

Congress of the United States

Washington, DC 20515

April 24, 2026

Dr. Martin A. Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Makary:

Thank you for your continued dedication to making our country safe and healthy. As you know, our nation is facing a crisis of illicit nicotine products. By some estimates, as much as 85% of the market for these products are illicit – most coming into the United States from China. Prior to your tenure, policies in place allowed an information vacuum to develop on the regulatory status of these products, creating challenges for legitimate market participants such as convenience stores and an opportunity for bad actors to flood the market.

We commend you for taking steps to address this the past year and request a few methods to intensify your efforts to rid the market of these illicit products and ensure a well-functioning and properly regulated market.

Specifically, we recommend you prioritize the following:

- First, regulatory clarity is essential. In the past, the FDA declined to identify specific nicotine products that were denied premarket approval. While the current database allows a search method for approvals, it lacks clarity on denials. This lack of transparency makes it difficult for retailers and customers to make informed decisions about inventory and purchases. Unlike new pharmaceuticals, nicotine products undergoing the application process are already available on the market – there is nothing confidential about their existence. By not identifying which products are denied approval and must be removed from shelves, the agency has created unnecessary information gaps leaving retailers and wholesalers uncertain about compliance obligations. Clarity into approvals and denials to the public is essential.
- Second, the FDA must address the backlog of premarket applications and act promptly on new submissions and we appreciate your contribution this year to clearing the backlog. Over 26 million tobacco product applications have been filed with FDA, but only 39 vapor products and 26 pouch products have been authorized, leaving consumer demand wholly unsatisfied. This prolonged regulatory inaction has incentivized the proliferation of illicit and unregulated products, contributing to the disorder we see in the marketplace today. Resolving pending applications will bring needed clarity and ensure lawful products can adequately meet demand. Delayed action drives illegal behavior and undermines effective enforcement.
- Third, the FDA must coordinate with other federal agencies to significantly strengthen enforcement against illicit nicotine products, like the Department of Justice’s multi-agency task force to combat illicit vapor products in the U.S. The market has become saturated with unregulated goods, and it urgently needs to be cleaned up. The FDA should employ every available tool to remove these products from the marketplace and reestablish a fair, lawful, and

transparent system. We look forward to seeing the findings and actions of this task force and other interagency coordination.

Lastly, we appreciate the reevaluation of Center for Tobacco Products (CTP) leadership. We need that leadership to ensure PMTAs and approvals do not continue to be backlogged. We look forward to the success the CTP can bring to consumer choice and safety.

We are eager to work with you to restore order to the market and ensure it operates as a lawful, well-regulated alternative for consumers. Thank you for your prompt attention to this important matter.

Sincerely,



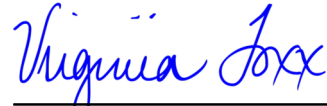
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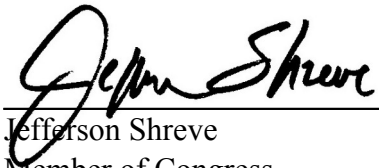
Tim Moore
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Virginia Foxx
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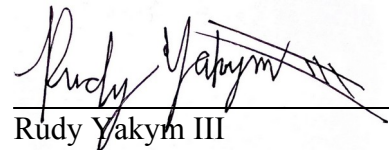
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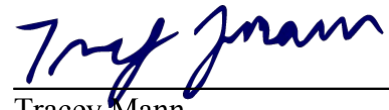
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