



# COMMONWEALTH of VIRGINIA

Office of the Attorney General

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The Honorable Robert Califf, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf:

I write to you today on behalf of the Commonwealth of Virginia to urge specific FDA action in a matter of increasing urgency. As the Attorney General of Virginia, I am increasingly presented with the concerns of Virginia residents and businesses regarding the proliferation of illegal and unregulated “ENDS” products (Electronic Nicotine Delivery Systems, commonly referred to as *e-cigarettes* or *vapes*). I am writing to urge the FDA to take action to prevent the distribution and sale of illegal and, in some cases, dangerous, disposable ENDS products flooding into the United States from China and other countries.

Recent federal actions to restrict the availability these products are a welcome first step, but they do not go far enough, particularly with respect to the protection of our children<sup>1</sup>. The Associated Press recently advanced the opinion that the influx of illegal disposable ENDS products are due to “*the Food and Drug Administration’s inability to control the tumultuous vaping market more than three years after declaring a crackdown on kid-friendly flavors.*”<sup>2</sup> The FDA’s ban on these products was not followed with the requisite introduction of a regulatory system that would control the ENDS product marketplace and establish enforcement authority over retailers and distributors. The inevitable result of this regulatory vacuum is that disposable vape device product sales have “**more than doubled**” since January 2020 because, according to reports, flavored disposable e-cigarettes “took a back seat in federal enforcement actions.”<sup>3</sup>

<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/fda-inspection-blitz-leads-more-180-warning-letters-retailers-illegal-sale-youth-appealing-elf-bar>

<sup>2</sup> <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f>

<sup>3</sup> <https://rollcall.com/2023/06/22/disposable-vape-sales-soared-after-fda-focused-efforts-elsewhere/>

I represent the interests of all Virginia residents, many of whom are parents, retailers, and healthcare workers. Increasing numbers of Virginians are contacting my Office and appealing to me directly with dire concerns regarding the increasingly unchecked availability and widespread use of these illegal products. These harmful and illegal products are now *inundating* our communities and alarmingly, our children's *schools*. The National Youth Tobacco Survey has recently reported that the usage of disposable vape products by *middle school* and *high school age students* continues to rise, having increased exponentially since 2019. On behalf of Virginia residents, I strongly urge the FDA to implement the necessary enforcement system to protect our citizens, especially our children, a vulnerable population that these products are *deliberately designed to target*.

In November 2022, my office launched "One Pill Can Kill," a public awareness initiative designed to generate conversations around the dangers of counterfeit drugs and fentanyl. In the absence of necessary regulatory action by the FDA, Virginia citizens are voicing deep concerns about reports of black market vaping products from China, potentially laced with *fentanyl*.<sup>4</sup> Across the state line from Virginia, in Sullivan County, Tennessee, school officials have sounded the alarm on the "increased number of vape products laced with fentanyl."<sup>5</sup> *The potential for catastrophic fatalities among our innocent youth, mirroring the surge of fentanyl deaths among drug users, is too grave a risk for the FDA to knowingly permit.*

In addition to the concerns expressed to my Office by concerned private citizens, our Tobacco Enforcement Section regularly receives requests for assistance from tobacco & vape *retailers* and *distributors*. These businesses struggle to maintain legal and regulatory compliance in a market lacking any effective regulatory framework for ENDS product sales and distribution. In addition to their understandable concerns relating to their own compliance, they find themselves at a distinct market disadvantage, with a multitude of competitors openly selling illegal, non FDA-approved ENDS product to the public. These illicit sales appear to be taking place without any restriction or legal consequence from the federal authority responsible for ENDS product approval.

The Commonwealth of Virginia is eager to implement compliance with federal requirements for the regulation of ENDS product. Virginia has a proven history of proactive partnership with federal agencies in the regulation of nicotine products. Both Virginia's Department of Taxation and Attorney General's Office rigorously secure monthly PACT Act Reports from all known tobacco and ENDS product distributors, in compliance with the requirements of the ATF's PACT Act. Our Office additionally aids in the ATF's enforcement of these requirements by submitting reports of non-compliant distributors to the ATF, resulting in documented federal enforcement action. Our Office also requires cigarette manufacturers to submit annual documented proof of compliance with both the U.S. Department of Treasury's

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<sup>4</sup> <https://www.fox35orlando.com/news/black-market-vaping-products-could-be-laced-with-fentanyl-experts-warn>

<sup>5</sup> <https://wcyb.com/news/local/rising-vape-use-among-teenagers-compounded-by-fentanyl-risk-a-local-schools-fight-against-a-dangerous-trend-sullivan-east-high-school-principal-andy-hare-appalachian-substance-abuse-coalition-executive-director-linda-austin>

Alcohol and Tobacco Tax and Trade Bureau (“TTB”) registration and reporting requirements, and the Center for Disease Control and Prevention (“CDC”) ingredient reporting requirements.

A clear and regularly updated public listing of FDA-approved ENDS products would enable Virginia’s legislature to enact its own integrated regulatory framework for the control of legal sales and distribution of ENDS products. Such regulatory system would include the creation of a statewide retail license/permit for the legal sale of ENDS product, and the publication of Virginia’s own state-approved ENDS Product Directory (as illustrated by the Virginia Tobacco Directory, maintained and published by the Attorney General’s Tobacco Enforcement Section for the last 20 years).<sup>6</sup>

On behalf of the Commonwealth of Virginia, I respectfully request that the FDA begin publication of a freely available internet resource for the clear listing of currently FDA-approved ENDS product. I furthermore request that the FDA begin effective ENDS product enforcement and partnership with state law enforcement agencies, providing support for these agencies in their efforts to implement inspections, seizures and prosecutions relating to illegal ENDS product market activity.

Thank you for your attention to this matter.

Sincerely,



The Honorable Jason S. Miyares  
Attorney General of Virginia

Cc: Members of Virginia Congressional Delegation  
Governor Glenn Youngkin

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<sup>6</sup> <https://www.oag.state.va.us/programs-outreach/tobacco-enforcement>