

May 11, 2026

Dr. Martin Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2025-D-0922 — Draft Guidance for Industry: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk

Dear Commissioner Makary:

The Coalition for Smarter Regulation of Nicotine ("Regulate Smarter") represents U.S.-based manufacturers, distributors, and retailers committed to operating responsibly within the regulated marketplace. The companies we and our members represent account for the large majority of tobacco and nicotine products moving from factory to store shelves within the FDA-regulated system. We collectively employ over 2.7 million Americans, in all fifty states, and account for over \$837 billion in U.S. economic activity.¹ We strongly support the success of FDA regulation of this industry. We share our perspectives here from the vantage point of industry members fully invested in a well-functioning, legal, and responsible marketplace.

We submit these comments in the context of a regulatory system in full-blown crisis.² The process FDA has built for reviewing less harmful products has made it so difficult for flavored e-cigarettes to be authorized that almost none has made it to the legal market. FDA's stated hope was to *limit* the availability of flavored e-cigarettes, yet it has had the opposite and much more dangerous effect – a thriving, multi-billion-dollar illicit market filled with vastly more varieties of flavored e-cigarettes than FDA says it wants, and in forms and designs far more dangerous than anything the Agency would or should authorize. This problem is now spreading rapidly to other categories like nicotine pouches.

For over three years, our members have joined with many others in calling attention to this crisis – the fact that this illicit market is here, endangers children and adults, increases crime, undermines public safety, rewards illegal actors for evading regulation, punishes businesses complying with it, and which, if left unaddressed, will render FDA regulation irrelevant to the public it is meant to protect.³

¹ NACS, NACS State of the Industry Report of 2024 Data (2025).

² See e.g. Reagan-Udall Found. for the FDA, *Operational Evaluation of Certain Components of FDA's Tobacco Program* (Dec. 2022); Letter from James Comer, Chairman, House Comm. on Oversight & Accountability, et al., to Robert M. Califf, Comm'r, U.S. Food & Drug Admin. (Mar. 28, 2023), <https://oversight.house.gov/wp-content/uploads/2023/03/Letter-to-FDA-re-Premarket-Tobacco-Product-Applications-1.pdf>

³ See e.g., Letter from Various Regulated Industry Members to Brian King, Dir., Ctr. for Tobacco Prods., U.S. Food & Drug Admin. (Oct. 25, 2023) (on file with FDA).

In the face of all of this, FDA is proposing *not* to change direction in any meaningful way, but to *recommit* to the policies that led to this disaster. That is the wrong choice. Instead of the status quo, FDA should embrace and boldly implement fundamental reform of the system. To have lasting impact, this reform should be focused on three things. First, *fully enforce the law* on companies that have seceded from FDA regulation and are now reaping billions in revenue for having done so and, in the process, endangered American lives. Second, *comprehensively reform the authorization system to deliver within the legal marketplace* the less harmful products adult consumers want as better alternatives to smoking, including flavored e-cigarettes. And third, *educate adult consumers* on the facts about authorized smoke-free products so they can make the fully informed decisions they have every right to make.

We support a well-regulated marketplace driving toward the harm reduction goals Congress expected this system to deliver. To achieve this, FDA should act on these full-scale reforms and overhaul the policies that have gotten in the way of a well-regulated marketplace. Because this Guidance would further delay these necessary reforms, we urge the Agency not to adopt them.

FDA Not Delivering on Smoke-Free Choices for Adults Seeking Better Options

The Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act") became law on June 22, 2009, providing FDA with authority to regulate tobacco products, including requiring FDA review of any new products entering the marketplace.⁴ Central to Congress creating this pre-market tobacco application ("PMTA") process was its embrace of harm reduction. Congress understood the settled science that smoke, not nicotine, causes almost all tobacco-related disease, and understood the potential for these products to displace cigarettes, accelerate reductions in smoking, and save millions of lives.⁵ The powers Congress gave FDA came with all the tools necessary to build a well-regulated legal market the right way – with smoke-free products aimed at and sold only to adults, not with products designed for or marketed to kids.

Implementation of the Tobacco Control Act has not gone as planned. Despite over \$10 billion in user fee revenues in the last 16 years, FDA has authorized only 45 e-cigarettes out of the millions reviewed.⁶ These 45 authorizations comprise, in reality, only nine individual e-cigarette devices for adult consumers to choose from, the majority of which are tobacco-flavored products.⁷ This exceptionally low rate of authorization – a tiny fraction of 1% – is not a function of what the Tobacco Control Act requires, but a series of policy decisions FDA has made while building the PMTA authorization system.⁸

⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 21 U.S.C. §§ 387–387u).

⁵ Inst. of Med., *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* (Kathleen Stratton et al. eds., Nat'l Acad. Press 2001).

⁶ See U.S. Food & Drug Admin., *Tobacco Products Marketing Orders* (listing FDA-authorized ENDS products) (updated Mar. 2026).

⁷ U.S. Food & Drug Admin., *Searchable Tobacco Products Database* (May 5, 2026), <https://www.accessdata.fda.gov/scripts/searchtobacco/>.

⁸ Among many other things, FDA adopted a "comparative benefit" test for flavored e-cigarettes that, on its face, places a higher burden of proof on flavored e-cigarettes compared to non-flavored or tobacco-flavored e-cigarettes – even though flavored e-cigarettes are overwhelmingly what adult consumers want in comparison to unflavored or tobacco-flavored varieties. *Food & Drug Admin. v. Wages & White Lion Invs., L.L.C.*, 604 U.S. ____ (2025).

The Illicit Market Crisis

FDA built this exceptionally high barrier to authorizing flavored e-cigarettes precisely as adult consumers were surging toward them as better alternatives to smoking. Today there are more than 20 million adult e-cigarette consumers in the U.S., up from less than 1 million in 2010, with most of the growth occurring after FDA asserted authority over the category in 2016.⁹

Failing to respect the market demand of so many millions of adults seeking smoke-free alternatives led to the inevitable. In the last five years, the illicit flavored e-cigarette market has exploded in size and scope, with estimates that it now comprises as much as 85% of the \$12.1 to \$14.5 billion U.S. e-cigarette market.¹⁰ This flood of illicit products is fed and sustained overwhelmingly by Chinese manufacturers smuggling these products through the borders, and relying on domestic distributors and retailers – many involved in or connected to major organized crime and cartel organizations – to reach the millions of adult consumers unable to find what they want from among the scant options FDA has authorized.¹¹

The costs of this multi-billion-dollar illicit market include risks to adult consumers, risks to children, more crime, more burden on law enforcement, threats to national security, lost tax and tariff revenues, and a weaker regulatory system. For the regulated businesses we represent, it means watching the illicit Chinese manufacturers and their U.S.-based allies that successfully seized control of the e-cigarette market in a few short years, make similar progress in nicotine pouches, and without foundational changes, these illegal actors face few impediments to overtaking the marketplace.¹²

FDA's Policy Choices Reward the Worst Market Actors

The net impact of all of this is an incentive structure working directly opposite what Congress envisioned. Legitimate manufacturers face an authorization process requiring sometimes tens of millions of dollars in investment, but which virtually guarantees endless reviews, rejection, or both. Under the Tobacco Control Act, FDA is statutorily required to issue a marketing order decision no later than 180 days after it receives an application.¹³ FDA has yet to meet this 180-day timeline, instead typically taking years to review a single product. Congress also gave FDA the authority to issue product standards,¹⁴ a tool FDA could use to direct regulated industry on

⁹ Ctrs. for Disease Control & Prevention, *Awareness and Use of Electronic Cigarettes Among U.S. Adults, 2010–2011*, 60 MMWR 1400, 1400–02 (2011), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>;

¹⁰ *U.S. Retail Sales Data Show 86% of E-Cigarette Sales Are for Illegal Products*, Truth Initiative (Nov. 6, 2024), <https://truthinitiative.org/research-resources/tobacco-industry-marketing/us-retail-sales-data-show-86-e-cigarette-sales-are>; *U.S. E-Cigarette & Vape Market Size & Outlook, 2025-2030*, Grand View Research, <https://www.grandviewresearch.com/horizon/outlook/e-cigarette-and-vape-market/united-states>.

¹¹ U.S. Gov't Accountability Off., *Combating Illicit Substances: DOJ Enforcement of Unauthorized E-Cigarettes*, GAO-26-107991 (Mar. 12, 2026); U.S. Gov't Accountability Off., *Combating Illicit Substances: DOJ Enforcement of Unauthorized E-Cigarettes*, GAO-26-107991 (Mar. 12, 2026).

¹² U.S. Food & Drug Admin., *FDA Clarifies Import Alerts on Detention of Unauthorized E-Cigarettes, Smokeless Tobacco, and Nicotine Pouches* (Jan. 3, 2025), <https://www.cspdailynews.com/tobacco/fda-clarifies-import-alerts-detention-unauthorized-e-cigarettes-smokeless-tobacco>.

¹³ 21 U.S.C. § 387j(c)(1)(A).

¹⁴ 21 U.S.C. § 387g.

precisely what FDA expects for products meant only for adult consumers, yet FDA has yet to propose or formally adopt any such standards.

Add to this FDA's apparent reluctance to enforce the law on illicit manufacturers and provide transparency for adult consumers, and what emerges are powerful incentives for illicit players to keep doing exactly what they have done here: flood the U.S. with flavored e-cigarettes designed without constraint, earn billions in the process, and rest secure in the knowledge that FDA won't punish the illicit actors for defying its authority. Without foundational reforms, FDA will continue keeping responsible U.S. competitors tied up in years long product reviews and issuing marketing denials without scientific rationale. This is not common-sense regulation.

The Draft Guidance Commits FDA to the Status Quo

The Draft Guidance issued on March 11 is a major missed opportunity. Rather than acknowledge that the framework it has built around e-cigarettes isn't working, FDA is proposing only to *clarify* how it will continue to use that flawed framework going forward.

There is no good argument that supports this approach. To begin with, the core assumption FDA makes in defending the status quo – that flavors in and of themselves drive underage use – can't be squared with the data. Recently-released National Youth Tobacco Survey ("NYTS") data shows that underage use of e-cigarettes has dramatically *declined* since 2020 – precisely as flavored e-cigarettes massively *proliferated* throughout the U.S. through the surging illicit market.¹⁵ If FDA's assumption were correct, you would expect underage rates to *rise* in tandem with the growth in flavors, not decline as dramatically as NYTS shows – from 20% in 2019 to 5.2% as of 2025.¹⁶

This data points out a more fundamental flaw in FDA's reasoning. FDA grounds its position on flavors in e-cigarettes on the belief that flavors *alone* or *primarily* are what drives underage use. But the research clearly shows it is a *combination* of many factors – including factors unrelated to the product itself – that together influence the phenomenon.¹⁷ Notably, the NYTS questionnaire itself recognizes the multifactorial nature of youth initiation, asking respondents to identify from among numerous reasons why they first used an e-cigarette, including peer and family influence, curiosity, stress and anxiety, the perception that e-cigarettes are less harmful than cigarettes, the ability to use them unnoticed, and the availability of flavors. The inclusion of these varied factors in NYTS is precisely correct – but undermines FDA's essentially binary view of flavors used in these products.

¹⁵ In 2024, the CDC and the Truth Foundation reported on this “explosion in new products” in the illicit market “with flavor categories like fruit, candy, mint, menthol and desserts accounting for more than 80 percent of those sales.” <https://www.cdcfoundation.org/pr/2024/Monitoring-E-Cigarette-Trends-in-the-United-States-Report>

¹⁶ <https://www.fda.gov/tobacco-products/youth-and-tobacco/national-youth-tobacco-survey-nyts>

¹⁷ U.S. Dep't of Health & Hum. Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* (2016)/ Lindpere et al., *Reasons for E-Cigarette Use, Vaping Patterns, and Cessation Behaviors Among U.S. Adolescents*, 25 *Nicotine & Tobacco Res.* 975 (2023).

Illicit Markets and Underage Use

By proposing to continue with the existing FDA framework, the Draft Guidance guarantees intensification of the biggest risk factor of all for underage use: the illicit market. Illicit manufacturers are a danger to youth because they ignore FDA regulation altogether. They don't just use flavors freely, they put them in *egregiously youth-oriented designs* using *egregiously youth-oriented marketing*. Illicit products today come in forms that look like toys, purses, or other child-friendly formats.¹⁸ They use cartoons or other youth-oriented packaging and marketing materials. They incorporate video games into the devices. They use any levels of nicotine or sweeteners without any regulatory review. They come in outrageously high puff counts – some in the tens of thousands. Whether or what precise flavors are in these products is hardly the point – it is the full set of characteristics, not simply the flavors, that FDA should be focused on.

By keeping the illicit market status quo, FDA isn't just shifting e-cigarette manufacturing to illicit foreign competition – it is also tolerating the widespread distribution and retail sale of these products by the wrong actors – like vape shops unconcerned with what they are selling or to whom they are selling.¹⁹ FDA should see reform as a massive opportunity to shift the market back to where it belongs: the licensed, legal, and responsible distributors and retailers invested in a transparent and accountable regulatory system. It is this distributor and retail community – the community that respects the law – that has lost countless jobs and billions of dollars to their illicit counterparts. It is this community that has demonstrated time and again that they know their role in the legal system and accept their responsibilities within it. It is this community – not the illicit market – that has been responsible for successful implementation of minimum age laws, which, among many other things, has contributed to the lowest levels of underage use of tobacco products in a generation. FDA should acknowledge that this community is a far better place for this industry to operate than in the illicit networks dominating e-cigarettes today.

A Better Path Forward: Product Standards for E-Cigarettes

We believe FDA has the opportunity to chart a better course that embraces harm reduction and the role that flavored smoke-free products are already playing in accelerating reductions in smoking. We join with the diverse chorus of voices from public health, policy experts on the left and the right, law enforcement, and so many others in making a simple point. To reverse the disastrous outcome of FDA's prohibition-based practices and policies, FDA must acknowledge

¹⁸ U.S. Food & Drug Admin., *FDA Warns Firms for Selling Illegal E-Cigarettes That Look Like Toys, Food, and Cartoon Characters* (Nov. 16, 2022), <https://content.govdelivery.com/accounts/USFDA/bulletins/3384973>; Truth Initiative, *Bigger, Stronger, and Cheaper: Disposable E-Cigarettes Have More Nicotine and Are More Accessible Than Ever* (Aug. 9, 2023), <https://truthinitiative.org/research-resources/emerging-tobacco-products/bigger-stronger-and-cheaper-disposable-e-cigarettes>.

¹⁹ National Association of Convenience Stores (NACS), *Solving the Illicit Nicotine Problem* (Mar. 3, 2026); National Association of Convenience Stores, *Smoking Out the Illegal Vape Industry*, NACS Mag. (July 2025); NACS et al., Letter to the Trump Administration Urging Action on Illicit Chinese E-Cigarettes (July 18, 2025), summarized in *U.S. Convenience Store Association Urges Trump Administration: Expedite Product Approvals, Strengthen Enforcement, Crack Down on Illegal Chinese E-Cigarettes*, 2Firsts (July 21, 2025).

prohibition doesn't work and that harm reduction is the far better path for successfully regulating this industry, driving down harm, and saving millions of lives.²⁰

With e-cigarettes, we believe FDA should implement reform through product standards designed to clearly delineate the full range of expectations the Agency has for determining that a product is in fact less harmful for adult consumers *and* is unlikely to appeal to youth. FDA has the opportunity to mitigate youth appeal with product standards that address *all* of the product characteristics that, taken together, create youth appeal – flavor descriptors, marketing claims, product names, product packaging, and, of course, marketing plans. In setting these standards, FDA should make clear that even with a product that reaches the legal market, FDA can and will use its extensive oversight power to ensure products it has authorized do not lead to acceleration of youth use. Indeed, Congress gave FDA these extensive post-market surveillance tools precisely because it intended for a smoke-free product marketplace that may require post-market oversight.

Conclusion

Regulate Smarter respectfully urges FDA to use this moment not to wed itself further to the status quo, but to adopt meaningful reform through product standards that will open up the pathway for a smoke-free product marketplace for adults and preserve FDA's power to prevent illicit, youth-oriented nicotine products from reaching the market. With rigorous enforcement, FDA can consign this illicit market crisis to the past.

The Agency has the tools and the authority to act—what is needed now is the will to change.

Regulate Smarter appreciates the opportunity to submit these comments and looks forward to continued engagement with FDA on these critical issues.

Sincerely,



Richard Burr
Chairman, Coalition for Smarter Regulation of Nicotine

²⁰ Jeffrey S. Smith, *The FDA's Center for Tobacco Products Ignores the Science of Tobacco Harm Reduction*, R Street Institute (Feb. 28, 2024); Sally Satel et al., *Regulating the Tobacco and Nicotine Market in the American Public Interest: A Reform Agenda for the FDA*, Am. Enter. Inst. (Sept. 25, 2025); Progressive Policy Inst., *Comments on Draft Guidance: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk*, Docket No. FDA-2026-D-1817 (Mar. 30, 2026); Eric N. Lindblom, *How Might FDA Fix This E-Cigarette PMTA Mess?*, Tobacco Control 33:e106 (2024).