



**NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE**

Alister F. Martin, MD, MPP
Commissioner

May 11, 2026

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Gotham Center
42-09 28th St.
Long Island City, NY 11101

Via Electronic Submission

<http://www.regulations.gov>

Re: Food and Drug Administration Docket No. FDA-2026-D-1817-0002 for Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk - Draft Guidance for Industry

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (Health Department or NYC Health Department) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) regarding considerations related to youth risk in flavored electronic nicotine delivery systems premarket applications.

Overall, while we appreciate the intention of the guidance, as described in more detail below, it does not sufficiently acknowledge the availability of products lacking marketing authorization and fails adequately to account for youth behavior.

I. Most of the flavored ENDS that youth are currently using lack FDA marketing authorization and thus are not currently legal for sale in the United States.

The FDA has made it clear that ENDS lacking marketing authorization should not be available. Yet, the market continues to be flooded with disposable ENDS in a wide range of flavors, all lacking marketing authorization¹, demonstrating that many companies are not interested in adhering to laws or guidance. To adequately address this problem, additional enforcement resources are needed.

II. Youth will use what is available, even if it is not their preferred flavor.

The current guidance does not acknowledge how availability can affect youth use patterns and appeal. When the FDA prohibited flavors other than menthol and tobacco in pod-based ENDS, both the number and proportion of New York City youth using mint- or menthol-flavored products doubled, rising from 19,000 (24%) in 2016 to 39,000 (56%) in 2020.² Although menthol



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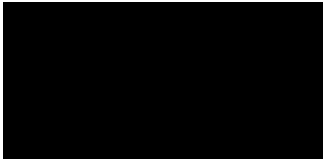
has limited youth appeal per national data,³ if marketing authorization is enforced effectively (stopping the flow of other most flavors), it is almost certain that the relative appeal of menthol would increase.

Therefore, we recommend an adjustment to the section with recommendations on potential study approaches to assess youth appeal (e.g., sensory perception and consumer response studies). When assessing relative appeal of proposed flavors, benchmark flavors should not include fruit, candy, etc. as described in the current guidance. Instead, proposed flavors should only be compared to those with marketing authorization to more accurately assess their appeal and potential for youth use.

Conclusion

For these reasons, we urge caution in the issuance of new guidance and encourage greater investment in enforcement activities. Thank you for allowing public comments on this guidance to the industry.

Sincerely,



Alister F. Martin, MD, MPP
Commissioner
New York City Department of Health and Mental Hygiene

¹ U.S. Food & Drug Administration. Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products. Content current as of 03/12/2026. Accessed 5/5/2026 from <https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products>

² NYC Health Department internal analysis. Youth Tobacco Survey 2016-2020.

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.