

FDA Enforcement Actions Against Tobacco Retailers

This week, FDA issued a new round of civil money penalties (CMPs) to 22 brick and mortar and online retailers for the sale of allegedly violative vapor products. Since May 2023, there has been a significant increase in warning letters and CMPs, with more than 550 warning letters and 170 CMPs issued to retailers for selling allegedly violative flavored disposable products popular with youth. These actions have focused on major brands including Breeze, Elf Bar/EB Design/EB Create, Lost Mary, Funky Republic/Funky Lands, Esco Bars, Lava Plus, Cali Bars, Hyde, and Kangvape.

Warning letters are typically the first step FDA takes before issuing escalating enforcement actions such as injunctions, seizures, or CMPs. Retailers issued warning letters have 15 days to respond to FDA with the actions they will adopt to correct the violation and prevent future violations (or to refute the alleged violations).

FDA has issued substantially more CMPs, or monetary fines, in recent months to retailers that continue selling allegedly violative vapor products. FDA has also started seeking maximum fines of \$20,678 from each retailer for a “single violation.” FDA notes on its website that the agency has the authority to issue even larger fines for “intentional violations,” which could be as high as \$1,378,541 in a single proceeding.

In summary, we emphasize the following recent trends in FDA’s enforcement approach:

1. Increased warning letters to retailers for allegedly violative vapor products;
2. Increased CMPs to retailers that continue selling allegedly violative vapor products; and
3. Increased use of maximum CMPs amounting to \$20,678 for each single violation.

NATO has been tracking FDA’s recent enforcement actions, and below are the disposable vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters. Please note that just because a brand is identified below does not necessarily mean that all SKUs in that brand family have been cited for enforcement. We strongly recommend that all retailers check with their suppliers to ascertain the status of each individual product. We further note that the fact that a brand is included in the below list does not constitute any commentary on (i) the status of other non-vape categories of tobacco products that may bear the same or similar brand names or (ii) the validity of FDA’s allegations in the civil money penalty complaint, import alert, or warning letter.

Brands Cited in FDA CMP Complaints:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar(s)
- Flum Gio
- Lost Mary
- Puff Bar/ Puff Flow/ Puff Max/ Puff Plus/ Puff Xtra/Puff XXL

Brands cited in FDA Import Alerts:

- Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EB Create/ BC5000
- Esco Bar(s)
- RandM/Fumot

Brands Cited in FDA Warning Letters						
Elf Bar/ Elfbar/ Elf Bar TE6000/ EB/ EB Design/ EBCreate/ BC5000	Puff Bar/ Puff Flow/Puff Max Puff Plus/ Puff Xtra/ Puff XXL	A+++	Airis	AIS Krim	Aquabar	Bang
BBK-RG	Beco	Blow	Bluum Lab	Boss Bar	Bot-It	Breeze
Cali	DO3	Dotmod	Dragbar	Elf Tank	Esco Bar(s)	Fantasia Vape-PRO Unit
Flair	Fliq	Flum Gio	FOUNS	Friobar	Funky Republic	Game Puff
Gazzbar	Glamee	High Light	HQD Cuvie	Hyde	IJOY Bar	JODK
KangVape	KERG-BBK	Lava	Lavie	Loaded	Loon-300 /Loon Bullet	Lost Mary
Luckee	Mochivap	MOTI	Mr. Fog	Mylé	Oly	Pod Mesh FLO
PURE	Quawins	R&M	RandM/Fumot	RG Plush	Snowwolf	Space V
STIG	Straw	Super Bucks	VAAL	VapeCam	VapeTape	Vapin' Donuts
VapMod	Vaporlax	Vaportech	Vpro	Wave	WDG	