July 18, 2025

The Honorable Donald Trump
President of the United States of America
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

RE: The Market Needs Clarity and Enforcement to Stop Illicit Vapes from China

Dear President Trump,

The convenience store and travel center industries are facing a crisis of illicit product from China. Vape and e-cigarette products have been flooding our country for years and drawing business away from law-abiding retailers. We need change at the Center for Tobacco Products (CTP) and help from the federal enforcement agencies to clean up this mess. We are asking for your help to do that.

The convenience store and travel center industries are a major driver of economic activity in every community in the country. The convenience and retail fuels industry employed approximately 2.74 million workers and generated $837.4 billion in total sales in 2024, representing 3% of U.S. gross domestic product.[1] The industry, however, is truly a collective of small businesses. More than 60 percent of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses. Members of the industry process more than 165 million transactions every single day. That means about half the U.S. population visits one of the industry's locations on a daily basis. In fact, 93% percent of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and center of a community.

Today, however, the businesses in our industry are systematically losing sales to businesses that sell illicit products. The reasons why this is happening are clear and solvable. The CTP has abandoned its fundamental responsibility as a regulator.

The CTP required manufacturers of vapor products (also known as e-cigarettes) to submit premarket approval applications in order for those products to remain on the market. The ultimate

[1] Data on the industry comes from the NACS, State of the Industry Annual Report of 2024 Data *available at* *NACS State of the Industry Report® of 2024 Data | NACS*.

deadline for submitting those applications was September 2020 ("Deemed tobacco-derived products") and also 2022 ("synthetic nicotine"). That move made sense.

The conduct of the CTP since that time, however, has missed the mark. First, the CTP has dragged its feet on deciding the premarket authorization of these deemed products. It is now nearly five years since the application deadline and applications for thousands of products remain undecided and innovation remains in limbo consequently. That is not acceptable.

The agency received millions of premarket submissions. It was understandable that it would take time to evaluate them. But, that time has long passed. The hold-up at CTP today is not a problem of workload, it is a problem of will. The CTP wants to deny approval for many of these products but knows that it does not have a reliable legal basis to do so and distinguish between the products it wants to permit (which are very few with extremely low market share and little commercial and consumer interest) and those it wants to reject (which are many with commercial and consumer interest). The result is that CTP avoids deciding these applications at all because it knows it will lose legal challenges to those rejection decisions. It has chosen uncertainty and chaos instead of promoting public health and innovation. The willingness of CTP to abandon what the law requires and instead try to assert its own product preferences and general bias of an entire industry is inexcusable.

Second, the CTP's refusal to do its job in deciding applications has been compounded by its refusal to provide the basic level of regulatory clarity required for the industry to follow the law. The CTP has refused, for example, to identify the actual vapor products for which it has denied premarket authorizations.[2] These products, unless they have an ongoing legal challenge, should be barred from the market. But, they have not been and cannot reliably be barred because CTP will not disclose what products those are, so legitimate manufacturers, distributors, retailers and consumers alike remain powerless and ill equipped to make informed purchasing choices. CTP only discloses the names of the manufacturers, not the actual products that have been denied. Those manufacturers, however, all have multiple products, and it is not clear which ones have been denied, and which remain under premarket review.

Third, there are products that remain in legal limbo. CTP has denied certain premarket applications, but those decisions are not in effect due to legal or administrative challenges that remain ongoing. CTP has not provided clear information regarding which products are in that legal limbo whereby they can still be sold even though there has been a denial order, which creates an opportunity for irresponsible manufacturers to take advantage. This is confusing for retailers, who have to search CTP's website to find the list of these exceptions, and even then, the information CTP provides is incomplete. Most of these exceptions do not even list product names, just the manufacturers who market a number of products, begging the question which products are affected. For example, on a number of these exceptions, CTP notes, "FDA partially rescinded this denial with respect to certain products."[3] There is no further explanation given to retailers.

The net result of these decisions is that the industry does not know how to distinguish licit products from illicit products. CTP has not provided that information. Instead, CTP has said that retailers

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[2] CTP claims that it cannot disclose the names of the products because they are confidential. This is wrong. These are actual products commercially sold on the market. This is not like submissions of a new drug or device that are in the developmental stage. The product names are fully public because they are being sold everyday. CTP needs to reevaluate and overturn this mistaken reading of its authority.

[3] List of companies that have received marketing denial orders from CTP (Last updated 6/11/25) - https://www.fda.gov/media/184544/download?attachment

should only sell vape products that are on the list of ones that CTP has authorized (39 vapor products[4]), which is miniscule in comparison to the illicit products widely available. While CTP does provide the list of the actual products it has authorized, its claim that those products are the only ones that can be sold is false and they have admitted that. At the least, many products that have litigation and administrative challenges can be sold. But, as noted, CTP has not provided the information to differentiate between those categories of products.

That uncertainty has been compounded by the fact that the list of vape products authorized by the CTP cannot come close to satisfying market demand or consumer preference. Tens of thousands of store shelves would be bare if all vape products other than those on the authorized list were removed from the market. It is not, however, an outcome called for by the law nor is it a practical commercial and economic solution.

It should not be surprising, given these facts, that the market has seen a flood of clearly illicit products manufactured from companies that did not submit premarket applications by the 2020 deadline (or have not submitted them at all). The regulatory ambiguity has created an opening for illicit products, predominantly manufactured in China, to grow their market share – if no one knows what products can and cannot be sold.

Businesses in China are exploiting the refusal of a U.S. regulator to provide clarity and the tools that U.S. businesses need to combat this influx of illicit product.

Not surprisingly, enforcement entities have not been able to keep up. Customs and Border Protection, the FBI, and the Department of Justice were slow to react to the influx of vapes from China – in part because they did not get clear information from CTP on which products to interdict either. The enforcement authorities need to reprioritize and redirect their efforts in a concerted manner in ordr to catch up to the illicit activity and eradicate it.

Law abiding retailers are directly impacted by this situation. They do their best to police the products that they sell, ensure they deal with reputable distributors, and keep their operations above board. Yet, while they are doing that, vape shops and others who are willing to ignore the law are selling flavored and other vape products that more reputable stores will not sell. The regulatory ambiguity is creating a market dynamic where consumers can find these products outside of reputable spaces and without age verification and other safety protocols. The steady loss of sales to this illicit market harms both consumers and legitimate retailers. These businesses are not just losing the sale of a legal vape product, but the entire basket the customer would have purchased at their stores.

We need your help to clean up the mess that CTP helped create. To do that, we recommend the following:

- **Require CTP to decide all premarket applications:** The indecision must end. CTP should render decisions, and fast. Many products awaiting decisions are very similar to authorized products and seem easy to authorize. Regardless of which way these are decided, however, process clarity is better than uncertainty. Even denials will at least start the process of legal challenges and getting to final decisions.

[4] E-Cigarettes Authorized by the FDA

- **Require CTP to provide clarity:** CTP must be told to reveal exactly which products (not just manufacturers) have been denied, exactly which products remain in legal limbo, and exactly which products submitted timely applications. The majority of stores in the U.S. are small businesses that do not have in-house legal teams to read through agency jargon. They need clear and concise information from CTP.

- **Supercharge the multi-agency task force:** Once product clarity has been provided, the federal multi-agency task force led by FDA and DOJ, which was established in June 2024 to combat illicit vapes,[5] should be directed to bring the strongest civil and criminal enforcement actions against the worst offenders to deter ongoing noncompliance. Illicit product, wherever it is found, should be seized. FDA has direct authority to regulate the distribution chain, and it should fully utilize this power.

- **Require more from Customs and Border Protection:** CBP should strengthen its efforts to prevent the importation of illicit Chinese vapes by increasing targeted inspections throughout the supply chain, expanding the use of risk-based analytics tools, and pursuing civil and criminal penalties in cases of fraudulent import misdeclarations.

We look forward to working with your administration to ensure we have a properly functioning regulatory system for vapor and e-cigarette products. Thank you for your attention to this important issue that impacts the entire industry.

Sincerely,

Energy Marketers of America
National Association of Convenience Stores
National Association of Tobacco Outlets
NATSO, Representing America's Travel Plazas and Truckstops
SIGMA: America's Leading Fuel Marketers

cc: Dr. Martin Makary, Commissioner, U.S. Food and Drug Administration

[5] FDA, Press Release, Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb the Distribution and Sale of Illegal E-Cigarettes (6/10/24).