September 25, 2025

The Honorable Martin Makary, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993-0002

Re: Marketing of unauthorized new tobacco products by Reynolds and Altria

Dear Dr. Makary:

Under the Family Smoking Prevention and Tobacco Control Act, no new tobacco product is permitted to be introduced into commerce without first undergoing a thorough scientific evaluation and issuance of a marketing granted order (MGO) from the U.S. Food and Drug Administration (FDA). We write to express our deep concern that major tobacco companies – specifically R.J. Reynolds Vapor Co. (Reynolds) and Altria subsidiary Helix (Altria) – are overtly stating their intent to openly defy the statutory requirement that they receive an MGO *before* they introduce a new tobacco product into commerce. We appreciate FDA'S recent enforcement efforts directed at the marketing of unauthorized products.[1] Consistent with those efforts, we urge the agency, with the necessary involvement of the U.S. Department of Justice, to take immediate and appropriate action to prevent Reynolds and Altria from their planned and intentional violation of the law.

According to press reports, Reynolds is planning to launch Vuse One, a new disposable synthetic nicotine e-cigarette product, during the fourth quarter of the year, in Florida, Georgia, and South Carolina.[2] The latest national data indicate that disposable e-cigarettes have become the most popular e-cigarettes among U.S. youth by a large margin.[3] In addition, Vuse One will be sold in multiple flavors appealing to young people, including fruit flavors such as Raspberry Chill, Watermelon Chill, and Berry-Melon.[4] The Youth Vaping Resource Guide, recently

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[1] See, e.g. "HHS, CBP Seize $86.5 Million Worth of Illegal E-Cigarettes in Largest-Ever Operation," FDA News Release (September 10, 2025). https://www.fda.gov/news-events/press-announcements/hhs-cbp-seize-865-million-worth-illegal-e-cigarettes-largest-ever-operation

[2] R. Craver, "Reynolds plans big debut splash in controversial disposable vaping market," Winston-Salem Journal, August 29, 2025. https://journalnow.com/news/local/business/article_d13c5ce4-9800-4518-bb8c-33c4da2cd679.html. *See also*, E. Romney, "Battling unregulated vapes, Big Tobacco tries a new strategy: joining in," https://www.reuters.com/world/europe/battling-unregulated-vapes-big-tobacco-tries-new-strategy-joining-2025-08-21/

[3] Park-Lee E, Jamal A, Cowan H, et al. Notes from the Field: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:774–778. DOI: http://dx.doi.org/10.15585/mmwr.mm7335a3.

[4] Craver, note 1 *supra*, at 1.

released by the Office of the Surgeon General, highlights the role of disposable e-cigarettes and flavored products in driving youth use and addiction.[5] Reynolds has made it clear that, although a premarket application for Vuse One has been filed, the company intends to begin sales of the product *even though no MGO has been issued by FDA.*[6]

Reynolds is well aware that introduction of Vuse One without a marketing order will violate the premarket review provisions of the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA). Indeed, in 2023, an affiliate of Reynolds Vapor (RAI Services Co.) submitted a Citizen Petition calling on FDA to prioritize enforcement against "[a]ny disposable ENDS containing nicotine derived from any source other than tobacco that lacks premarket authorization."[7] That, of course, accurately describes the current status of Vuse One. The Reynolds Citizen Petition pointed out that Congress, in 2022, extended the regulatory authority of FDA to include products "containing nicotine from any source," meaning that "[a]fter July 13, 2022, the manufacturer of a non-tobacco nicotine product was required to have a marketing granted order in order to sell or distribute that product."[8] Reynolds acknowledges now that it has no such order for Vuse One. It is also well aware of the requirements and process necessary to secure premarket authorization given that it has previously received authorization for several tobacco-flavored Vuse e-cigarette products.[9]

The fact that there is a pending premarket application for Vuse One in no way alters the illegality of the product should it be marketed by Reynolds. FDA has repeatedly and prominently stated that "[h]aving a pending application does not create a legal safe harbor to sell a product."[10] Moreover, the fact that the Vuse One application may have been pending more than the statutory review period of 180 days is immaterial to the legality of the product. The TCA unequivocally requires an MGO before a new product can be legally marketed and nothing in the statute remotely suggests that surpassing the 180-day period confers a right to market a product without the issuance of a MGO.[11] Moreover, that there are many other competing products being marketed without MGOs is equally immaterial to the legal status of Vuse One. If products can avoid enforcement simply because there are other illegal products on the market, then the entire system of premarket review intended by Congress under the TCA will collapse.[12]

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[5] "Sound the Alarm: Youth Vaping Can Harm," U.S. Department of Health and Human Services, Office of the Surgeon General, September 8, 2025. https://www.hhs.gov/sites/default/files/osg-youth-vaping-data-sheet.pdf

[6] *Id.*

[7] RAI Services Co., Citizen Petition, February 6, 2023. https://www.regulations.gov/document/FDA-2023-P-0430-0001, at 2.

[8] *Id.* at 5.

[9] https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JAN2025.pdf

[10] Craver, note 1 *supra*, at 3. *See also* FDA "Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products," https://www.regulations.gov/document/FDA-2023-P-0430-0001 ("For the vast majority of unauthorized e-cigarettes on the market today, the pendency of an application does not create a legal safe harbor to sell that product.")

[11] *See generally*, 21 U.SC. 387j(a) and (c)

[12] Reynolds also has been selling new Velo Plus synthetic nicotine pouches in certain U.S. markets since late 2024, again without a MGO. Craver, *supra* note 1, at 2. *See also* https://tobaccoinsider.com/velo-plus-usa/ (describing flavors of Velo Plus). A Reynolds spokesperson was quoted as claiming that because FDA was exercising "enforcement discretion" for products with pending applications, "they could be marketed legally." *Id.* This is directly contrary to FDA's repeated statements that the pendency of an application creates no legal "safe harbor".

Altria subsidiary Helix has similarly announced the planned launch of its on!PLUS nicotine pouches in North Carolina, Texas, and Florida this fall.[13] Like Reynolds' Vuse One e-cigarettes, these Altria nicotine pouch products are the subject of pending premarket applications (apparently filed in June 2024),[14] *but do not have MGOs*. Altria notes that its premarket application has been pending more than 180 days, that FDA has not taken enforcement actions against products with applications pending more than 180 days, and asserts that "Helix is satisfying all requirements under the Tobacco Control Act . . . ."[15] Altria's plan to launch new nicotine pouch products will make this statement of legal compliance flatly untrue; the company intends to sell these products without satisfying the core premarket requirement of an MGO and the illegality of its intended conduct is unaffected by the length of time its application has been pending or whether other products with pending applications have been the subject of enforcement actions.

Like Reynolds, Altria is well aware that the marketing of its products without MGOs will violate the TCA. In an April 5, 2024 letter to the CTP Director, Altria noted that the growing problem of "unlawful and unregulated e-vapor products" is "now spreading to new product forms such as illicit nicotine pouches," as it also acknowledged that "[s]ince 2016, it has been plainly illegal to introduce a new tobacco product without prior authorization."[16] Indeed, as late as February of this year, Altria recognized the requirement of prior authorization and stated its intent to follow the law. In its Q4 and Full Year 2024 earnings call in February 2025, Altria's CEO stated, "We look forward to bringing on!PLUS to the US *once authorized*."[17] It is also well aware of the requirements and process necessary to secure premarket authorization given that it has previously received authorization for several tobacco-and menthol-flavored NJOY e-cigarettes.[18] However, Altria now plans to introduce its new nicotine pouch products without prior authorization, thus hypocritically engaging in the same conduct that it decried a year ago.

It is undeniable that Reynolds and Altria are planning to act in brazen defiance of the premarket provisions of the TCA, in the hope that FDA will allow them to get away with it in the name of "enforcement discretion." In both cases, this is a direct and very public challenge to FDA's enforcement authority. FDA must respond in the strongest possible terms by making it clear that the marketing of these and other new tobacco products without MGOs violates the law, regardless of whether those products are the subject of pending premarket applications, regardless of the amount of time the applications have been pending, and regardless of whether other unauthorized products remain on the market. It also is imperative that FDA, with the necessary involvement of the U.S. Department of Justice, commence appropriate enforcement

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[13] Altria [@AltriaNews]. (2025, August 21). *Helix is excited to announce the launch of on! PLUS™ Nicotine Pouches - available this fall in North Carolina, Texas, and Florida* [Post]. X. Retrieved from https://x.com/AltriaNews/status/1958639851235917956.

[14] *Id*.

[15] Altria, "Helix Adds on! Plus to on! Portfolio," August 2025, https://edge.sitecorecloud.io/altriaclien9c5f-altriaclien2f33-prod0b41-3d12/media/Project/Altria/Altria/moving-beyond-smoking/smoke-free-product-platforms/on-plus-one-pager.pdf?sc_lang=en

[16] Letter from Paige C. Magness to Dr. Brian King, April 5, 2024, at 1,2. https://edge.sitecorecloud.io/altriaclien9c5f-altriaclien2f33-prod0b41-3d12/media/Project/Altria/Altria/about-altria/federal-regulation-of-tobacco/regulatory-filings/documents/ALCS-Letter-to-CTP-040524.pdf?sc_lang=en

[17] https://seekingalpha.com/article/4753508-altria-group-mo-q4-2024-earnings-call-transcript (emphasis added).

[18] https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JAN2025.pdf

action to prevent the launch of these products without MGOs. The integrity of the statutory premarket review system is at stake.

On April 17, 2025, we wrote to you requesting an in-person meeting to discuss the importance of curbing the illicit e-cigarette market and other topics critical to FDA's mission to protect the public, and particularly our youth, from the hazards of tobacco products. The open defiance of FDA's regulatory authority by the two largest U.S. manufacturers of tobacco products underscores the importance of our requested meeting. We look forward to your response. Please have your staff direct your response to Dennis Henigan of the Campaign for Tobacco-Free Kids, dhenigan@tobaccofreekids.org.

Thank you for your consideration of our views and this request.

Respectfully,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

CC: Dr. Bret Koplow, Acting Director, Center for Tobacco Products