REYNOLDS
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August 31, 2026

VIA Email
The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Ranking Member Wyden:

We are writing in response to your August 3, 2026,[1] letter regarding the Food and Drug Administration's ("FDA") May 2026 enforcement-priorities guidance[2] for certain tobacco products, including electronic nicotine delivery systems ("ENDS") products, marketed without premarket authorization. RAI Services Company[3] ("Reynolds") shares your concern that youth should not have access to tobacco or nicotine products and welcomes the opportunity to address the questions and requests in your letter.

Your letter acknowledges that "[y]ou and I can likely agree on the need to remove unauthorized Chinese vaping products from the U.S. market."[4] Reynolds agrees. Indeed, this goal has been a focus of our advocacy efforts for the better part of the decade. We believe that tobacco policies best serve public health when they combine rigorous enforcement against these Chinese products—evading FDA oversight and driving the existing youth use that is occurring—with timely, science-based review of product applications from responsible manufacturers.

Your letter also acknowledges the potential role that vaping can play in reducing harm from cigarette smoking.[5] Reynolds is committed to developing and offering noncombustible products such as ENDS for adult consumers, as they "represent[] a promising foundation for a

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[1] Letter from Sen. Ron Wyden, Ranking Member, S. Comm. on Fin., to David Waterfield, President & CEO, Reynolds Am. Inc. (Aug. 3, 2026) ("Wyden Letter").
[2] U.S. Food & Drug Admin., Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization (May 2026) ("May Enforcement Guidance").
[3] RAI Services Company is a wholly owned subsidiary of its parent Reynolds American Inc., and it provides corporate and support services to Reynolds American Inc. and its distinct affiliates, including R.J. Reynolds Vapor Company. The term "Reynolds" is utilized here for convenience and refers to Reynolds American Inc. and/or one of its independent subsidiary operating companies, as applicable.
[4] Wyden Letter, at 4.
[5] Wyden Letter, at 3.

comprehensive approach to tobacco harm reduction."[6] Importantly, the public health community, including FDA across multiple administrations, has publicly supported the availability of ENDS to adult tobacco users for years.[7] And over a decade of data shows that ENDS help smokers quit cigarettes.[8]

At the outset, Reynolds believes it is important to state its position on the issues your letter raises. Your letter expresses concern about youth nicotine addiction and about unauthorized Chinese products in the U.S. market. Reynolds shares those concerns. More specifically, Reynolds maintains the following positions:

- Nicotine is addictive. Youth should not use any tobacco or nicotine products, including ENDS. Period. Adults who do not use these products or who have quit using these products should not start.
- Adult smokers should have access to alternative and less harmful products, like ENDS, that have demonstrated through substantial scientific evidence they are lower on the risk continuum than cigarettes (FDA and public health authorities agree).
- A lawful, FDA-regulated marketplace—supported by timely, science-based premarket review—best serves public health.
- Illicit imports—particularly misdeclared (e.g., smuggled in at the border as "flashlights") Chinese ENDS products—pose a real and serious threat to public health.

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[6] Scott Gottlieb & Mitchell Zeller, *A Nicotine-Focused Framework for Public Health*, 377 New Eng. J. Med. 1111 (2017), available at https://tinyurl.com/msntfeyf (last visited Aug. 26, 2026).

[7] *Id.* at 1113 ("There are already products, such as electronic nicotine delivery systems, that could conceivably deliver nicotine without posing the dangers associated with tobacco combustion."); King, Brian et al., *Commentary on Wackowski et al.: Opportunities and Considerations for Addressing Misperceptions About the Relative Risks of Tobacco Products among Adult Smokers*, Addiction, 118(10):1892 (Oct. 2023), available at https://tinyurl.com/yc6cwa7u (last visited Aug. 26, 2026) ("switching to lower risk alternatives (e.g. e-cigarettes) has been suggested to reduce smoking-attributable risks. The 2018 National Academies of Science, Engineering, and Medicine report concluded there is 'conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.'").

[8] *See* Lindson, Nicole et al., *Electronic cigarettes for smoking cessation*, Cochrane Database of Systematic Reviews (Aug. 2026), available at https://tinyurl.com/4ptnu3wk (last visited Aug. 26, 2026) ("Nicotine [e-cigarettes] result in increased quit rates compared to nicotine replacement therapy…."); *see also* Karin A. Kasza et al., *Association of e-Cigarette Use With Discontinuation of Cigarette Smoking Among Adult Smokers Who Were Initially Never Planning to Quit*, 4 JAMA Network Open 1, 2 (2021) available at https://tinyurl.com/ryjcf37b (last visited Aug. 26, 2026) ("daily e-cigarette use was associated with greater odds of cigarette discontinuation among smokers who initially had no plans to ever quit smoking."); *see also* Katie Myers Smith et al., *E-Cigarettes Versus Nicotine Replacement Treatment as Harm Reduction Interventions for Smokers Who Find Quitting Difficult: Randomized Controlled Trial*, 117 Addiction 224, 226 (2022), available at https://tinyurl.com/evcfs654 (last visited Aug. 26, 2026) ("The primary outcome was reduction in cigarette consumption of at least 50% at 6 months, defined as self-reported reduction of ≥ 50% in the number of cigarettes smoked per day, confirmed by a reduction in end-expired CO levels of ≥ 50% compared to baseline.").

- Interagency enforcement coordination is necessary to tackle the illicit ENDS market, and federal agencies should use the full range of enforcement tools against unregulated actors.
- FDA and the Department of Justice ("DOJ") should act decisively—through robust enforcement (e.g., going beyond Warning Letters or Civil Money Penalties)—to remove illicit products that defy regulation and are marketed to children.
- A comprehensive regulatory framework is needed to provide adult tobacco consumers with access to tobacco and nicotine products that are lower on the risk continuum—like ENDS—while eliminating the sale of unregulated, illicit products.
- The enforcement framework reflected in the May Enforcement Guidance can serve public health objectives if properly implemented.

Reynolds has shared these positions over the past decade in formal comments to FDA when invited through the rulemaking process. For example, through:

- Formal comments to FDA on its proposed Deeming Rule (August 8, 2014), discussing the continuum of risk, the importance of the availability of flavors for adults to switch to potentially lower-risk tobacco products, and youth access prevention;
- Formal comments to FDA on its Draft Concept Paper, "Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard" (July 13, 2018), urging enforcement action against illicit products and youth access prevention;
- Formal comments to FDA on its advance notice of proposed rulemaking relating to FDA's regulation of flavor in tobacco products (July 18, 2018), providing comments on the importance of the availability of flavors for adults to switch to potentially less risky tobacco products, youth access prevention, and increased enforcement action against illicit products;
- Formal comments to FDA on CTP's Strategic Plan (August 29, 2023), urging substantive reform of the premarket tobacco product application ("PMTA") pathway and enhanced enforcement against illicit products;
- Formal comments to the U.S. Trade Representative (March 11, 2025), urging action against illicit Chinese ENDS imports;
- Formal comments to FDA on its Flavored ENDS Draft Guidance (March 2026), providing scientific evidence supporting a regulated flavored ENDS framework.

Each of these filings is a matter of public record.[9] And Reynolds proudly stands by these positions

[9] RAI Servs. Co., Comment on Docket No. USTR-2025-0001, at 1–6 (Mar. 11, 2025); RAI Servs. Co., Comment on Deeming Rule, Docket No. FDA-2014-N-0189, at 2–4; RAI Servs. Co., Comment on Draft Concept Paper, Docket No. FDA-2018-N-0529-0001, at 9–11, 18–20; RAI Servs. Co., Comment on Regulations of Flavors in Tobacco Products, Docket No. FDA-2017-N-6565, at 36–42, 45–48; RAI Servs. Co., Comment on FDA CTP Strategic Plan, Docket No. FDA-2023-N-2873, at 3–5 (Aug. 29, 2023); RAI Servs. Co., Comment on Docket No. FDA-2026-D-1817, Flavored Electronic Nicotine Delivery Systems

through its public statements, including on its website, "Growing A Smokeless America."[10]

In any event, the regulatory framework reflected in the May Enforcement Guidance applies not just to Reynolds—but the entire ENDS category, including Reynolds' competitors. For those manufacturers that are not evading FDA review (like Reynolds), pending applications with FDA remain subject to the same "appropriate for the protection of public health" standard that applies to all applicants. The May Enforcement Guidance does not change that standard, does not exempt products from FDA's scientific review, and does not guarantee marketing authorization. Indeed, Reynolds believes more reform is necessary for additional clarity on FDA's regulatory standards and enforcement actions.

Regulatory Background: The Regulatory Gap: How the Illicit Market Developed

We share the critical goal of removing illicit Chinese vaping products from the U.S. market. As documented below, the current ENDS marketplace reflects a significant gap between the regulatory framework Congress established and the enforcement outcomes FDA has been able to achieve. Independent reviewers, bipartisan members of Congress, and state law enforcement officials have each identified structural factors that contributed to the growth of an illicit market that by some estimates accounts for approximately 80% of U.S. ENDS sales.

The growth of illicit ENDS products reflects both delays in FDA's premarket review process and gaps in enforcement. Congress directed FDA to act on PMTAs "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application."[11] According to publicly available data, FDA has never met this statutory timeline for ENDS or nicotine pouch applications. Congress also directed FDA to enforce a regulated marketplace, yet enforcement actions to date have not prevented illicit ENDS products that evade all FDA review from achieving significant market penetration.

The nonpartisan Congressional Research Service ("CRS"), in its April 2025 report titled "U.S. Food and Drug Administration (FDA) Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Selected Policy Issues,"[12] confirmed that as of the report's publication only 34 ENDS products had been authorized for legal sale in the U.S., while "thousands more may be illegally found in stores and available for purchase." The CRS report identifies multiple structural gaps in FDA's enforcement regime that have collectively allowed the illicit market to grow unchecked: (1) FDA has never finalized regulations requiring foreign facility registration, despite having statutory authority to do so since 2009;[13] and (2) FDA's import alerts are, according to CRS, "easy to circumvent" because manufacturers simply rename their companies or mislabel shipments.

(ENDS) Premarket Applications—Considerations Related to Youth Risk, at 32–37 (May 11, 2026) ("Reynolds May 2026 Comment").

[10] *See* https://tinyurl.com/2s4ytdw8 (last visited Aug. 19, 2026).

[11] 21 U.S.C. § 387j(c)(1)(A).

[12] Cong. Rsch. Serv., R48298, U.S. Food & Drug Administration (FDA) Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Selected Policy Issues 8–12 (2025).

[13] On June 29, 2026, FDA issued a proposed rule titled, "Establishment Registration and Product Listing for Tobacco Products." This proposed rule remains open to public comment.

FDA has publicly emphasized its Warning Letters and Civil Money Penalties as enforcement tools.[14] However, independent observers have questioned whether these mechanisms are calibrated to the scale of the illicit market. A coalition of state attorneys general reported in April 2026 that illicit e-cigarettes "are generating over $11 billion in annual retail sales," account for "more than 80% of all e-cigarette sales nationwide," and "are sold in more than 100,000 retail locations nationwide," while FDA had authorized only 41 ENDS products for the entire country.[15] Importantly, FDA's civil money penalties filed against retailers selling these illicit e-cigarettes are minimal compared to the business generated by the sale of these illicit products.[16] The May Enforcement Guidance itself acknowledges that FDA "lacks the resources to pursue enforcement against every product that has not received authorization."[17]

By any measure, the Agency's enforcement efforts—compared to the scale of the problem—did not keep pace with the growth of the illicit market. As a result, U.S. consumers, public health, and law-abiding industry have been negatively impacted. Reynolds has long advocated to Congress, FDA, and administrations of both parties for robust enforcement against illicit ENDS products and a clear pathway for rule-following applicants to receive prompt FDA authorization of their ENDS.

We also offer the following factual observations relevant to understanding the important accomplishment reflected by the May Enforcement Guidance:

- Combustible cigarette smoking among adult smokers has significantly declined since the late 1960s. Long term, smoking rates have fallen 73% among adults, from 42.6% in 1965 to 11.6% in 2022.[18] This is excellent progress.
- Available estimates indicate that more than 8 million American adult smokers have completely switched from combustible cigarettes to ENDS products, with FDA data suggesting that adults who used ENDS were more likely to quit smoking than those who did not. This is the public health opportunity of offering choices to adult smokers.
- Youth ENDS use has declined substantially from its 2019 peak—according to the National Youth Tobacco Survey ("NYTS"), by more than 70%—and is at its lowest level in a decade. This welcome trend warrants consideration in evaluating predictions about the effects of flavor availability on youth uptake—especially as these trends have continued in a marketplace with widely available illicit flavored ENDS.

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[14] *See* U.S. Food & Drug Admin., Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, available at https://tinyurl.com/2pp6yjb8 (last visited Aug. 26, 2026).

[15] Letter from Brenna Bird, Att'y Gen. of Iowa, et al., to Payment Card Networks 1–2 (Apr. 14, 2026) ("State Attorneys General Letter").

[16] *See, e.g.*, FDA, "FDA Files Another Round of Actions Seeking Fines Against Retailers for Selling Illegal E-Cigarette Products" (December 2023), available at https://tinyurl.com/bdf4npkb (last visited Aug. 26 2026) (stating the FDA filed civil money penalty complaint against 25 retailers for the sale of illegal e-cigarettes and that "the complaints seek **the maximum civil money penalty of $19,192 for a single violation** from each retailer" (emphasis added)).

[17] May Enforcement Guidance, at 4.

[18] Ctrs. for Disease Control & Prevention. Nat'l Ctr. for Health Statistics. Nat'l Health Interview Survey 1965-2022.

- Data from the NYTS document parallel year-over-year declines in both youth ENDS use and youth smoking since 2019: youth ENDS use has fallen approximately 74%—from roughly 20% of high school students at its 2019 peak to 5.2% in 2025—while youth cigarette smoking has fallen approximately 68% over the same period to its lowest level on record. Both declines continued in the most recent survey year, with youth ENDS use declining an additional 12% between 2024 and 2025.[19]
- According to the 2025 NYTS, the daily youth ENDS use rate stands at 1.4%. The survey also reports that 93% of youth did not use any ENDS product in the prior 30 days, and only 1.5% of youth who use ENDS cited flavors as a reason they started.[20] As flavored vapes are widely available through the illicit market, if flavors were driving youth ENDS use, youth ENDS use would not be declining year after year. The overwhelming majority of the low youth use that is occurring, however, is with illicit products.

These data points illustrate that a well-regulated ENDS marketplace, our shared goal, would complement and build on the continued declines in adult smoking, increased adult switching, and continued declines in youth nicotine use—acknowledging that regulatory outcomes often depend on the specifics of implementation and enforcement.

Independent Support for Enforcement Reform

Independent stakeholders have called for changes to FDA's ENDS enforcement approach long before May 2026. Those stakeholders include:

- The Reagan-Udall Foundation's (December 2022) independent expert panel documented systemic failures in FDA's tobacco program;
- Senator Durbin repeatedly criticized FDA and DOJ for allowing thousands of unauthorized e-cigarettes to remain on shelves;
- A bipartisan coalition of 13 state attorneys general (April 2026) investigated and documented the $11 billion illicit market;
- The House Oversight Committee (April 2025) held a hearing on FDA's failure to authorize products or enforce the law;
- FDA's CTP Director testified that the application volume was "overwhelming"; and
- Numerous public health advocates, responsible manufacturers, retailers, and other stakeholders have submitted comments to FDA's public dockets calling for reform.

Reynolds respectfully disagrees with the characterization that the May Enforcement Guidance "greenlight[s] the retail sale of flavored e-cigarettes and vaping devices across the

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[19] *See* Ctrs. for Disease Control & Prevention, Nat'l Youth Tobacco Survey, available at https://tinyurl.com/2s3u9w4u (last visited Aug. 26, 2026); *see also* Eunice Park-Lee et al., *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students—United States, 2024*, 73 Morbidity & Mortality Wkly. Rep. 774 (2024), available at https://tinyurl.com/4cep377r (last visited Aug. 26, 2026).

[20] *See* FDA, Results from the Annual Nat'l Youth Tobacco Survey, available at https://tinyurl.com/p4jurpc8 (last visited Aug. 26, 2026).

country."[21] Rather, as discussed above, the market is already flooded with illicit flavored vapes and youth ENDS use continues to decline year over year. The May Enforcement Guidance, which distinguishes between applicants who have submitted comprehensive scientific data to FDA and entities that have made no attempt to comply with premarket review requirements, simply allows for the marketing of those flavored ENDS that are responsibly made and marketed to adult tobacco consumers. This critical distinction reflects an allocation of FDA's enforcement resources—it does not exempt any product from the statutory "appropriate for the protection of the public health" standard, nor does it guarantee marketing authorization for any applicant.[22]

Reynolds' Compliance Programs

Reynolds maintains compliance processes designed to ensure product quality and regulatory adherence. As required by the Tobacco Control Act, Reynolds submits PMTAs to FDA for review for each ENDS product it markets. Reynolds currently markets ENDS products under the Vuse brand; all Reynolds ENDS products contain nicotine.[23] Reynolds has received marketing granted orders for sixteen products in the Vuse portfolio, including the first ever ENDS marketing granted order issued through the PMTA pathway. A majority of Reynolds' pending ENDS PMTAs fall within the framework described in FDA's May Enforcement Guidance.

Your letter asks what impact Reynolds' products would have on a person who "began to use the product regularly but had never previously smoked cigarettes."[24] Reynolds' mission is to offer products to assist in the transition of adult smokers—who are not interested in or are having difficulty quitting smoking entirely—to noncombusted alternatives. Reynolds is clear that no tobacco or nicotine product is safe. That said, the scientific literature—and FDA's own public statements and product authorization decisions—indicates that ENDS products present substantially lower health risks than combustible cigarettes for individual users. And it is that comparative health benefit for individual smokers that should be measured against a market in which responsibly made and marketed ENDS and nicotine pouches are not readily available for adult tobacco consumers seeking to switch to tobacco or nicotine products that are lower on the continuum of risk.

Regarding flavors other than tobacco and menthol: peer-reviewed research indicates that flavor availability materially increases the likelihood that adult smokers will switch from combustible cigarettes to ENDS.[25] Reynolds believes that a limited set of flavored ENDS—when appropriately named, marketed responsibly, and offered by manufacturers who comply with FDA's premarket review requirements—may help adult smokers transition away from

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[21] Wyden Letter, at 1.
[22] Reynolds May 2026 Comment, at 32–37 (May 11, 2026); *see also* May Enforcement Guidance, at 3–5.
[23] Response Wyden Letter, at 4 (Question 2).
[24] Wyden Letter, at 5.
[25] 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*, 25 Nicotine & Tobacco Rsch. 541, 543, 549 (2023), available at https://tinyurl.com/37p8hjuv (last visited Aug. 26, 2026) ("those who use e-cigarettes more intensely (at least 20 of the past 30 days) and those who use flavored e-cigarettes have both a higher odds of making a quit attempt and of succeeding in quitting cigarette smoking.").

combustible cigarettes while reducing demand for illicit products.[26] This position aligns with FDA's recognition that noncombusted products may enable complete switching or significant reduction in combusted cigarette use.[27] Reynolds acknowledges that the ultimate public health impact depends on how such a framework is implemented and enforced.

Youth Access Prevention

Reynolds maintains programs designed and intended to prevent underage access to its products. These include retailer age-verification requirements, participation in We Card, sponsorship of TruAge®, monitoring of FDA compliance-check data, and restrictions on digital access and marketing.

Reynolds' marketing communications must comply with the Reynolds Marketing Guidelines.[28] These include, among other things, all communications must be truthful and non-misleading, Reynolds makes no health or modified risk claims unless and until specifically authorized by FDA, and Reynolds does not market "up the risk continuum." Reynolds also restricts advertising to measured media whose audience is verified by independent third parties (such as Nielsen and comScore) to be at least 85% age 21 or older, prohibits the use of celebrities or others judged to have special appeal to youth, and bars content depicting underage activities or suggesting that Reynolds' products are essential to social prominence, success, or sexual attraction. Reynolds prohibits the use of social media influencers for marketing.

Reynolds is also implementing a retail compliance program applicable to flavored ENDS products in its portfolio. The program includes: (1) requiring scanning of a valid government-issued ID for every purchase of such products; (2) capping sales to four pod packs per adult consumer per day; (3) requiring display of "Responsible Retailer" decals at participating retail outlets; and (4) establishing enhanced consequences for retailers with documented underage sale violations as reported by FDA.

Your letter asks about the "expected lifetime value (in earned revenue) of a new customer who has never smoked but who begins using vaping products at age 21."[29] The premise of this question is inconsistent with Reynolds' mission. And Reynolds does not maintain financial projections or customer lifetime value calculations premised on acquiring never-smoker customers.

The Regulatory Record

Regulatory actions and policies, like the May Enforcement Guidance, are developed through FDA's established processes, informed by years of public comment, stakeholder input, rigorous scientific review, and the extensive regulatory record described above. FDA's decision-making authority under the TCA resides with the Agency; Reynolds did not—and could not—direct FDA to adopt any particular policy.

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[26] Reynolds May 2026 Comment, at 1–2, 15–16, 24–25.
[27] *See* U.S. Food & Drug Admin., The Relative Risks of Tobacco Products, https://tinyurl.com/3vwymf5j.
[28] *See* https://tinyurl.com/23mw54m8 (last visited Aug. 26, 2026).
[29] Wyden Letter, at 5.

The regulatory record supports the independence of FDA's action. The May Enforcement Guidance was the outcome of years of public comment, stakeholder engagement, and documented enforcement challenges. And the regulatory record, as detailed in Appendix A, demonstrates the longstanding foundation for this guidance. The Reagan-Udall Foundation, bipartisan Congressional committees, state attorneys general, and FDA's own personnel had each called for enforcement reform of the type reflected in the May Enforcement Guidance.

And the regulatory framework reflected in the May Enforcement Guidance is not unique to Reynolds. It applies to the entire ENDS category—including Reynolds' competitors—and its primary enforcement targets are illicit products that evade FDA review. Reynolds' pending applications remain subject to the same statutory standard ("appropriate for the protection of the public health") that applies to every other applicant. The May Guidance does not alter that standard, does not guarantee marketing authorization for any applicant, and does not exempt any product from FDA's scientific review. To the extent the Guidance allows FDA to prioritize enforcement resources, it does so by distinguishing applicants who have submitted scientific data from those who have not—a distinction that benefits public health by focusing enforcement on the highest-risk products. And, importantly, Reynolds believes more reform is likely necessary to provide clarity on FDA's regulatory standards relating to its premarket review of ENDS and nicotine pouches and allow for FDA to prioritize its enforcement actions.

Contrary to your inaccurate allegations of improper activity, Reynolds engages with regulators, policymakers, and elected officials at both federal and state levels in compliance with all applicable law. Such regular engagement pertains to various matters affecting the tobacco industry—including the need for robust enforcement against illicit ENDS products. Reynolds' views are consistent with the positions the company has stated publicly for years, including in formal comments to the FDA and the U.S. Trade Representative, and in other submissions to Congress. Our practice of communicating with regulators, policymakers, and elected officials is lawful and consistent with the practice of regulated entities. Reynolds makes all required federal and state lobbying and campaign finance disclosures. Reynolds categorically rejects any allegation to the contrary.

Conclusion

Reynolds agrees that youth should not use tobacco or nicotine products and that FDA and DOJ should take effective action against illicit ENDS products that evade FDA review. In Reynolds' view, the most effective approach combines vigorous enforcement against illicit products with a regulatory pathway that allows FDA-reviewed ENDS products to compete in a lawful marketplace.[30] Reynolds supports bipartisan legislative efforts to strengthen enforcement against illegal tobacco or nicotine products and stands ready to work with Congress, FDA, state attorneys general, and other stakeholders to reduce youth access, restore regulatory order to the ENDS market, and advance the public health objective of transitioning adult smokers away from combustible cigarettes.

[30] May Enforcement Guidance, at 3–5; Reynolds May 2026 Comment, at 32–37.

We appreciate the opportunity to respond to your letter, and we hope this information is helpful to the Committee's understanding of these issues.

APPENDIX A

Regulatory Timeline:
From the Tobacco Control Act to the May Guidance

It is important to understand that the May Enforcement Guidance is a step toward reforming the regulatory process that has been documented over nearly two decades—from the enactment of the Tobacco Control Act in 2009 through successive missed deadlines, structural enforcement gaps, and resource constraints that independent reviewers, bipartisan members of Congress, and state attorneys general have each identified. The following chronology, drawn from public records and independent analyses, provides context for understanding the May Guidance.

2009: The Tobacco Control Act Creates a Premarket Framework. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("TCA"), giving FDA authority to regulate the manufacture, distribution, and marketing of tobacco products and establishing the Center for Tobacco Products ("CTP") to implement the law. The TCA required premarket authorization for any "new tobacco product" not commercially marketed as of February 15, 2007, and directed FDA to act on premarket tobacco product applications "[a]s promptly as possible, but in no event later than 180 days."[31] The TCA thus established a pre-market authorization framework.

2009–2016: Seven Years Without ENDS Regulation. Although e-cigarettes began entering the U.S. market shortly after the TCA's enactment, FDA did not extend its regulatory authority to cover ENDS products until 2016. According to the CRS report, the TCA "grants FDA broad authority to regulate any other product" meeting the statutory definition of a tobacco product—yet it took the Agency seven years to exercise that authority over ENDS. During that period, the ENDS market grew entirely outside the premarket authorization framework Congress had established—with no application requirements, no manufacturing standards, and no enforcement infrastructure. This delay allowed a massive unregulated market to develop before FDA asserted jurisdiction.

May 2016: The Deeming Rule—Too Late, Too Broad. FDA's "deeming" regulation finally extended premarket authorization requirements to ENDS products and other previously unregulated categories. And while the rule allowed tobacco products—including lower risk tobacco products—that had been on the market as of August 8, 2016, to remain on the market without immediate FDA premarket authorization, the rule came seven years after the TCA's enactment, by which time thousands of ENDS products were already on the market. The deeming rule included staggered compliance dates for premarket review requirements, but FDA was unable to issue PMTA regulations describing submission requirements before those deadlines.[32] The result, as the Reagan-Udall Foundation later concluded, was "an inefficient review process where CTP has been largely

[31] 21 U.S.C. § 387j(c)(1)(A).

[32] The Final PMTA Rule was not published until October 5, 2021. Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55300 (Oct. 5, 2021).

reactive, responding to a deluge of applications, rather than proactive and directing the content, and flow, of submissions."[33]

2017–2018: The Rise of JUUL and the Youth Vaping Spike. Because of numerous safeguards implemented by Reynolds to ensure its VUSE products are marketed for adult tobacco consumers that are age 21 and older, during the period 2015-2017 when VUSE was the leading ENDS brand sold in the United States, reported underage use of e-cigarettes declined. However, between 2017 and 2018, JUUL's rapid market growth corresponded with a sharp increase in youth e-cigarette use. In 2017, FDA announced a comprehensive regulatory plan placing nicotine and addiction at the center of its tobacco regulation efforts, but the Agency subsequently stated that the dramatic increase in youth e-cigarette use caused it to "reevaluate certain parts of the plan." By 2018, then-FDA Commissioner Gottlieb publicly declared youth vaping an "epidemic"—yet the Agency's response focused on public statements and enforcement against cartridge-based flavored products rather than the structural PMTA reforms needed to establish a lawful, regulated marketplace. Critically, FDA never established clear PMTA review standards during this period, leaving both applicants and its own reviewers without a predictable framework.

September 2019: Presidential Declaration. President Trump, along with various members of his administration including Alex Azar, announced that his administration would propose banning thousands of flavors used in e-cigarettes and FDA would develop guidelines to remove all e-cigarette flavors other than tobacco (and later all flavors other than tobacco and menthol).

January 2020: The Disposables Loophole. FDA's January 2020 enforcement guidance (revised April 2020), with which responsible manufacturers quickly complied and removed flavored products from the market, prioritized enforcement against flavored "cartridge-based" ENDS but, according to the CRS report, expressly excluded "completely self-contained, disposable" products from that definition—creating what the CRS report describes as a widely identified "loophole" for disposable ENDS. This gap opened the floodgates to cheap Chinese imports. The CRS report documents that "the majority of these illicit products are disposable ENDS, many of which are flavored, manufactured in" China. The report further confirms that in October 2022, China banned the domestic sale of all non-tobacco-flavored e-cigarettes while continuing to permit their export to the United States—a deliberate unfair trade practice that the CRS report specifically identifies as a policy concern for Congress. Your letter states that "[i]n February 2020, the FDA had finally taken [James Johnston's] advice" and that "[f]lavored vapes were indeed banned for retail sales."[34] However, and importantly, FDA's January 2020 enforcement guidance prioritized enforcement against flavored cartridge-based ENDS but expressly excluded "completely self-contained, disposable products" from that enforcement priority.[35] This distinction—sometimes referred to as the "disposables loophole"—is relevant to understanding the subsequent growth of disposable ENDS imports. The May Enforcement

[33] Reagan-Udall Found. for the FDA, Operational Evaluation of Certain Components of FDA's Tobacco Program, at 19 (2022) ("Reagan-Udall Report").
[34] Wyden Letter, at 2.
[35] Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry (Jan. 2020).

Guidance addressed this gap; it did not overturn a blanket flavor ban, because no such ban existed.

September 2020: A Court-Imposed Deadline Results in Application Volume. A court-imposed PMTA application deadline resulted in more than eight million applications.[36] According to the CRS report, FDA's Acting Commissioner testified in June 2021 that the Agency had "completed initial processing of premarket tobacco product applications (PMTAs) for more than 6.5 million products submitted by over 550 companies." FDA's CTP Director later testified that the application volume was "overwhelming."

2020–2022: Limited Authorization Activity. FDA acted on ENDS applications at a slow pace relative to application volume. According to the CRS report, FDA denied more than 99% of the millions of ENDS applications it received.[37] The CRS report documents the following authorization timeline: by October 2021, FDA had authorized just three Reynolds tobacco-flavored ENDS products—the first ENDS ever granted marketing authorization under the PMTA pathway; the total grew to only 23 tobacco-flavored products by mid-2022; and by July 2024, the total had reached just 34 authorized ENDS products for the entire country. The CRS report further documents that FDA has had statutory authority under FD&C Act Section 905(h) since 2009 to require foreign facility registration—which would facilitate detection of illicit imports at the border—but has never finalized such a regulation.[38] Reynolds' own application for a tobacco-flavored Vuse Alto product took nearly four years for FDA to decide—significantly longer than the statutory 180-day limit.

December 2022: The Reagan-Udall Foundation Report. The independent Reagan-Udall Foundation—commissioned by FDA Commissioner Califf—published an operational evaluation of FDA's tobacco program.[39] The report found:

- "[T]he current environment reflects an unintended shift from what was structured by law as a pre-market authorization framework to the reality of a post-market regulatory environment."
- "Millions of products have entered the market without pre-market authorization and remain on the market today."
- FDA demonstrated a "lack of transparency and timeliness in authorizing e-cigarettes."
- "Failure to take timely enforcement action jeopardizes public health and undermines FDA's credibility."

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[36] *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019); *see also Vapor Tech. Ass'n v. FDA*, 977 F.3d 496, 497–502 (6th Cir. 2020) (summarizing shifting deadlines).

[37] Cong. Rsch. Serv., R48298, U.S. Food & Drug Administration (FDA) Regulation of Electronic Nicotine Delivery Systems (ENDS): Background and Selected Policy Issues, at 1-6 (2025).

[38] On June 29, 2026, FDA issued a proposed rule titled, "Establishment Registration and Product Listing for Tobacco Products." This proposed rule remains open to public comment.

[39] Reagan-Udall Report, at 3, 22.

- "The Agency has not been transparent regarding the reasons it has failed to clear the market of illegal products, or even whether its policy preference is to do so."

The Foundation recommended that CTP develop a "clear and predictable framework" for PMTA reviews[40]—a recommendation that aligns with objectives reflected in the May Enforcement Guidance.

2023: A Strategic Plan Without Substantive Reform. In 2023, FDA issued a five-year strategic plan that contained "generalities with no substantive changes to the PMTA pathway."[41] The plan did not address the mismatch between FDA's enforcement capacity and the scale of the illicit market.

2024: The Illicit Market Continues to Grow. By 2024, a coalition of state attorneys general reported that illicit ENDS products generate over $11 billion in annual retail sales and are sold in more than 100,000 retail locations nationwide.[42] FDA had authorized only 41 ENDS products for legal sale in the entire U.S.[43] The average PMTA processing time had grown to approximately three years—against a statutory requirement of 180 days.

April 2025: Congressional Hearings on FDA Enforcement. The House Oversight Committee held hearings titled "Restoring Trust in FDA: Rooting Out Illicit Products."[44] Witnesses testified that FDA had authorized just 34 ENDS products total (only 8 devices); that 90% of ENDS products were being sold without authorization and that CTP had collected $3.5 billion in user fees while the market remained largely unregulated.[45]

April 2026: State Attorneys General Sound the Alarm. On April 14, 2026, a bipartisan coalition of 13 state attorneys general wrote to payment card networks detailing the explosion of illicit Chinese ENDS products, including connections to transnational criminal networks, Chinese money laundering operations, and Mexican drug cartels.[46] The attorneys general documented that illicit products account for more than 80% of all ENDS sales, generate over $11 billion in annual retail sales, and are sold in more than 100,000 retail locations—and that FDA had authorized only 41 ENDS products for the entire country.

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[40] Reagan-Udall Report, at 3, 22.
[41] *See* RAI Servs. Co., Comment on FDA CTP Strategic Plan, Docket No. FDA-2023-N-2873, at 3–5 (Aug. 29, 2023).
[42] State Attorneys General Letter, at 1–2.
[43] State Attorneys General Letter, at 1–2
[44] Restoring Trust in FDA: Rooting Out Illicit Products: Hearing Before the H. Comm. on Oversight & Gov't Reform, 119th Cong. (2025).
[45] Restoring Trust in FDA: Rooting Out Illicit Products: Hearing Before the H. Comm. on Oversight & Gov't Reform, 119th Cong. (2025) (testimony noting FDA had authorized just 34 vaping products total, only 8 devices, and that 90% of e-cigarettes were being sold without authorization).
[46] State Attorneys General Letter, at 1–3, app. A-1.