FDA Issues Draft Guidance Regarding Flavored E-Cigarette Pre-Market Applications and the Risk of Youth Usage

On March 9, 2026, the U.S. Food and Drug Administration (FDA) issued a **draft guidance** to assist companies in submitting Pre-Market Tobacco Applications (PMTAs) for electronic cigarette products. The draft guidance is titled "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications: Considerations Related to Youth Risk." A draft guidance is not legally binding and describes the FDA's current thinking on a specific topic and should only be viewed as recommendations. The public may submit comments on the draft guidance to the FDA on or before May 8, 2026, at which time the agency will review comments and finalize the draft guidance.

The FDA has issued Marketing Granted Orders (MGOs) authorizing the marketing of 39 e-cigarette devices and e-liquids that are either tobacco-flavored or menthol flavored products. In order to receive a MGO from the FDA authorizing the sale of an e-cigarette product, a manufacturer's PMTA must demonstrate that the product is "appropriate for the protection of public health," which is known as the "APPH" standard.

Specifically, a PMTA must show that the benefits of an e-cigarette product, including the benefits to adults who smoke cigarettes, are greater than the risks, including risks of youth usage, resulting in a net benefit to the public health. For some time, the FDA has determined that flavored e-cigarettes pose a substantial risk of youth usage, which is greater than the risk of tobacco-flavored e-cigarettes.

The draft guidance focuses on another question that arises during the review of a PMTA for a flavored e-cigarette, namely, how much of an added benefit compared to a tobacco-flavored e-cigarette must a manufacturer demonstrate for the FDA to find that a flavored e-cigarette meets the APPH standard. The FDA's position is that an e-cigarette, which has a fruit, candy, dessert or other sweet flavors, is a substantial public health risk to attracting youth usage and, for this reason, has a high evidentiary burden to demonstrate that the benefits to adult smokers in terms of quitting or reducing cigarette smoking outweigh the risks of youth usage.

To date, the FDA has not identified any e-cigarette with a flavor other than tobacco or menthol which has a high enough public health benefit to overcome the risk of youth usage. However, the draft guidance states that the FDA will now consider evidence in the PMTA regarding the level of risk for youth usage that a specific flavor poses when assessing the risks and benefits of the e-cigarette product. For example, in the draft guidance, the

FDA states, “Some flavors may be shown to have lower youth appeal, perhaps such as coffees, teas, or spices, such that they may pose a lower risk of appeal to youth and may be APPH if the added benefit they provide compared to tobacco-flavored products is relatively small.”

Moreover, the draft guide notes that menthol-, mint- and spice-flavored e-cigarettes may “present a lower risk of youth initiation and use relative to flavors [than to] fruit and candy/dessert/other sweet-flavored products.” The agency goes onto state that a manufacturer "can also provide [flavored] product-specific information regarding the likely extent of youth initiation and use.”

In short, the draft guidance concludes that where evidence in a PMTA for a flavored e-cigarette demonstrates lower risk of youth usage, then the FDA may consider a lower level of benefits for adults to find that the flavored e-cigarette product meets the APPH standard, which could result in the issuance of a Marketing Granted Order for the product.

Read the full draft guidance document, which includes instructions on where and how to submit comments, **here**.