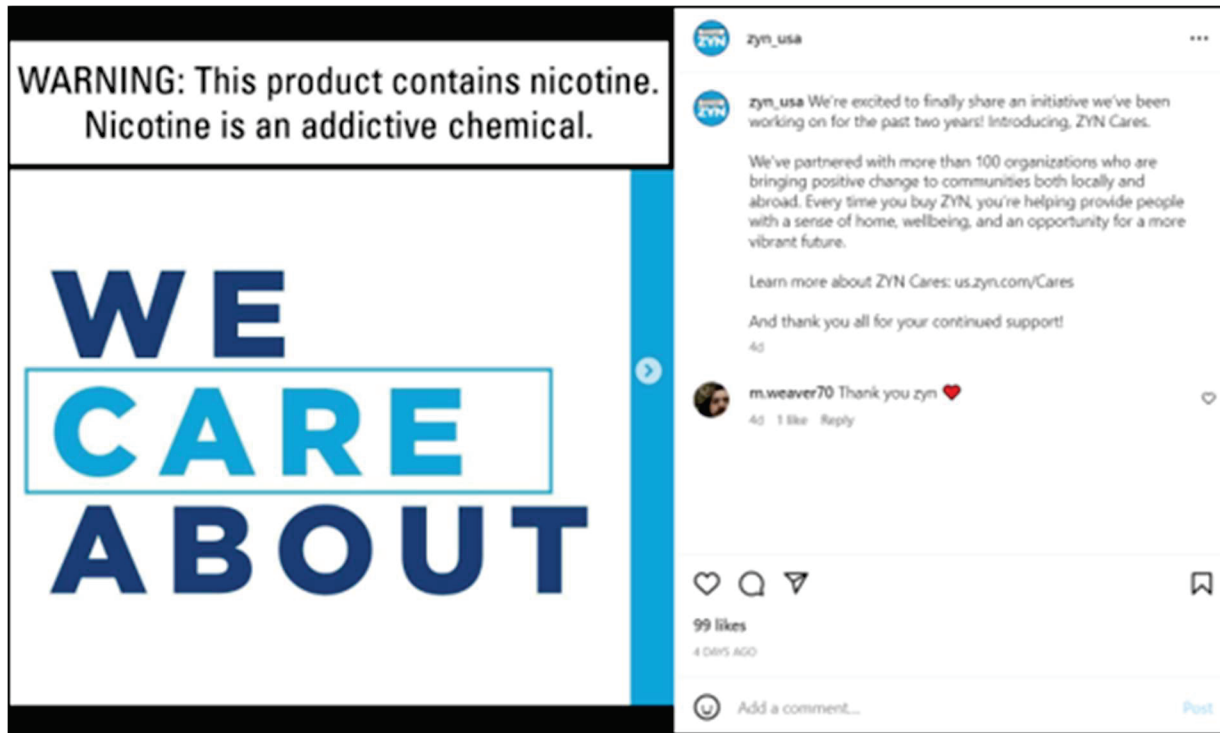
ZYN’s “Go for It Giveaway” offered a chance to win all-expense-paid experiences worth thousands of dollars.



Source: [https://www.instagram.com/p/DHG\\_bkoJ0CW/](https://www.instagram.com/p/DHG_bkoJ0CW/) (March 12, 2025).

## “ZYN Cares”

ZYN has promoted its “ZYN Cares” initiative, encouraging purchases of ZYN with the message that: “Every time you buy ZYN, you’re helping provide people with a sense of home, wellbeing, and an opportunity for a more vibrant future.”



Source: <https://www.instagram.com/p/Ciaa8-5MV4w/> (Sept. 12, 2022).

## Print and Poster Advertising



This ZYN advertisement in the October 27, 2025, issue of *Us Weekly* magazine depicted a woman in a transportation terminal. It invited the reader: “Wherever you’re headed this season, Find Your ZYN”

(Courtesy of Trinkets & Trash, <https://www.trinketsandtrash.org/detail.php?artifactid=15942&page=1>).

This display above a gas pump in Hillsborough, North Carolina, advertised a sale on multiple cans on ZYN, 2021.

(Courtesy of [CounterTobacco.org](http://CounterTobacco.org).)



## Limited Edition Products

ZYN engaged people to “Vote for the next limited-edition color.”



The image shows an Instagram post from the account 'zyn\_usa'. The post features a blue graphic with the ZYN rewards logo and the text 'Vote for the next limited-edition color.' A warning box at the top left states: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical.' The post text reads: 'Introducing the first limited-edition metal can color: Electric Rose. Vote for the next shade now at us.ZYN.com. See site for terms and conditions. The next limited-edition color is subject to change. Voting period runs 9/8/25-9/22/25.' There are three comments from users: 'eli\_rawls' asks for new flavors, 'safezach' says they need more cans, and 'native\_hetke' says they've ordered. The post has 133 likes and a '21+ ON' age restriction icon.

Source: <https://www.instagram.com/p/DOWdBrCITDm/> (Sept. 9, 2025).

ZYN has also promoted “ZYN After Dark” flavors of “Spiced Cider,” “Mojito,” and “Espresso Martini”: flavors “made for the night.”



The advertisement features the ZYN logo and 'NICOTINE POUCHES' at the top left. The main text reads: 'COMING SOON: ZYN AFTER DARK. MADE FOR THE NIGHT. 21+. Available only while supplies last.' Below this is a button that says 'REGISTER TO LEARN MORE →'. On the right, three circular tins of ZYN After Dark pouches are shown: 'SPICED CIDER 10 NICOTINE POUCHES', 'MOJITO 6-- 12 NICOTINE POUCHES', and 'ESPRESSO MARTINI 3-- 12 NICOTINE POUCHES'. The background is a blurred city night scene.

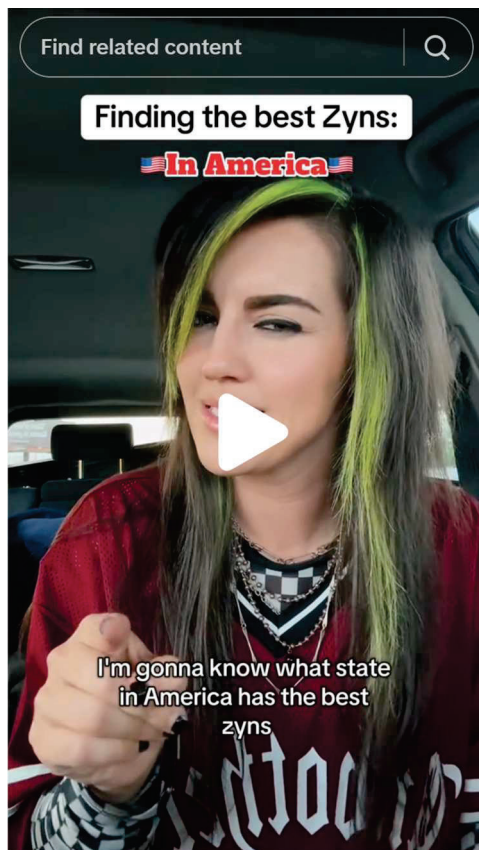
Source: <https://us.zyn.com/zyn-after-dark-limited-edition/> (accessed Nov. 7, 2025).

## User-Generated Social Media Content

Sharing information through peer-to-peer networks is very different in the age of social media. Even if Swedish Match/PMI are not paying influencers to market their products, shared content still promotes ZYN products. Social media posts featuring ZYN have increased brand recognition and has contributed to normalizing its use among young people.

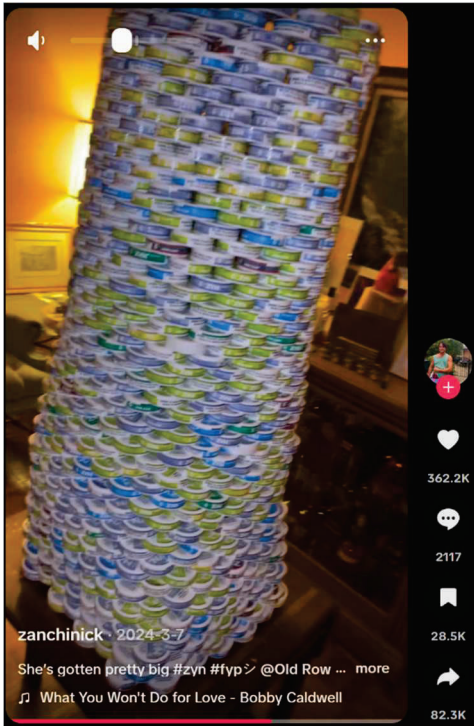
### TikTok

The musician and creator @spammygmoney has posted a series of videos about trying ZYN flavors and finding “the best in America.”



Sources: <https://www.tiktok.com/@spammygmoney/video/7538833642806627598> (August 15, 2025);  
<https://www.tiktok.com/@spammygmoney/video/7532337448790084919> (July 28, 2025).

The creator @zanchinick posted a video of a giant tower of ZYN tins. This video received 2.4 million views.



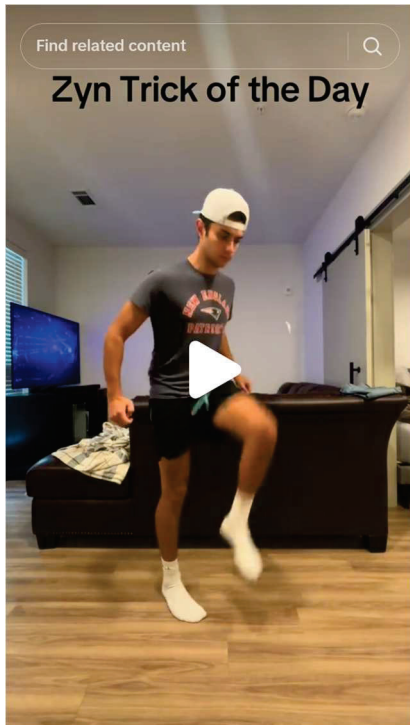
Source: <https://www.tiktok.com/@zanchinick/video/7343792166373739819> (March 7, 2024).

The creator @vinceunaesthetic, who has 75,000 followers, posted a video of a young person trying their first ZYN pouch. This video has 2.6 million views.



Source: <https://www.tiktok.com/@vinceunaesthetic/video/7427544149425081646> (October 19, 2024).

The creator @thepouchjuggler, who has over 18,000 followers, posts videos of himself using ZYN pouches like a hacky sack, ending with the ZYN pouch landing in his mouth. This video has 8.1 million views.



Source: <https://www.tiktok.com/@thepouchjuggler/video/7546690704613854495> (September 9, 2025).

The creator @meganmiddendorf, who has 378,000 followers, posted a video of making her boyfriend a "ZYN birthday cake." The video has 5.2 million views.



Source: <https://www.tiktok.com/@morganmiddendorf/video/7321020357010525486?q=> (Jan. 6, 2024).

# Instagram

On Instagram, artist Dolly Faibyshev shared an image of the November 3, 2024, cover page of The New York Times’ SundayStyles section, which featured her photograph of a young man using a ZYN nicotine pouch. The associated article discussed why young men have taken to ZYN.



Source: [https://www.instagram.com/p/DB63yZfyH2b/?img\\_index=2](https://www.instagram.com/p/DB63yZfyH2b/?img_index=2) (Nov. 3, 2024).

A young woman shares an image of herself with “the best cake in the world”: one designed to look like a ZYN Smooth 6mg can. Below the cake is written: “ZYning into 33!”



Source: [https://www.instagram.com/p/DSQCjxzife3/?img\\_index=1](https://www.instagram.com/p/DSQCjxzife3/?img_index=1) (Dec. 14, 2025).

Video of Nelk Boys giving Tucker Carlson a giant ZYN container that garnered millions of views across various social media platforms.



Source: <https://www.instagram.com/kyle/reel/C1H4143OUAv/?hl=en> (December 21, 2023). See also, <https://x.com/nelkboys/status/1737887008066818084?lang=en> (December 21, 2023).

## ZYN-Inspired Merchandise

Products like “Z Caddy” are marketed to “elevate your ZYN experience.” These “premium” metal cans can be laser engraved with a custom message.



The screenshot shows the Z Caddy website interface. At the top, there is a navigation bar with a hamburger menu icon, the Z Caddy logo, a 'Shop Now' button, and a user profile icon. Below the navigation bar is a dark blue banner with the text '60-Day Risk Free Returns'. A white pop-up box in the top left corner reads 'Holiday 10% Off Save for the Holidays!'. The main content area features a large image of a black Zyn can with a custom laser engraving. The engraving includes the text 'EAST COAST UNITED' at the top, 'EST.' on the left, '2009' on the right, and 'JIU JITSU & MUAY THAI' at the bottom. In the center is a circular graphic of a mountain range with waves. To the right of the image is the heading 'Custom, Laser Engraved Zyn Cans' and a paragraph of text: 'Want something unique and personalized to you? We'll create a **custom, laser-engraved Z Caddy** with the image of your choice. Whether it's a company logo, a patch for your squadron, or your initials, **it feels awesome to grab your custom can** every time you pop a Zyn.'

Source: <https://zcaddystore.com/> (Dec. 22, 2025).

Also sold are “tactical” ZYN holsters “[b]uilt for Warriors that upper deck a 6 mili on the regular.”



Source: <https://www.etsy.com/listing/4372608044/tactical-zy-holster-nicotine-pouch/> (Dec. 23, 2025).

ZYN's popularity has inspired dog toy parodies like "ZEN," available in flavors like "DROOL MINT" and in "6 wags" strength. The warning statement reads: "WARNING: This product may cause excessive tail wags."

Source: <https://a.co/d/if6m30X> (Dec. 22, 2025).



## Nestpark Zen Pupper Deckies Parody Dog Toy - Plush Squeaky and Crinkle Funny Dog Toy - Drool Mint

Visit the Nestpark Store

4.7 ★★★★★ (347)

Overall Pick

4K+ bought in past month

\$13<sup>95</sup> (\$13.95 / count)

Get Fast, Free Shipping with Amazon Prime

FREE Returns

Save 10% on 2 select item(s) Shop items >

Get \$60 off instantly: Pay \$0.00 upon approval for the Amazon Store Card.

Color: Drool Mint



ZYN's popularity on the internet can result in exposure offline, too, such as from t-shirts like the one for sale below.



Source: <https://thegoodshirts.com/products/jesus-died-for-your-zyns/> (Dec. 23, 2025).