

Congress of the United States

Washington, DC 20515

October 6, 2026

The Honorable Kyle Diamantas
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas:

I write regarding the Food and Drug Administration's (FDA) September 28th announcement that it is considering new rulemaking to replace the 2021 regulations governing Premarket Tobacco Product Applications (PMTAs).¹ Those regulations govern the process through which FDA determines whether allowing a new tobacco product onto the market would be appropriate for the protection of public health.

FDA announced this review less than four weeks after Altria subsidiaries NJOY and Helix Innovations sued the agency over the current PMTA framework.² FDA itself cited this recent litigation challenging the framework, along with the widespread illicit tobacco market, in explaining its decision to consider replacing the rule.

I am particularly concerned that FDA is citing the proliferation of illicit tobacco products as a reason to reconsider the PMTA framework. I have repeatedly urged FDA, the Department of Justice, and other federal agencies to strengthen enforcement against manufacturers, importers, distributors, and retailers selling unauthorized e-cigarettes, including flavored products that appeal to young people.³ The widespread sale of illegal products is an enforcement problem. It should not become a justification for lowering the evidentiary requirements manufacturers must satisfy before FDA authorizes their products.

These concerns are heightened by FDA's recent authorizations of flavored e-cigarette products, including the agency's May 5th authorization of Glas products in mango and blueberry flavors – despite the agency's own data indicating that fruit flavored e-cigarettes are the most popular flavor among youth⁴ and the director of the FDA's Center for Tobacco Products indicating in a summary memo⁵ that the agency did not require the manufacturer to demonstrate that these flavors provide an added benefit to adults attempting to transition from combustible products. Former FDA Commissioner Marty Makary reportedly resigned in part due to the unprecedented political interference that resulted in this authorization.

Further, FDA on August 28 authorized additional JUUL products, including a JUUL2 menthol product. FDA acknowledged that the menthol product carries risks “including youth appeal,” but concluded that its benefits

¹U.S. Food and Drug Administration, “FDA intends to evaluate changes to the PMTA regulatory framework,” September 28, 2026.

²*Helix Innovations LLC et al. v. U.S. Food and Drug Administration et al.*, No. 5:26-cv-00199, U.S. District Court for the Northern District of Texas, filed September 2, 2026.

³Letter from Congressman Raja Krishnamoorthi and colleagues to the U.S. Department of Justice regarding enforcement against illegal flavored vaping products, April 10, 2024.

⁴Park-Lee, E., et al., “Tobacco product use among middle and high school students in the United States: National Youth Tobacco Survey, 2025,” *Nicotine & Tobacco Research*, published online June 23, 2026, <https://doi.org/10.1093/ntr/ntag116>.

⁵FDA, *Director's Summary of Glas G2 Electronic Cigarette Products*, <https://www.accessdata.fda.gov/static/searchtobacco/2026/PMP/Glas-Director-Summary-Redacted.pdf>.

to adults who smoke outweighed those risks.⁶ Exactly one month later, FDA announced that it may replace the broader framework governing applications for new tobacco products.

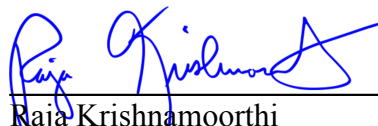
Accordingly, please provide written responses to the following questions by October 20, 2026:

1. Which specific provisions of the 2021 PMTA rule is FDA considering changing or eliminating, and what evidence supports each potential change?
2. Will FDA commit that any replacement framework will not lower the scientific evidentiary bar manufacturers must meet to demonstrate that marketing their products is appropriate for the protection of public health? If not, why not?
3. Did FDA discuss potential changes to the 2021 PMTA rule with any tobacco product manufacturer, industry association, or party challenging the 2021 PMTA rule before announcing its review? Please identify each such entity and provide all communications since January 20, 2025, between FDA officials and those entities. Please also provide all communications since January 20, 2025, between FDA officials and Altria, Reynolds American, their subsidiaries or representatives, and any other party challenging the rule concerning the PMTA framework or potential changes to it.
4. How does the existence of a widespread illicit market justify changes to the regulatory requirements governing products seeking lawful authorization? What connection has FDA identified between illegal sales and the scientific evidence manufacturers should be required to provide before receiving authorization?
5. What additional enforcement actions will FDA take, in coordination with the Department of Justice and U.S. Customs and Border Protection, to remove unauthorized e-cigarettes from the U.S. market?

The FDA's job is to protect public health, not make it easier for tobacco companies to evade rigorous scientific review. The agency should crack down on companies selling illegal products, not use their lawbreaking as a rationale for weakening safeguards governing products seeking FDA authorization.

Thank you for your prompt attention to this matter. I look forward to your response.

Sincerely,



Raja Krishnamoorthi
Member of Congress

⁶[U.S. Food and Drug Administration, "FDA Authorizes Marketing of JUUL2 E-Cigarette Device and Tobacco- and Menthol-Flavored Pods," August 28, 2026.](#)