



Enforcement Readiness

David Spross - Executive Director
National Association of Tobacco Outlets

NATO®

NATO Footprint

TPE24



National Retail Trade Association Representing
66,000 Tobacco Retailers throughout the Country



Membership made up of Retailers, Wholesalers,
Manufacturers, and State Associations



Federal, State & Local
Advocacy on Tobacco Issues



NATO News

News Resource



FDA Engagement



NATO

Enforcement



Enforcement – Who & Where

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FEDERAL

ALL 50 STATES



STATES



Many Localities Have Enacted Tobacco Restrictions / Licensing

Enforcement – Who & Where

TPE24

FEDERAL

ALL 50 STATES



STATE

CA • MA • NY • NJ • RI

■ Enacted Flavor Bans



Many Localities Have Enacted Flavor Bans

FDA Types of Inspections

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Undercover Buys Inspection



- Minor Attempts to Purchase Tobacco Products (Brick & Mortar)
- Won't be aware of Inspection

- Selling to anyone under 21
- Failing to ask for photo ID under 27



Advertising and Labeling Inspection



- FDA agent identified (no preannouncement of visit)

- Selling products without FDA Authorization (e.g. PMTA)
- Providing free samples
- Selling "loosies"
- Selling without warnings

Import Review and Detention



- Entry Screening
- Import Alerts

- FDA "Detain" Notice
- FDA "Refusal" Notice
- Import "Red" List

Online Surveillance



- Online tobacco surveillance program uses a multi-pronged approach to comprehensively monitor all aspects of online activity related to tobacco products, including sales, distribution, marketing, and advertising

SINCE 2010, FDA

- ~20,000 reviewed
- ~1,000 warning letters issued

Inspector General Report



- Review: raised questions about effectiveness of FDA's efforts to prevent youth access online

RECOMMENDATION

- Collaborate with ATF
- Complete rulemaking
- Use data
- Be transparent



Warning Letters – Now What? **TPE24**



Advertising



Underage Sales



Online Sales

15 Days to Respond

Not a final agency action

Describe Corrective Measures

Be specific

Include Dates

Corrective action taken

Provide Plan for Continued Compliance

Plan for future inspections



Warning Letters–What's Next? **TPE24**



Warning Letters Issued to
over **133K** to
Manufacturers • Distributors •
Retailers

CIVIL MONETARY PENALTIES

Over 31K issued to date including last fall, for the first time, issued the maximum (\$19,102) civil monetary penalty fine to 22 retailers selling Elf Bar/EB Design vapor products

NO TOBACCO SALE ORDER

Over 200 issued to date prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time

SEIZURE

Collaboration with Customs & Border Protection against the importation of illegal e-cigarettes by placing certain firms on an FDA import alert red list, which allows the FDA to detain products without conducting a full inspection at the time of entry & FDA domestic product seizures through a federal court / federal marshals

PERMANENT INJUNCTION

7 issued to date to selling, manufacturing and distributing unauthorized e-cigarette products



What They Are Saying

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“FDA is committed to **TAKING ACTION** across the supply chain, including among retailers, to **REMOVE UNAUTHORIZED TOBACCO PRODUCTS** from the marketplace. This includes continued **MONITORING** of the **ONLINE MARKETPLACE** to identify and combat against emerging products of concern.”

“To date, FDA has **AUTHORIZED 23 TOBACCO-FLAVORED E-CIGARETTE** products and devices. These are the only e-cigarette products that currently may be **LAWFULLY SOLD** in the U.S.”

“Currently, **NO NTN (SYNTHETIC) PRODUCT** has received marketing authorization.”

“Give **GREATER WEIGHT** to retailers’ **PAST NON-COMPLIANCE** and take **STRONGER ENFORCEMENT ACTIONS** against retailers with histories of violations.”





What They Are Also Saying

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“**ENFORCING** against unauthorized e-cigarette products, including unauthorized products popular with youth, are among the **HIGHEST** enforcement **PRIORITIES.**”

“**THE FDA CANNOT BE EVERYWHERE ALL THE TIME.**”

“Recognizing that it will not be possible to clear the market of illegal products, **CTP** should be explicit about its **ENFORCEMENT STRATEGY.**”

“The Panel strongly recommends **CTP** use **PUBLIC COMMUNICATIONS** to provide greater transparency about the Agency’s approach to **COMPLIANCE & ENFORCEMENT** including **POSTING and DISSEMINATING a LIST** of legally marketed products.”

Vaping Media Attention

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US officials block Elf Bar-maker and others from importing 1.4 million illegal e-cigarettes

Story by By MATTHEW PERRONE • 2w

AP The Associated Press



HEALTH NEWS
SEN. SCHUMER PRESSER ON NEW E-CIG TARGETING YOUNG PEOPLE

FDA, DOJ Seek Permanent Injunction Against E-Cigarette Manufacturer

Manufacturer failed to take corrective action after being warned it was violating the law

December 4, 2023



NC Attorney General

@NCAGO

BREAKING: Attorney General @JoshStein_ led a bipartisan coalition of 33 attorneys general calling on the @US_FDA and its Center for Tobacco Products to do more to protect kids from e-cigarettes.

ncdoj.gov/attorney-gener...



“E-cig companies don’t care if you’re a Republican or a Democrat – they’re targeting your kids either way. My fellow state attorneys general and I are taking action to fight back, but we cannot play whack-a-mole. We need the FDA to put in place rules that stop these companies from making and selling dangerous products that harm our kids and that fuel another

Wittman, Krishnamoorthi, Colleagues Urge Administration to Prohibit Illicit Vaping Products from China



Washington, December 8, 2023

Attorney General Bonta Files Lawsuits Against Two California Online E-Cigarette Retailers for Violating State and Federal Laws

Press Release / Attorney General Bonta Files Lawsuits Against Two California...



Thursday, December 14, 2023



Mayor Adams, Corporation Counsel Hinds-Radix Announce Lawsuit Against Four Companies Illegally Selling Disposable Flavored E-Cigarettes

July 10, 2023

ERIC ADAMS

(D) NEW YORK CITY MAYOR

Chinese e-cigarettes smuggled as toys and shoes seized at LAX

USA TODAY

WARNING LETTERS: Online retailers selling e-cigarettes in **YOUTH APPEALING PACKAGING** in youth-appealing toys and drink containers, including soda bottles and slushies (Nov. 2023)

WARNING LETTERS: Youth-appealing e-cigarette products, including **DISPOSABLES**, brand names Elf Bar, EB Design, Lava, Cali, Bang, and Kangertech (Sept. 2023)

PERMANENT INJUNCTION: Junkie Ejuice (Dec. 2023)

WARNING LETTERS: Online retailers selling e-cigarettes, brand names Lost Mary, Funky Republic/Funky Lands, Elf Bar/EB Design, Kangvape, Cali, and Breeze (Dec. 2023)



SEIZURE: 1.4 million units of unauthorized e-cigarette products, including brands such as Elf Bar, which according to the 2023 NYTS - most common brand among youth e-cigarette users (Dec. 2023)

Areas of Focus: Youth-Appealing Flavors, Packaging & Disposables



Regulation in the States

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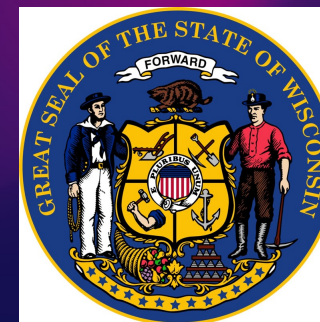
State & Local Flavor Ban



Regulation

- Strengthens the California flavored tobacco products retail law by establishing the California Department of Public Health as the primary state enforcement agency
- Increases penalties for retailers who do not comply with the law

State Directories – 4 states Enacted, More considering in 2024



Responsible Retailing

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Use Available Resources

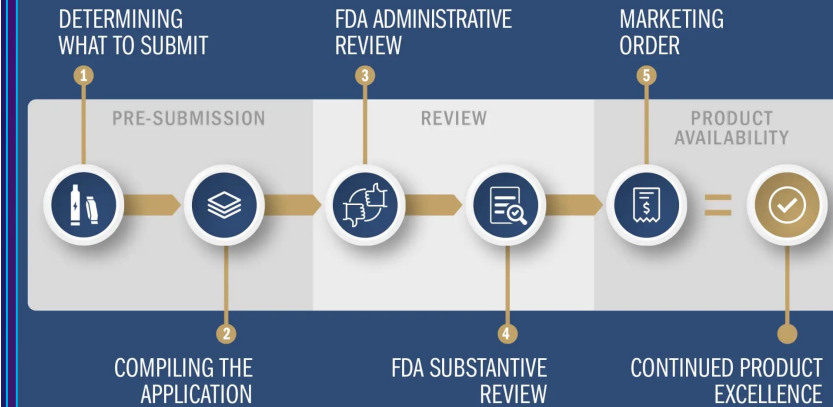


Sell PMTA MGO Products

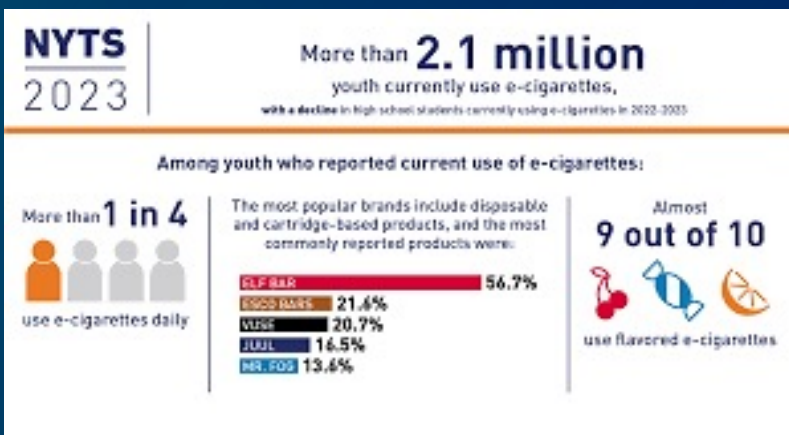
Premarket Tobacco Product Marketing Granted Orders

To legally market a [new tobacco product](#) in the United States, a company must receive a written **marketing order** from FDA. Companies may receive marketing authorization through one of the three pathways; the following products have been issued marketing granted orders (MGO) under the PMTA pathway.

Ask for Proof PMTA Pending



Know Data



Engage



Reporting Violations

- Submit **ONLINE** Form (FDA 3779)
- **CALL** the Tobacco Call Center: 1.877.CTP.1373
- Send an **EMAIL**: CTPCompliance@FDA.hhs.gov

Stay Informed



NATO Membership

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NATO.
NATIONAL ASSOCIATION OF TOBACCO OUTLETS

For more than 20 years, NATO has been the leading trade organization working to protect all retailers that sell tobacco products from unfair taxation and overly restrictive legislation and regulations.

The Premiere Retail Association
Every Retailer Should Join

NATO Membership Value: Information • Engagement • Knowledge • Education

20 YEARS

www.natocentral.org/join

