

Food and Drug Administration
Rockville, MD 20852

In The Matter of Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications–
Considerations Related to Youth Risk; Draft Guidance for Industry; Availability

The American Consumer Institute is an independent 501(c)(3) education and research organization. Its mission is to identify, analyze, and protect the interests of consumers in selected legislative and rulemaking proceedings in information technology, health care, insurance, and other matters.

These comments address the Food and Drug Administration’s (FDA) draft guidance for flavored electronic nicotine delivery systems (ENDS), including vapes. This guidance takes a modest step toward aligning the FDA with scientific evidence that flavored vapes are less harmful than smoking and are among the most effective tools smokers use to quit. However, it remains, at best, a marginal improvement. The FDA continues to treat sweet and fruit flavors—the flavors adults prefer and that have the greatest potential to help smokers quit—as inherently targeting children, despite evidence to the contrary.

The FDA’s claim that sweet and fruit flavors are inherently aimed at children is not supported by the administration’s own data or by broader evidence on nicotine use. The proposed framework rests on an assumed link between flavor availability and youth uptake, yet CDC National Youth Tobacco Survey data consistently show that teens rank flavors relatively low among their reasons for vaping, behind factors such as curiosity and social influences.¹

More importantly, real-world trends contradict the FDA’s position. Youth nicotine use has declined sharply since 2019—a fact the FDA itself acknowledges in its draft guidance—even as flavored products remained available. If flavors were the dominant causal factor, usage would have increased or at least remained stable as vapes became more available. Instead, the opposite occurred. This suggests that enforcement, age restrictions, and broader social trends—not flavor bans—are the primary determinants of youth use.

¹ Steve Pociask and Justin Leventhal, “Tobacco Harm Reduction and the Teen Epidemic: Health Impacts from Vaping,” The American Consumer Institute, June 8, 2023, <https://www.theamericanconsumer.org/2023/06/aci-white-paper-tobacco-harm-reduction-and-the-teen-epidemic-health-impacts-from-vaping/>.

While flavors are not driving youth vaping, adults clearly prefer flavored vapes, as evidenced by their prevalence in the market. When considering potential benefits for smokers trying to quit, the FDA suggests that flavors such as coffee, tea or spices should be held to a lower standard than sweet and fruit flavors. This ignores basic consumer behavior, adults overwhelmingly prefer sweet flavors, and smokers rely on flavored vapes to quit.² In fact, flavored vapes—particularly sweet flavors—are more effective at promoting smoking cessation than many alternative methods.³ The FDA cannot engineer consumer preferences.

The agency's differential standard for approval highlights another flaw in the guidance: the requirement that products demonstrate their flavor is more effective than tobacco-flavored vapes at helping smokers quit. This is redundant. The general effectiveness of flavored products—and of sweet and fruit flavors in particular—has already been demonstrated in multiple studies.⁴

The FDA also applies an asymmetrical standard of evidence. It demands near-clinical proof that flavored vapes produce cessation benefits for adults while accepting speculative evidence regarding youth appeal. This approach effectively creates a de facto prohibition on flavored products, despite the statutory requirement under the Family Smoking Prevention and Tobacco Control Act to evaluate overall population health effects. Adult smokers disproportionately prefer non-tobacco flavors and report higher success switching when those options are available—evidence the FDA systematically discounts.

In assessing overall population health, the FDA should give appropriate weight to the fact that vaping is significantly less harmful than smoking⁵—estimated to be no more than five percent as harmful.⁶ The agency's analysis also fails to account for substitution effects. Restricting flavored vapes does not eliminate nicotine demand. Evidence from previous flavor bans shows increased cigarette sales following restrictions, indicating that some users—both youth and adults—shift toward more harmful combustible products when less harmful alternatives are constrained.⁷ By ignoring this dynamic, the FDA fails to evaluate flavors in context of the full nicotine market.

² Abigail Friedman and SiQing Xu, "Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation," *JAMA Network Open*, vol. 3, no. 6, June 5, 2020, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766787>.

³ Yoonseo Mok, et. al., "Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey," *Nicotine & Tobacco Research*, October 17, 2022, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9910159/>.

⁴ Lin Li, et. al., "How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys," *Nicotine & Tobacco Research*, February 25, 2021, <https://pmc.ncbi.nlm.nih.gov/articles/PMC8500174/>.

⁵ "Vaping myths and the facts," United Kingdom National Health Service, accessed April 22, 2026, <https://www.nhs.uk/better-health/quit-smoking/ready-to-quit-smoking/vaping-to-quit-smoking/vaping-myths-and-the-facts/>.

⁶ "Nicotine without smoke: Tobacco harm reduction," Royal College of Physicians, October 28, 2019, <https://www.rcp.ac.uk/resources/nicotine-without-smoke-tobacco-harm-reduction/>.

⁷ Brad Davis, Abigail Friedman, and Michael Pesko, "Restricting Sales of Flavored Nicotine Vaping Products: Effects on Cigarette and Nicotine Vaping Product Sales in Canada," SSRN, November 20, 2025, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5705282; Jenny Blair, "Tobacco purchases rise following restrictions on e-cigarette sales," Yale School of Public Health, October 17, 2023, <https://ysph.yale.edu/news-article/tobacco-purchases-rise-following-restrictions-on-e-cigarette-sales/>.

Combustion, not flavor, is the primary driver of smoking-related disease. By focusing on flavor profiles rather than relative product risk, the FDA treats all nicotine products as functionally similar, obscuring the substantial differences in health outcomes between cigarettes and non-combustible alternatives. The result is a policy approach that restricts lower-risk products based on weak assumptions about youth behavior, while allowing hundreds of new cigarettes enter the market each year.⁸

This draft guidance also fails to recognize that excessive regulatory barriers have not eliminated flavored vapes; they have displaced them into black and grey markets, where safety standards are absent. Rather than trying to dictate consumer preferences, the FDA should ensure the sweet and fruit flavored products consumers choose to use meet appropriate standards.

The FDA should revise this guidance to align with its statutory mandate and the available evidence. This means abandoning the presumption that sweet and fruit flavors are uniquely youth-oriented, applying a consistent evidentiary standard across products, and explicitly incorporating substitution effects and relative risk into its analysis. A framework that permits the authorization of flavored ENDS, subject to strict age-restriction and product standards, would better serve public health. Absent these changes, the agency will continue to suppress safer alternatives, entrench illicit markets, and undermine the public health objectives it is charged with advancing.

Respectfully,

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⁸ Justin Leventhal, "Why Is the FDA Easier on Cigarettes Than Smoking Cessation Tools," RealClear Health, October 23, 2025, https://www.realclearhealth.com/articles/2025/10/23/why_is_the_fda_easier_on_cigarettes_than_smoking_cessation_tools_1142909.html.

