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Bureau of Tobacco Free Florida's Statement Regarding FDA's Premarket Tobacco Product Applications



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TALLAHASSEE, FLA. – Recently, the U.S. Food and Drug Administration (FDA) began issuing limited, controlled marketing approval for the sale of new tobacco products through its premarket tobacco product application (PMTA) process. The FDA established the PMTA process as part of its efforts to regulate emerging tobacco products, such as e-cigarettes and other new tobacco and nicotine delivery systems.

The FDA has considered over one million PMTA submissions and rejected over 99% of them. These applicants, which did not meet the standards for addressing public health concerns, received Marketing Denial Orders (MDOs).

FDA's actions come on the heels of a national youth e-cigarette epidemic that has included a significant impact in Florida. **After decades of successful youth tobacco prevention efforts, Florida has one of the lowest high school cigarette smoking rates in the country.** However, that progress is threatened by the rise in e-cigarette use. More than 1 in 5 (21.6%) Florida high school students reported current e-cigarette use in 2020.¹

"The FDA has taken the necessary steps to render judgement on these nicotine-packed products," **said Bureau Chief of Tobacco Free Florida, Laura Corbin.** "As anticipated, some will now be sold legally. However, as a result of these products being on the market for the last decade, Florida, like the rest of the U.S., is facing a youth e-cigarette epidemic. Parents and educators must recognize what these products are and have conversations with young people about the importance of staying tobacco and nicotine free."

Even with the review, e-cigarette manufacturers are not permitted to claim the products can help tobacco users quit as they are not an FDA-approved cessation device, nor are they "safe." Further, the Agency has reserved the right to revoke the permitting should a tobacco brand's marketing or targeting indicate increased risk to youth. As Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products explained in [a recent announcement](#):

"We must remain vigilant with this authorization and we will monitor the marketing of the products including whether the company fails to comply with any regulatory requirements or if credible evidence emerges of significant use by individuals who did not previously use a tobacco product, including youth. We will take action as appropriate, including withdrawing the authorization."

While manufacturers continued selling these products nationwide during the review process, the e-cigarette industry created millions of nicotine-addicted youth. In fact, current e-cigarette use among Florida high schoolers has increased by 100% since 2014.^{2,3}

The 1 in 5 high school students (21.6%) in Florida using e-cigarettes in 2020 indicates a disturbing increase, compared to 2014 when the rate was closer to just 1 in 10 (10.8%).^{4,5} It should come as no surprise that the industry invested their time and money into targeting young people with highly addictive nicotine products and making those products more appealing by using flavors and sleek designs.

The bottom line is that e-cigarettes lead to addiction and are unsafe for kids, teens and young adults. **Using e-cigarettes can increase your odds of developing respiratory disease by 95% and can impact brain development until about age 25.**^{6,7,8} Additionally, evidence suggests that teens who use e-cigarettes may be at greater risk of starting to smoke regular cigarettes.^{9,10,11,12}

Restricting youth access to all tobacco products, including e-cigarettes and other products like cigars and hookah, is critical to reducing youth tobacco use and initiation. Tobacco Free Florida's youth prevention campaign, THE FACTS NOW, provides critical and trusted information to youth to help curb tobacco and e-cigarette use. Additionally, Students Working Against Tobacco (SWAT), Florida's youth-led movement, is active in all 67 counties and works with local leaders to restrict and limit e-cigarette access to underage youth.

Tobacco Free Florida's Quit Your Way program offers several options to teens and adults who need help overcoming nicotine addiction, regardless of what tobacco products they use. The Bureau also works through Tobacco Free Partnerships to educate parents and other local leaders in supporting healthier communities.

For more information and updates on the FDA's PMTA process, please visit tobaccofreeflorida.com/blog/pmta.

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About Tobacco Free Florida

The Florida Department of Health's Tobacco Free Florida campaign is a statewide cessation and prevention campaign funded by Florida's tobacco settlement fund. Since the program began in 2007, more than 254,000 Floridians have successfully quit using one of Tobacco Free Florida's free tools and services. There are now approximately 451,000 fewer adult smokers in Florida than there was 10 years ago, and the state has saved \$17.7 billion in health care costs.¹³ To learn more about Tobacco Free Florida's Quit Your Way services, visit www.TobaccoFreeFlorida.com or follow the campaign on Facebook at www.facebook.com/TobaccoFreeFlorida or on Twitter at www.twitter.com/tobaccofreefla.

¹ Florida Youth Tobacco Survey (FYTS), Florida Department of Health, Office of Public Health Research, 2020.

² Florida Youth Tobacco Survey (FYTS), Florida Department of Health, Office of Public Health Research, 2014.

³ Florida Youth Tobacco Survey (FYTS), Florida Department of Health, Office of Public Health Research, 2020.

⁴ Florida Youth Tobacco Survey (FYTS), Florida Department of Health, Office of Public Health Research, 2014.

⁵ Florida Youth Tobacco Survey (FYTS), Florida Department of Health, Office of Public Health Research, 2020.

⁶ Bhatta, DN, et al. Association of E-Cigarette Use With Respiratory Disease Among Adults: A Longitudinal Analysis. American Journal of Preventive Medicine, Volume 58, Issue 2, 182 – 190. Accessed January 28, 2020.

⁷ Bhatta, DN, et al. Association of E-Cigarette Use With Respiratory Disease Among Adults: A Longitudinal Analysis. *American Journal of Preventive Medicine*, Volume 58, Issue 2, 182 – 190. Accessed January 29, 2020.

⁸ U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. 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, 2016. Accessed January 28, 2020.

⁹ Berry, KM, Fetterman, JL, Benjamin, EJ, et al. Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths. *JAMA Netw Open*. 2019;2(2):e187794. doi:10.1001/jamanetworkopen.2018.7794. Accessed January 31, 2020.

¹⁰ Miech, R, Patrick, ME, O'Malley, PM, et al. E-cigarette use as a predictor of cigarette smoking: results from a 1-year follow-up of a national sample of 12th grade students *Tobacco Control* 2017; 26:e106-e111. Accessed January 31, 2020.

¹¹ National Academies of Sciences, Engineering, and Medicine. 2018. *Public Health Consequences of E-Cigarettes*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>. Accessed January 31, 2020.

¹² U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. 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, 2016. Accessed January 31, 2020.

¹³ Mann, NM, Nonnemaker, JM, & Thompson, J. "Smoking-Attributable Health Care Costs in Florida and Potential Health Care Cost Savings Associated with Reductions in Adult Smoking Prevalence." 2016.