October 16, 2025

Dr. Bret Koplow
Acting Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: Pilot program re premarket review of nicotine pouch products – request for public meeting and public science policy memoranda and reviewer guides

Dear Dr. Koplow:

We write concerning FDA's recent announcement that it has launched a "pilot program" to "increase efficiency and streamline the review process for premarket tobacco product applications (PMTAs) for nicotine pouch products."[1]

We appreciate efforts to identify efficiencies in the review process to help reach the 180 day review deadline established by Congress. However, because so little information has been made available on this pilot program, it is difficult to determine whether the program is consistent with the premarket review provisions of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA). Importantly we, as public health organizations, want to ensure that the pilot program maintains the kind of rigorous scientific review necessary to protect the public health from the risks of new tobacco products, including oral nicotine pouches. We therefore urge the agency to be far more transparent about how the pilot program is operating and how it differs from the premarket review process it has been adhering to until now. We recommend that FDA convene a public meeting to discuss the pilot program and that it produce, and make public, science policy memoranda and reviewer policy guides to clarify the scientific and regulatory requirements for nicotine pouch products to meet the statutory standards through the pilot program's expedited review pathway.

As you are aware, no new tobacco product can be introduced into commerce in the United States without an order from FDA finding that its manufacturer has met its burden of demonstrating that the product is "appropriate for the protection of the public health," requiring an assessment of the "risk and benefits to the population as a whole," taking into account the

[1] "FDA Launches Program to More Efficiently Review Nicotine Pouch Applications," Sept. 18, 2025 (nicotine pouch announcement). https://www.fda.gov/tobacco-products/ctp-newsroom/fda-launches-program-more-efficiently-review-nicotine-pouch-applications#:~:text=FDA%20Launches%20Program%20to%20More%20Efficiently%20Review%20Nicotine%20Pouch%20Applications,-CTP%20Newsroom&text=This%20month%2C%20FDA%20launched%20a,PMTAs)%20for%20nicotine%20pouch%20products.

impact of the product on tobacco initiation and cessation on a population-wide basis.[2] The TCA also requires all PMTAs to include several categories of specific information about the product.[3]

FDA's announcement that it has begun a pilot program to "streamline" premarket review of nicotine pouch products raises serious concerns about whether the program is being implemented in a manner consistent with the TCA and with the rigorous scientific standards FDA has applied to PMTAs to date. For example, a press report, citing a transcript of an internal FDA meeting, suggests that manufacturers may not be required to submit product-specfic studies – such as evidence of a particular product's "effectiveness in helping smokers cut back," -- but could instead rely on "general research" about the category of nicotine pouches.[4] While we recognize that internal meetings do not establish enforceable policy, this report appears to be consistent with FDA's own characterization of the pilot program, which rests on the agency's finding that "[t]here is evidence that nicotine pouches can help some adults switch away from more harmful tobacco products . . . ;"[5] a finding that may conflict with the existing peer-reviewed scientific literature, which suggests more uncertainty.[6] However, giving a category of new tobacco products an easier path to authorization based on an agency conclusion about the relative risks of the products has been found inconsistent with the TCA.[7] The burden is on the applicant to demonstrate that its specific products are "appropriate for the protection of the public health" and that burden should not be affected by FDA's conclusions about the general category of products, reached prior to PMTA review. Hence, if the public reporting is accurate, we are concerned that this pilot program and any lessening of the scientific review process would appear to be a sharp departure from the agency's previous rigorous, product-specific evaluation of e-cigarettes, nicotine pouches,[8] and other new products, and would raise serious questions about whether the pilot is consistent with the TCA, which plainly requires a product-specific showing that the public health standard has been met.

We ask that FDA convene a public meeting to make clear that the pilot program will maintain rigorous scientific review while striving to complete reviews within the 180 days required by statute. Such a meeting – similar to the meeting the agency convened in the Fall of

---

[2] 21 U.S.C. §§ 387j(a) and (c); *See also*, *Food and Drug Administration v. Wages and White Lion Investments, L.L.C., dba Triton Distribution, et al.,* 604 U.S. 542, 552 (2025).

[3] 21 U.S.C. § 387j(b)(1).

[4] P. Wingrove and E. Rumney, "FDA nicotine pouch pilot to ease manufacturers' research burden, transcript shows," Reuters, Sept. 21, 2025, https://www.reuters.com/sustainability/boards-policy-regulation/fda-nicotine-pouch-pilot-ease-manufacturers-research-burden-transcript-shows-2025-09-19/

[5] Nicotine pouch announcement, at 1. It is important that FDA publicly share evidence that it used in determining that nicotine pouches can help some adults switch from more harmful products.

[6] Felicione NJ, Ozga JE, Eversole A, Hart JL, Tackett A, Hrywna M, Halquist M, Stanton CA. Oral Nicotine Pouches: Rising Popularity and State of the Science. Public Health Rep. 2025 Apr 28:333549251313668. doi: 10.1177/00333549251313668. Epub ahead of print. PMID: 40293136; PMCID: PMC12037535.

[7] *Nicopure Labs, LLC v. FDA,* 944 F.3d 267, 281 (D.C. Cir. 2019) ("In requesting an easier path, the industry impermissibly assumes the very public health conclusion that premarket authorization requires be substantiated before a product may be sold: that e-cigarettes are no more risky to the population as a whole than preexisting tobacco products, balancing the prospect that they may lead existing users to less harmful products or usage patterns against the risks that existing tobacco users will postpone reductions or intensify their usage and non-users will start.")

[8] For example, in finding that 20 Zyn nicotine pouch products met the public health standard in the TCA, FDA engaged in what it termed an "extensive scientific review" of those specific products. See FDA News Release, "FDA Authorizes Marketing of 20 ZYN Nicotine Pouch Products after Extensive Scientific Review," January 16, 2025, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-20-zyn-nicotine-pouch-products-after-extensive-scientific-review. *See also*, Technical Project Lead Review of PMTAs, Swedish Match USA, Inc., January 16, 2025. https://www.accessdata.fda.gov/static/searchtobacco/ZYN/PMTA_TPL_PM593-PM612_Zyn_01_13_2025_Redacted.pdf

2023 to discuss improving public understanding and assisting persons considering submitting applications[9] – will allow industry, public health and other stakeholders to ask questions that may result in improved understanding of the pilot program and its implications. We also urge FDA to issue a science policy memorandum outlining the pilot program, including when and how the agency will engage with applicants, the triggers for initiating those interactions and the criteria for participation in the pilot. FDA committed to posting these memos in response to the 2022 Reagan-Udall Foundation's operational evaluation of the Center for Tobacco Products and we urge FDA to do this for the pilot program. Releasing reviewer guides also would create additional clarity and transparency.

Additionally, the FDA announcement promises greater communication "between FDA and applicants," but says nothing about facilitating such communication between FDA and other stakeholders or the public.[10] The need for greater transparency about the pilot program is underscored by the growing significance of nicotine pouches in the marketplace. From January 2023 to April 2025, the last date for which data is available, nicotine pouch sales in the U.S. increased an astonishing 207%, from $145.5 million to $446.8 million.[11] Of particular concern, nicotine pouch use among youth more than doubled between 2021 and 2024 and pouches were the only category of tobacco product to have increased in youth usage during 2022-2024.[12] According to the most recent data, more than 480,000 youth reported using nicotine pouches in the previous 30 days, making them the second most-used tobacco product among youth, exceeded only by e-cigarettes.[13] Nicotine pouches share multiple characteristics with e-cigarettes that have been shown to lead to significant youth usage, including high concentrations of nicotine, youth-appealing flavors, easy concealability and a significant presence on social media.[14]

In conclusion, FDA's pilot program announcement promises improved "regulatory efficiency while upholding the agency's rigorous scientific standards for tobacco product review." We ask that FDA be sufficiently transparent about the pilot program to allow the public to determine whether those "rigorous scientific standards" are being met for nicotine pouch products. Convening a public meeting, and developing and releasing the scientific policy

---

[9] FDA, Premarket Applications: Opportunities for Stakeholder Engagement – A Public Meeting, Oct. 23-24, 2023, https://www.fda.gov/tobacco-products/ctp-newsroom/premarket-applications-opportunities-stakeholder-engagement-public-meeting-10232023

[10] In prior communications with FDA, we have urged FDA to make more significant disclosures about PMTAs to allow meaningful public input into the PMTA process, comparable to that available through the modified risk application process. *See e.g.* AAP et. al, "Principles to Guide FDA Premarket Review of E-Cigarettes and Other Deemed Products, at 1-2 (August 10, 2020). https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/regulatory/2020_08_10_Premarket-Principles.pdf

[11] CDC Found., *Nicotine Pouch Data Brief* (Apr. 20, 2025), https://tobaccomonitoring.org/wp-content/uploads/2025/07/Nicotine-Pouch-Brief-4.20.2025.pdf.

[12] E. Lee, et al., E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024, *Morbidity and Mortality Wkly. Rep.* 774 (Sept. 5, 2024) (Lee), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf; A.S. Gentzke, et al., Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021, *Morbidity and Mortality Wkly. Rep. Surveill. Summ.* 71 (March 11, 2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf.

[13] Lee, *supra* note 10.

[14] *See generally*, Letter to Dr. Brian King from AAP et al. on PMTAs for Nicotine Pouch Products (April 23, 2024), https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2024_04_23_nicotine-pouch-letter-to-FDA.pdf?_gl=1*17s3mtq*_gcl_aw*R0NMLjE3NTg3MzQ4OTkuRUFJYUlRb2JDaE1JOWZDUGhQYnhqd01WbmsxSEFSMEd0QUVnRUFBWUFTQUFFZ0k5WWZEX0J3RQ..*_gcl_au*MTI4MjY3MDA1OC4xNzU4NzI0Njcz

memoranda and reviewer guides, will explain how the pilot program is operating and, most importantly, how it differs from previous premarket review of new tobacco products, including identifying studies and other information applicants are no longer being required to submit.

Thank you for your consideration of our views and our request for a public meeting. Given that the program appears already to be underway, we hope that you will respond to this request with some urgency.

Respectfully submitted,

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. Martin Makary, Commissioner, U.S. Food and Drug Administration