

**FDA should consider the significant public health issues, especially for youth, created by Philip Morris International's co-marketing of its Swedish Match General Snus products with its Swedish Match ZYN oral nicotine products and deny Swedish Match's request to renew the MRTP order permitting it to market General Snus products with a modified risk claim**

Docket Number FDA-2014-N-1051

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FDA granted Modified Risk Tobacco Product (MRTP) marketing authorization for eight Swedish Match General Snus smokeless tobacco products (including four mint-flavored products) on October 22, 2019, permitting Swedish Match to market these products with the following modified risk information:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”<sup>1</sup>

Philip Morris International (PMI) purchased Swedish Match in 2022 for \$16 billion because it recognized a consumer shift away from traditional tobacco products and towards alternatives such as nicotine pouches and snus.<sup>2</sup>

In deciding whether to renew the existing MRTP order for General Snus, FDA is required to make a determination that General Snus products will benefit the health of individuals and the population as a whole, taking into account:

- (1) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to [General Snus];
- (2) The increased or decreased likelihood that persons who do not use tobacco products will start using [General Snus]; and
- (3) The risks and benefits to persons from the use [General Snus] as compared to the use of [FDA approved smoking cessation and nicotine dependence treatments].<sup>3</sup>

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<sup>1</sup> US Food & Drug Administration, Modified Risk Granted Orders – Risk Modification for eight General Snus Smokeless Tobacco Products, October 22, 2019. Available:

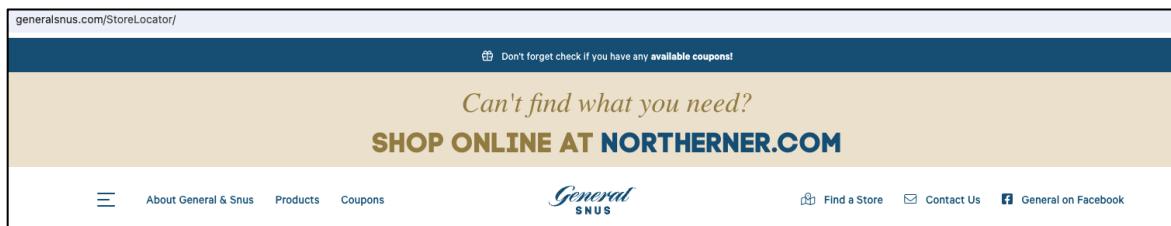
<https://www.fda.gov/media/131922/download?attachment>

<sup>2</sup> Ringstrom A, Philip Morris bets on cigarette alternatives with \$16 bln Swedish Match bid, May 11, 2022. Available: <https://www.reuters.com/business/philip-morris-launches-16-bln-cash-offer-swedish-match-2022-05-11/>

<sup>3</sup> Family Smoking Prevention and Tobacco Control Act, section 911(g)(4), Public Law 111-31, 21 USC 387k (June 22, 2009).

Of particular concern is whether General Snus products are or will be used concurrently with Swedish Match's ZYN nicotine pouches, which are among the most popular brands of nicotine pouches,<sup>4</sup> especially with adolescents and young adults.<sup>5, 6</sup> Mint-flavored ZYN is one of the most popular flavors,<sup>7, 8</sup> and nicotine pouch product marketing features their flavors.<sup>9,10</sup> As detailed below, Swedish Match submitted a PMTA application for ZYN in 2020, but, as of June 20, 2024, FDA has not made a decision on it. ***This concurrent use is of particular concern because Swedish Match co-markets mint-flavored and other flavors of ZYN with mint- and tobacco-flavored General Snus.<sup>11</sup>***

Although PMI announced on June 17, 2024, that it would suspend online sales of Swedish Match's ZYN pouches on its ZYN.com website,<sup>12</sup> as of June 19, 2024, Swedish Match's General Snus website<sup>13</sup> directed consumers to shop online with a link to Northerner.com where they could purchase ZYN:



Source: <https://generalsnus.com/StoreLocator/> (accessed June 19, 2024)<sup>14</sup>

<sup>4</sup> Dowd AN, Thrul J, Czaplicki L, Kennedy RD, Moran MB, Spindle TR. A Cross-Sectional Survey on Oral Nicotine Pouches: Characterizing Use-Motives, Topography, Dependence Levels, and Adverse Events. Nicotine Tob Res. 2024 Jan 22;26(2):245-249. doi: 10.1093/ntr/ntad179. PMID: 37712111; PMCID: PMC10803111.

<sup>5</sup> Liu J, Halpern-Felsher B. Popularity of Zyn and other nicotine pouch brands among US adolescents, young adults, and adults in 2021. Preventive Medicine. 2024 Aug 1;185:108068.

<sup>6</sup> Gaiha SM, Lin C, Lempert LK, Halpern-Felsher B. Use, marketing, and appeal of oral nicotine products among adolescents, young adults, and adults. Addict Behav. 2023 May;140:107632. doi: 10.1016/j.addbeh.2023.107632. Epub 2023 Jan 27. PMID: 36731224.

<sup>7</sup> Dowd AN, Thrul J, Czaplicki L, Kennedy RD, Moran MB, Spindle TR. A Cross-Sectional Survey on Oral Nicotine Pouches: Characterizing Use-Motives, Topography, Dependence Levels, and Adverse Events. Nicotine Tob Res. 2024 Jan 22;26(2):245-249. doi: 10.1093/ntr/ntad179. PMID: 37712111; PMCID: PMC10803111.

<sup>8</sup> Gaiha SM, Lin C, Lempert LK, Halpern-Felsher B. Use, marketing, and appeal of oral nicotine products among adolescents, young adults, and adults. Addict Behav. 2023 May;140:107632. doi: 10.1016/j.addbeh.2023.107632. Epub 2023 Jan 27. PMID: 36731224.

<sup>9</sup> Ling PM, Hrywna M, Talbot EM, Lewis MJ. Tobacco-Derived Nicotine Pouch Brands and Marketing Messages on Internet and Traditional Media: Content Analysis. JMIR Form Res. 2023 Feb 15;7:e39146. doi: 10.2196/39146. PMID: 36790840; PMCID: PMC9978966.

<sup>10</sup> Duan Z, Henriksen L, Vallone D, *et al* Nicotine pouch marketing strategies in the USA: an analysis of Zyn, On! and Velo *Tobacco Control* 2024;33:154-163.

<sup>11</sup> <https://www.northerner.com/us/the-northerner/review/snus-vs-zyn> (accessed June 19, 2024)

<sup>12</sup> Reuters, Philip Morris suspends nationwide sales on Zyn.com after D.C. subpoena, June 17, 2024. Available: <https://www.reuters.com/business/retail-consumer/philip-morris-suspends-nationwide-sales-zyncom-after-dc-subpoena-2024-06-17/>

<sup>13</sup> <https://www.generalsnus.com/StoreLocator/>

<sup>14</sup> [generalsnus.com/StoreLocator/](https://generalsnus.com/StoreLocator/) (accessed June 19, 2024)

The Northerner.com website offers smokeless tobacco and nicotine products “from top brands” including ZYN, General Snus, and Copenhagen.

**WARNING:** This product contains nicotine. Nicotine is an addictive chemical.

FROM \$4.44 /CAN

**ZYN**  
SPEARMINT  
16 NICOTINE POUCHES  
3 mg

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

**ZYN**  
ZYN.COM

BUY NOW

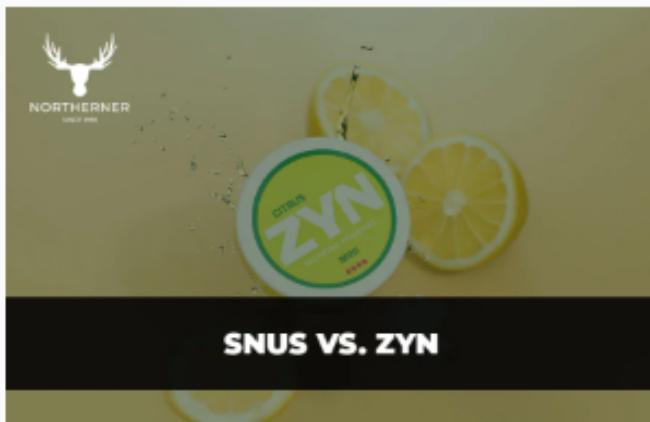
ZYN rewards

Source: <https://www.northerner.com/us/> (accessed June 19, 2024)<sup>15</sup>

Importantly, Swedish Match's General Snus and ZYN nicotine pouches are co-marketed as companion products to use in different situations: "If you find yourself craving tobacco, snus is the product for you. If you're looking for a nicotine kick while you're in meetings at work, or in transit somewhere, then ZYN nicotine pouches are the better option." Both are sold on the same Northerner webpage with links to purchase both products.<sup>16</sup>

<sup>15</sup> <https://www.northerner.com/us/> (accessed June 19, 2024)

<sup>16</sup> <https://www.northerner.com/us/the-northerner/review/snus-vs-zyn>



## Snus vs. ZYN

Snus and ZYN nicotine pouches may have a lot of qualities and characteristics in common, but the deeper you dive, the more obvious it is how different these two products are. To start, snus—which you'll find is more popular in Europe—is made with tobacco, while ZYN is a tobacco-free nicotine product. Below, we'll take a better look at the battle of snus vs. ZYN to understand exactly what sets these two very popular products apart.

[Shop ZYN](#) [Shop Snus](#)

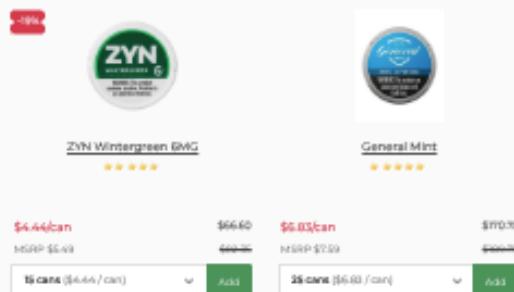
### What Are the Major Differences Between Snus vs. ZYN?

#### 1. Portion Material and Content

When comparing these two products side by side, you'll notice pretty instantly that snus' contents are much different than ZYN's. As we addressed above, the first major difference is that snus has tobacco, while nicotine pouches don't. This means that most snus will appear darker in color than nicotine pouches. You'll also notice that brands like General snus are much more moist than ZYN, which means it will ultimately produce more drip. ZYN, on the other hand, comes in a slim, all-white format and produces little to no drip. For this reason, ZYN is far more convenient and discreet than snus.

#### 2. Nicotine

Because of the higher moisture content found in brands like General snus, nicotine is released a lot faster than ZYN and other nicotine pouches, but it will also taper after a fairly short period of time. ZYN releases nicotine for a longer duration due to its drier pouch material. For this reason, it could feel like snus is much stronger than nicotine pouches, when the reality is, snus just delivers a strong experience up front, while ZYN offers a steadier delivery and peaks later in the experience.



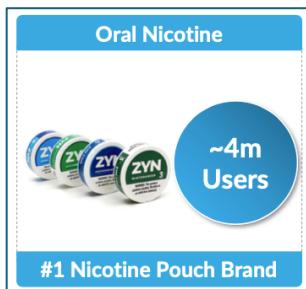
When it comes to both Snus and ZYN, you're always going to get quality, so it really comes down to what you prefer. If you find yourself craving tobacco, snus is the product for you. If you're looking for a nicotine kick while you're in meetings at work, or in transit somewhere, then ZYN nicotine pouches are the better option. You can shop ZYN pouches and snus right here on our website!

Source: <https://www.northerner.com/us/the-northerner/review/snus-vs-zyn> (accessed June 19, 2024)<sup>17</sup>

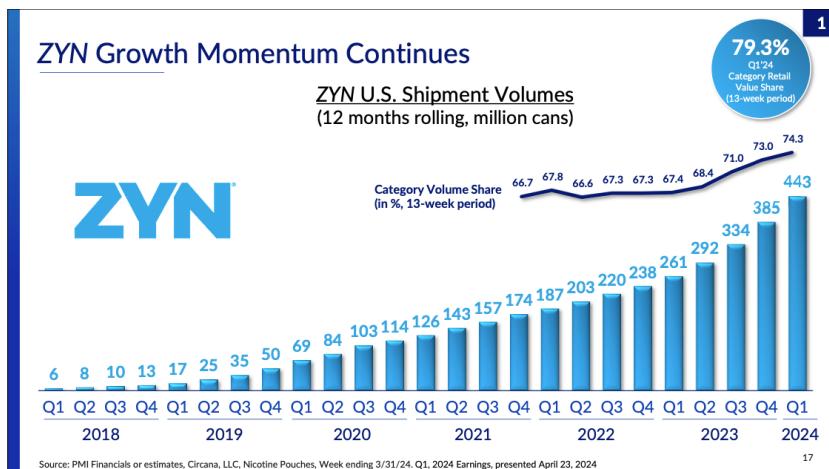
1. Co-marketing Swedish Match General Snus with Swedish Match ZYN oral nicotine products presents significant public health risks, especially for youth, that must be addressed in FDA's consideration of the General Snus MRTP renewal application.

<sup>17</sup> <https://www.northerner.com/us/the-northerner/review/snus-vs-zyn> (accessed June 19, 2024)

Swedish Match's ZYN oral nicotine products are the latest chapter in Philip Morris International's actions to addict adolescents and young adults to nicotine to maintain its market for nicotine products. ZYN's popularity and sales in the US have skyrocketed. In its investor report, PMI boasts that ZYN is the "#1 nicotine pouch brand" with approximately 4 million users, reaching a \$2 billion retail value brand in the US within five years of national launch, and estimated that as of the first quarter of 2024, ZYN accounted for 74.3% of the oral nicotine pouch market share.<sup>18</sup> Like General Snus, ZYN is available in several mint flavors appealing to kids and ZYN is sold in cans designed to look like popular mint candies. Like General Snus, ZYN can be used discretely at times and places where using other tobacco products would not be allowed. And like General Snus, ZYN is being promoted as healthy and a nicotine-cessation device, despite the fact that these claims have not been substantiated or authorized by the FDA.



Source: PMI Investor Information, May 2024.<sup>19</sup>



Source: PMI Investor Information, May 2024.<sup>20</sup>

PMI's Swedish Match applied for PMTA marketing authorization of its ZYN oral nicotine products in March 2020.<sup>21</sup> As of June 20, 2024, FDA had not acted on this application.

<sup>18</sup> PMI Investor Information, May 2024. Available: <https://www.pmi.com/investor-relations/overview>

<sup>19</sup> PMI Investor Information, May 2024. Available: <https://www.pmi.com/investor-relations/overview>

<sup>20</sup> Source: PMI Investor Information, May 2024. Available: <https://www.pmi.com/investor-relations/overview>

<sup>21</sup> <https://www.pmiscience.com/en/smoke-free/tobacco-regulation/us-regulation-tobacco-nicotine-products/#:~:text=For%20example%2C%20PMTAs%20for%20Swedish,only%20one%20variant%20so%20far.>

PMI's May 2024 investor presentation shows that the company is poised to market them as modified risk products if they obtain FDA marketing authorization:

Continuous efforts to further increase consumer awareness of the dramatic difference in the relative risk between smokefree products and cigarettes will remain a focus going forward.

...  
Swedish Match's 2020 PMTA applications for all its ZYN products presently on the US market show that almost all harmful and potentially harmful components commonly associated with tobacco products have been reduced below detection levels. Further, the consumer studies presented in the applications show that there is little interest in the ZYN products among consumers who are not tobacco consumers and that there is a large potential to attract existing tobacco users to the products. During 2022, Swedish Match has continued to work on new PMTA applications for products not presently on the US market.<sup>22</sup>

PMI's Swedish Match openly acknowledges that it intends to leverage the "SFP [Smoke-Free Products] Multi-Category Portfolio," concurrently marketing General Snus with ZYN.<sup>23</sup> PMI's marketing of both snus and ZYN raises public health concerns because ZYN is marketed aggressively on social media channels popular among youth,<sup>24</sup> and increasing numbers of youth report awareness of nicotine pouch products.<sup>25</sup> **Because PMI/Swedish Match co-markets its General Snus products with ZYN, consumers are likely to be confused and believe that ZYN is authorized to be sold in the US, despite the fact that FDA has not granted ZYN PMTA marketing authorization.**



Source: PMI Investor Information, May 2024.<sup>26</sup>

<sup>22</sup> <https://www.swedishmatch.com/Sustainability/focus-areas/improve-public-health/>

<sup>23</sup> PMI Investor Information, May 2024. Available: <https://www.pmi.com/investor-relations/overview>

<sup>24</sup> Dobbs PD, Kong G, Berman ML, et al. 'Cashing in' nicotine pouches for prizes

*Tobacco Control* Published Online First: 15 June 2024. doi: 10.1136/tc-2024-058691

<sup>25</sup> Birdsey, J. (2023). Tobacco product use among US middle and high school students—National Youth Tobacco Survey, 2023. *MMWR. Morbidity and Mortality Weekly Report*, 72.

<sup>26</sup> Source: PMI Investor Information, May 2024. Available: <https://www.pmi.com/investor-relations/overview>

**ZYN is also being marketed with modified risk claims (as of June 19, 2024) despite the fact that FDA has not posted any MRTP applications for ZYN.** A June 17, 2024, *Wall Street Journal* article includes a video that highlights how proponents of ZYN pouches are using their experience with Snus to justify ZYN's use and safety.<sup>27</sup> However, a recent systematic review found increased risk of cancer of the esophagus, pancreas, stomach and rectum as well as cancer-specific death associated with the use of Swedish snus.<sup>28</sup>

## 2. Conclusion:

- FDA must consider the joint marketing of ZYN nicotine pouches with Swedish Match General Snus as part of a determination that continued authorization of MRTP claims for Swedish Match is not “appropriate for the protection of public health” and deny Swedish Match’s MRTP renewal application.
- Further, FDA must act to prevent illegal marketing of ZYN, including marketing ZYN with modified risk claims, because FDA is still considering the PMTA application and has not issued any marketing orders for ZYN.

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<sup>27</sup> Ojea S, Zyn Nicotine Pouch Maker Halts Sales on Its Website, June 27, 2024. Available: [https://www.wsj.com/business/retail/philip-morris-international-suspends-zyn-com-sales-amid-d-c-probe-over-banned-flavored-nicotine-pouches-8f61ae5e?st=pflf1hyroqj9kfa&reflink=desktopwebshare\\_permalink](https://www.wsj.com/business/retail/philip-morris-international-suspends-zyn-com-sales-amid-d-c-probe-over-banned-flavored-nicotine-pouches-8f61ae5e?st=pflf1hyroqj9kfa&reflink=desktopwebshare_permalink)

<sup>28</sup> Valen H, Becher R, Vist GE, Holme JA, Mdala I, Elvsaaas IØ, Alexander J, Underland V, Brinchmann BC, Grimsrud TK. A systematic review of cancer risk among users of smokeless tobacco (Swedish snus) exclusively, compared with no use of tobacco. *Int J Cancer*. 2023 Dec 15;153(12):1942-1953. doi: 10.1002/ijc.34643. Epub 2023 Jul 21. PMID: 37480210.