American Lung Association.

May 11, 2026

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments in Docket No. FDA-2026-D-1817 for "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk: Draft Guidance for Industry"

Dear Director Koplow:

Thank you for the opportunity to submit comments on the *Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk: Draft Guidance for Industry*.

The American Lung Association is the oldest voluntary health organization in the United States. One of our four strategic imperatives is to create a tobacco-free future. Reducing youth tobacco use and helping people quit their addiction to tobacco is both integral to our mission and is of the utmost national importance. Tobacco use is the leading cause of preventable death and a leading driver of chronic disease in the United States. Tobacco use is responsible for the deaths of 492,000 people in the U.S. annually[1] and an additional 16 million people in the U.S. live with a disease caused by tobacco.[2] The Lung Association believes that everyone who uses and is addicted to commercial tobacco products[1] can quit, not just switch to another tobacco product.

The Lung Association was pleased to submit joint comments concerning this guidance with 73 other organizations. Our comments below include several additional points to build on and supplement those comments.

The Lung Association believes every tobacco user can quit for good. Tobacco and the nicotine it contains are harmful. The draft guidance is premised on the idea that some e-cigarettes, and specifically some flavored products, may help adult cigarette users switch from cigarettes to e-cigarettes. This assumption is not supported by the available evidence. Complete switching, which would be required to obtain any benefit, often does not occur.

Flavors are a primary driver of youth initiation and continued use of e-cigarettes. This was most recently illustrated by data released by CDC Foundation on April 23, 2026 finding that 92.5% of

[1]References to tobacco refer to commercial tobacco and not the sacred and traditional tobacco that may be used for ceremonial or medicinal purposes by some Native or Indigenous communities.

youth ages 13 to 17 and young adults ages 18 to 28 who have ever used e-cigarettes started with a non-tobacco flavored product and 94.6% of youth and young adults who report current e-cigarette use indicate they used a non-tobacco flavored product within the past 30 days.[3]

There is significant evidence that a number of adult e-cigarette users also use cigarettes or other tobacco products at the same time, which research is starting to show is worse for people than using either product alone.[4] In addition, creating more dual users, rather than people who completely switch, increases harm to the population as a whole.

The Lung Association is also concerned with the draft guidance's approach to categorizing flavors into varying levels of risk and suggesting that some non-tobacco flavors may pose lower risk than others. Creating tiers of "lower" and "higher" risk flavors risks establishing a pathway for certain flavored products to receive marketing authorization based on these distinctions. The tobacco industry has historically used similar frameworks to sustain product sales and avoid regulation, including marketing cigarettes "light" and "low tar" cigarettes, which then were falsely perceived as less harmful. It is reasonable to expect that manufacturers will similarly rebrand or reformulate flavored e-cigarette products to fit into categories that are viewed as more favorable under this framework.

In short, allowing flavored products to remain on the market can both attract kids and harm adult tobacco users. Due to these risks, the Lung Association continues to conclude that no flavored tobacco product, including flavored e-cigarettes, should be granted marketing authorization as appropriate for the protection of public health.

There are currently seven FDA-approved drugs that are safe and effective for smoking cessation. They are available to most people with no cost-sharing. FDA has not found any e-cigarette product safe and effective in helping people who smoke quit, nor has there been an application for classification of an e-cigarette product as effective for cessation of smoking or vaping. An e-cigarette manufacturer can apply to the FDA's Center for Drug Evaluation and Research to be designated as safe and effective as a cessation medication but, to our knowledge, no manufacturer has done so. Without going through this process, e-cigarettes are not required to follow the same strict regulatory requirements and quality control as FDA-approved smoking cessation medications.

On May 5, 2026, FDA granted marketing orders to four flavored e-cigarette products, including two fruit-flavored products for the first time. The Lung Association strongly opposes this decision, which runs counter to the framework laid out in the draft guidance in two ways. First, it contradicts statements in the guidance that flavored e-cigarettes have greater appeal to American youth, with fruit and candy/dessert/other sweet e-cigarettes specifically listed as facing "a correspondingly high evidentiary burden to demonstrate that the benefits to adult smokers in terms of quitting or significantly reducing cigarette use outweigh the risks of youth

initiation and use." High school and middle school students cite fruit as the type of flavored e-cigarette they use most often in the 2025 National Youth Tobacco Survey, and there is no evidence included in the guidance that fruit flavored e-cigarettes specifically help adult cigarette smokers switch. Yet, FDA still authorized the two fruit flavored e-cigarettes.

Second, FDA's press release for the May 5, 2026 authorizations seem to contradict the guidance on device access restrictions (DAR) technology. The guidance states that DAR technology is untested and that applicants would need adequate and substantial evidence demonstrating mitigation of youth risk. However, FDA's press release announcing the marketing orders indicates that the agency believes DAR technologies and marketing restrictions are sufficient to prevent youth access and use. The Lung Association remains skeptical that these technologies will adequately prevent youth access and does not believe FDA should be testing the effectiveness of these technologies through the authorizations of fruit-flavored e-cigarette products.

The American Lung Association strongly encourages FDA to prioritize keeping flavored e-cigarette products off the market from both domestic and international manufacturers, due to the high risk of addicting children and young adults to nicotine. We urge FDA to update the draft guidance to better reflect the risks from flavored e-cigarettes and reconsider its decision to authorize kid-friendly, fruit flavored e-cigarettes. No flavored e-cigarette product should be found by FDA to be appropriate for the protection of public health.

Sincerely,

Harold P. Wimmer
President and CEO

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[1] U.S. Department of Health and Human Services. Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2024.

[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

[3] CDC Foundation. (2026). Monitoring Tobacco Product Use Among Youth and Young Adults in the U.S. TEEN+ Data Snapshot, Issue 3. Accessed April 28, 2026.

[4] Hamoud J, Hanewinkel R, Andreas S, et al. A Systematic Review Investigating the Impact of Dual Use of E-Cigarettes and Conventional Cigarettes on Smoking Cessation. ERJ Open Res 2024; in press (https://doi.org/10.1183/23120541.00902-2024).