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Client Alert

White Collar Defense

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Federal Government Increases Crackdown on Illegal Sale of Vapes

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The U.S. Food and Drug Administration (FDA) has recently filed civil actions in federal court highlighting a crackdown on a black market that, in many cases, exists in plain sight. Vapes and electronic cigarettes (e-cigarettes), part of a broader category of products called electronic nicotine delivery systems (ENDS), are staple products at local grocery stores and can even be purchased online. According to the FDA, however, there is an influx of illicit products, often imported from China, that are marketed and sold to U.S. consumers, including young people. In two complaints filed in the District of New Jersey and another filed in the Eastern District of North Carolina,[1] the FDA is seeking a permanent injunction against companies allegedly involved in the manufacture and distribution of illicit products in violation of the Federal Food, Drug, and Cosmetic Act.

Regulatory Landscape

Perhaps unbeknownst to most consumers, before a new tobacco product can be lawfully marketed and sold, it must receive FDA authorization. As a "product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product,"[2] ENDS are subject to significant regulation.

To market and sell a "new tobacco product," which includes "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007,"[3] companies must obtain FDA permission through one of three avenues:

- Submit a premarket tobacco product application (PMTA) and receive an FDA-issued marketing granted order (MGO) upon a finding that, among other things, the new tobacco product is appropriate for public sale.
- Submit a substantial equivalence (SE) report, and receive from the FDA a substantially equivalent order, which is issued upon a finding that, among other things, the new tobacco product is substantially equivalent to a tobacco product that was already commercially marketed as of February 15, 2007.
- Submit a substantial equivalence exemption request (EX REQ) and receive from the FDA an exemption order upon a showing that the new tobacco product is a minor modification to a legally marketed tobacco product.

FDA authorization is not easy to obtain. To date, the FDA has approved only 39 ENDS products for sale. By authorizing these products for sale, the FDA is not judging them to be safe. The law and FDA both recognize that the use of e-cigarettes is not risk-free. E-cigarettes, however, are deemed to be a lower-risk alternative for smokers. Accordingly, in issuing an MGO, the FDA determines whether marketing of the new product is "appropriate for protection of the public health." In making this finding, the FDA considers, among other factors, the PMTA applicant's data and research with regard to whether those who currently use tobacco products would be likely to switch entirely to the new product, whether those who do not use tobacco products would be likely to start using the new product, and the new product's appeal to young people.

Increased Enforcement

Recently, the federal government has increased enforcement of unauthorized vape sales. In May 2025, the FDA seized $33.8 million worth of e-cigarette products at a Chicago port of entry. In September 2025, the FDA announced a joint operation with U.S. Customs and Border Protection that resulted in the seizure of $86.5 million worth of e-cigarette products at the same port, the largest such seizure to date. Additionally, the FDA has sent warning letters to hundreds of retailers and issued civil money penalty actions to over 100 more.

The government is also pursuing legal relief through the courts. In the recently filed actions in the District of New Jersey, the FDA alleges the defendants ignored warnings from the FDA and continued to manufacture, distribute, or sell illicit products. In *U.S. v. PSM101, LLC d/b/a Center Point Distributors*,[4] the FDA asserts the defendant company, through its owner, sold ENDS products manufactured in China that had not been approved for marketing and sale in the U.S. According to the complaint, in 2021, the FDA sent the defendant's predecessor company a letter warning the company to cease the sale of illicit products. While the company responded to the letter and assured the FDA of future compliance, an August 2025 FDA inspection revealed defendants "continued to receive, distribute, and sell adulterated and misbranded ENDS products in interstate commerce." The complaint also notes that some of the flavors of the unauthorized products, such as "Orange Dragon," "Blue Razz," and "Cool Mint," which suggests that the products are designed to appeal to young people.

The other New Jersey action, *U.S. v. Gorilla Vapes LLC*,[5] follows a similar factual scenario. There, the FDA alleges the defendants ignored warning letters regarding the illicit distribution of products, some of which were made or manufactured in China; as a result, the government seeks a permanent injunction against the company and its owners. In August 2025, the Bureau of Alcohol, Tobacco, Firearms and Explosives inspected the defendants' facility and identified illicit ENDS products. This case also features products with flavors that may specifically appeal to young people, such as "Cotton Candy," "Triple Berry," and "Sour Strawberry."

Key Takeaways

These two New Jersey actions are indicative of a broader crackdown on the e-cigarette industry and signal robust future enforcement. Manufacturers and retailers alike should expect continued enforcement through inspections and investigations. Companies should take steps to ensure compliance with all applicable laws with respect to the manufacturing, distribution, and sale of ENDS products. If you have any questions about these cases, or the ENDS industry in general, please reach out to the White Collar Defense group at Lowenstein Sandler.

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[1] *U.S. v. Dream Distro LLC and Faisal A. Alhadrami*, No. 5:25-cv-577.

[2] *See* 21 U.S.C. § 321(rr).

[3] *See* 21 U.S.C. § 387j(a)(1).

[4] *U.S. v. PSM101, LLC d/b/a Center Point Distributors and Niravkumar G. Vora*, No. 2:25-cv-15436.

[5] *U.S. v. Gorilla Vapes LLC, Nick Jurczyk, and Russell Jurczyk*, No. 3:25-cv-15715.

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