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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-D-1817: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk - Draft Guidance for Industry

Dear Dockets Management Staff:

The American Psychiatric Association (APA), the national medical specialty society representing over 40,400 psychiatric physicians and their patients, appreciates the opportunity to comment on the FDA's draft guidance on Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications. It is known that nicotine is highly addictive and that people with mental illness are more susceptible to the use of combustible cigarettes than the general population. Similar trends are emerging related to the safety and impact of electronic cigarette use on other vulnerable populations with mental illness.¹

In clinical practice, flavored vaping products are often cited as adolescents' entry point into nicotine use; this pattern is consistent with national literature.² Youth patients commonly demonstrate a strong preference for flavored ENDS, even when they are aware of the associated health risks. FDA's draft guidance states that fruit and candy/dessert/other sweet-flavored ENDS pose particularly strong youth risk and cites evidence that youth who prefer fruit flavors are more likely to report ENDS as their first tobacco product.³ FDA also notes that youth using non-traditional flavors such as fruit and candy had substantially higher odds of continued vaping over time.

Assembly

¹ Javed, S., Usmani, S., Sarfraz, Z., Sarfraz, A., Hanif, A., Firoz, A., Baig, R., Sharath, M., Walia, N., Chérrez-Ojeda, I., A. Evan, & Ahmed, S. (2022). A Scoping Review of Vaping, E-Cigarettes and Mental Health Impact: Depression and Suicidality. *Journal of community hospital internal medicine perspectives*, 12(3), 33–39. <https://doi.org/10.55729/2000-9666.1053>

² Leventhal, A. M., Goldenson, N. I., Cho, J., Kirkpatrick, M. G., McConnell, R. S., Stone, M. D., Pang, R. D., Audrain-McGovern, J., & Barrington-Trimis, J. L. (2019). Flavored E-cigarette Use and Progression of Vaping in Adolescents. *Pediatrics*, 144(5), e20190789. <https://doi.org/10.1542/peds.2019-0789>

³ Groom, A. L., Vu, T. T., Kesh, A., Hart, J. L., Walker, K. L., Giachello, A. L., Sears, C. G., Tompkins, L. K., Mattingly, D. T., Landry, R. L., Robertson, R. M., & Payne, T. J. (2020). Correlates of youth vaping flavor preferences. *Preventive medicine reports*, 18, 101094. <https://doi.org/10.1016/j.pmedr.2020.101094>

Administration

Marketa M. Tills, M.D., M.B.A.
CEO and President

Nicotine poses a unique risk to young people because their brains are still developing. Nicotine can impede brain development and harm parts of the brain that control attention, learning, mood, and impulse control.⁴ Youth can start showing signs of nicotine addiction quickly, sometimes before the start of regular or daily use. Youth who use nicotine may be more likely to smoke cigarettes in the future and/or may be at increased risk for subsequent substance use disorders.

While e-cigarette aerosol generally contains fewer harmful chemicals than the deadly mix of 7,000 chemicals in smoke from cigarettes, this does not make e-cigarettes safe.⁵ E-cigarettes and vapes are not recommended as a way to quit smoking. They are not yet regulated or approved for smoking cessation by the U.S. Food and Drug Administration.⁶ Evidence to conclude that e-cigarettes increase smoking cessation is lacking, and the US Preventative Services Task Force (USPSTF) recommends that clinicians direct patients to safe, effective, and evidence-based interventions.⁷ Recommended cessation tools include behavioral counseling, Quitline support, and FDA-approved pharmacotherapies including Nicotine Replacement Therapy (NRT), varenicline (Chantix), and bupropion (Wellbutrin) when clinically appropriate. Psychiatrists, primary care providers, and other behavioral specialists can discuss and prescribe these medications. Combination NRT, such as a nicotine patch plus a short-acting product like gum or lozenge, is more effective than a single NRT product, and USPSTF notes that varenicline appears more effective than NRT or bupropion, based on available evidence. In practice, combining counseling with pharmacotherapy remains the most evidence-based and scalable approach for long-term smoking cessation.⁸

Behavioral health literature raises concern about ENDS products rather than reassurance, especially for youth. The Centers for Disease Control and Prevention (CDC) reported in 2025 that among youth who currently used e-cigarettes, those with moderate-to-severe symptoms of depression and anxiety were more likely to report dependence-related symptoms such as cravings and wanting to vape soon after waking, and were more likely to report using e-cigarettes because they felt anxious, stressed, or depressed.⁹ The CDC also notes that e-cigarette use among youth is associated with poor mental health. In addition, systematic reviews have found associations between youth e-cigarette use and depression, anxiety, suicidality, perceived stress, and externalizing symptoms, although causality is complex and likely bidirectional.

Therefore, the deliberate marketing of flavored ENDS to youth is dangerous and reinforces the need for a rigorous premarket application process.

⁴ U.S. Department of Health and Human Services. [E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General](#). Centers for Disease Control and Prevention; 2016. Accessed Feb 14, 2024.

⁵ National Academies of Sciences, Engineering, and Medicine. [Public Health Consequences of E-Cigarettes](#). The National Academies Press; 2018.

⁶ *Pediatrics* (2023) 151 (5): e2023061805. <https://doi.org/10.1542/peds.2023-061805>

⁷ Janssen BP, Walley SC; Section on Tobacco Control. Policy statement. E-cigarettes and similar devices. *Pediatrics*. 2019;143(2):e20183652

⁸ Mendelsohn C. (2022). Optimal use of smoking cessation pharmacotherapy. *Australian prescriber*, 45(1), 10–14. <https://doi.org/10.18773/austprescr.2022.001>

⁹ VanFrank B, Williams TR, Alcantara IC, Hertz M, Al-Shawaf M, Meyers C, et al. E-Cigarette Use and Symptoms of Depression and Anxiety Among US Middle and High School Students. *Prev Chronic Dis* 2025;22:250186. DOI: <http://dx.doi.org/10.5888/pcd22.250186>.

APA policy calls for the restriction of these marketing attempts.¹⁰ Nicotine products are not ordinary consumer goods; they are addictive products with major implications for population health, especially youth. A meaningful premarket review process is essential to ensure that manufacturers, not the public, bear the burden of showing that marketing a new product is appropriate for the protection of public health. Given the well-established appeal of flavored products to youth, this determination should rely on population-level evidence of initiation risk and flavor-specific impacts. Furthermore, the process should remain science-based, transparent, and product-specific.

APA recommends that in their guidance for premarket applications, FDA maintains the position that flavored ENDS pose a substantial risk to public health, particularly to the youth population, and that this outweighs the perceived benefit for adults in tobacco cessation, which has insufficient evidence.

Thank you for the opportunity to provide, and for your consideration of, these comments. Please contact egershenson@psych.org with any questions or for more information.

Sincerely,



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CEO and Medical Director
American Psychiatric Association

¹⁰ American Psychiatric Association (2022). Position Statement on Vaping Products and Electronic Cigarettes. <https://www.psychiatry.org/getattachment/f501ef06-caee-4479-b979-e901322abd7f/Position-Statement-on-Vaping-and-Electronic-Cigarettes.pdf>