

ELECTRONIC CIGARETTES AND ORAL NICOTINE POUCHES

- New Enforcement Information from the FDA
- January 6, 2026



DISCLAIMER

This information is provided for educational purposes only and is not to be construed as legal advice.

For legal advice, please contact your municipal attorney.



**WHAT ARE THESE
PRODUCTS AND
WHY DO WE CARE?**



HOW TO USE A NICOTINE POUCH: "DISCREET AND CONVENIENT DESIGN"



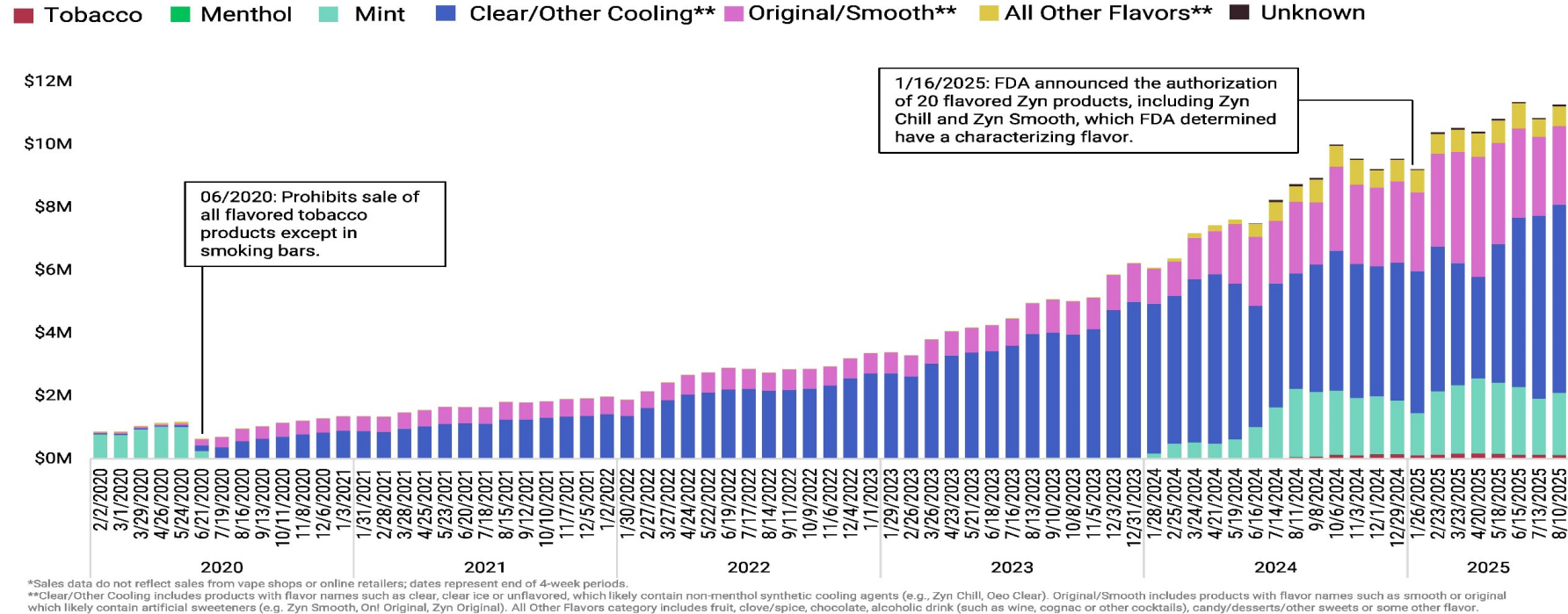
HOW POPULAR ARE THEY?

- From 2016 to 2023 sales increased from 6 million to 334 million. *(CDC)*
- From 2019 to 2023 current use among MA high students tripled. (1% to 3.2%) *(2023 MA YHS Tobacco/Nicotine Use)*
- Can be used discreetly in school.
- No smoke or vapor.
- Small.
- Containers look like they contain mints or gum.
- Can be used anywhere.
- 2nd most popular tobacco/nicotine product used by youth in 2024. *(NYTS 2024 data)*
- 480,000 middle and high school students using nationwide. *(NYTS 2024 data)*
- The only commercial nicotine product in MA not subject to any excise tax.

VAST MAJORITY ARE FLAVORED

Data Brief | August 2025 (Published October 2025)

Figure 3. Total Nicotine Pouch Dollar Sales, by Flavor, Massachusetts



Trends of Nicotine Pouch Dollar Sales by Flavor from 1/29/2023 to 8/10/2025

Total nicotine pouch dollar sales increased from \$3.4 million to \$11.3 million (+232.5%).

Tobacco-flavored nicotine pouch dollar sales increased from \$0 to \$119.7 thousand; dollar share increased from 0.0% to 1.1%.

Menthol-flavored nicotine pouch dollar sales increased from \$0.4 thousand to \$12.7 thousand (+2,905.4%); dollar share increased from 0.0% to 0.1%.

Mint-flavored nicotine pouch dollar sales increased from \$26.9 thousand to \$2.0 million (+7,212.6%); dollar share increased from 0.8% to 17.4%.

Clear/other cooling-flavored nicotine pouch dollar sales increased from \$2.7 million to \$6.0 million (+122.8%); dollar share decreased from 79.3% to 53.1%.

Original/Smooth nicotine pouch dollar sales increased from \$667.0 thousand to \$2.5 million (+273.9%); dollar share increased from 19.7% to 22.1%.

All other-flavored nicotine pouch dollar sales increased from \$7.3 thousand to \$625.6 thousand (+8,458.6%); dollar share increased from 0.2% to 5.5%.

Retail sales data are based on custom research by the CDC Foundation using Circana retail POS (Multi-Outlet and Convenience). According to Circana, new product coding is managed to consistently meet or exceed releasing products that cover a minimum of 95.5% of total dollar sales at any given time. Coding and releasing of new products are prioritized based on significance of dollar sales to continually comply with capturing at least 95.5% of total dollar sales in each period. Financial support was provided by Bloomberg Philanthropies through a grant to the CDC Foundation.

NICOTINE STRENGTH VARIES



- Low strength: 2 - 4 mg.
 - For beginners.
 - Marketed as “particularly beneficial for those who are experimenting with nicotine for the first time.”
 - <https://alppouch.com/>
- Medium strength: 6 – 8 mg.
 - For those with moderate nicotine tolerance.
- High Strength: 10 – 14 mg.
 - For those with high nicotine tolerance providing a “robust experience.”
- Extra High Strength: 16 – 20 mg.
 - For those with very high nicotine tolerance.
- Loon NYXX – Bad Bull: 28 mg.
 - Some higher.

HEALTH CONCERNS – ORAL NICOTINE POUCHES

- Youth use of nicotine in any form is unsafe.
 - Interferes with brain development, mental health, and long-term addiction risk. (CDC)
- Irritates digestive tract lining, and can contribute to acid reflux, gastritis, peptic ulcers. (https://healthline.com/health/nicotine-pouches?utm_)
- Evidence of significant impact on oral mucosa with white lesions that revealed important changes at the cellular level. (https://link.springer.com/article/10.1186/s13000-024-01549-3?utm_)
- Associated with increase mortality risk in those with pre-existing ischemic heart or cerebrovascular disease. (<https://pubmed.ncbi.nlm.nih.gov/39624904/>)
- Current evidence does not support meaningful performance-enhancing effects of nicotine use in athletics. Reviews generally find minimal or no ergogenic benefit. (https://pmc.ncbi.nlm.nih.gov/articles/PMC5684328/?utm_)
- High nicotine levels and inaccurate labeling of actual amount of nicotine – can result in nicotine poisoning. (<https://pubmed.ncbi.nlm.nih.gov/38378209>)

MARKETING STRATEGIES

- It's a harm reduction product.
 - No evidence that it helps quit smoking/vaping.
 - Not an FDA approved cessation device.
 - FDA authorized 3 mg. and 6 mg. Zyn products with explicit statement that:
 - "The authorization does not allow the company to make reduced risk claims about the products."
- Zynfluencers
 - Tucker Carlson
 - "Then you feel the power rising from your central nervous system, then going outward through all the nerve endings down to the tips of your fingers. And then up here, it just starts crackling the synapses."
 - "Zyn is a lifesaving medical product that enhances male vitality and mental acuity."



IS ZYN THE NEW JUUL? A CAUTIONARY TALE

- Philip Morris International (MPI) bought Swedish Match for \$16 billion in 2022.
- PMI sales are at record highs.
- Sales fueled by sale of Zyn.
- In 2024 shipments of Zyn rose 644 million cans, up by more than half from 2023.
- PMI cannot keep up with the demand.
- Expanding a factory in Kentucky.
- Building a new factory in Colorado for \$600 million.
- PMI pledged to make two-thirds of its income from products like Zyn by 2030.
- ALTRIA bought Juul for \$12.8 million.
 - Within 4 years it was nearly bankrupt by lawsuits blaming it for targeting youth.
 - Or is this wishful thinking?

VAPING BASICS



- **November 2019** – Governor Baker declared public health emergency and ordered a 4-month ban of e-cigarettes.
 - 200 reported cases
 - 82% required hospitalization
 - Of confirmed cases
 - 30% vaped only nicotine
 - 39% vaped only THC
 - 25% vaped nicotine and THC
- **Currently**, more than 1.6 million kids use e-cigarettes
 - 42% of high school users report frequent or daily use.
 - Most popular tobacco/nicotine product used by youth in 2024.
 - Nicotine levels have skyrocketed.
 - As much nicotine as in 20 packs of cigarettes
 - Products designed as video games, guns, etc.
 - CTFK, 2024 National Youth Tobacco Survey

HEALTH CONCERNS – VAPING PRODUCTS

- Youth use of nicotine in any form is unsafe.
 - Interferes with brain development, mental health, and long-term addiction risk. (CDC)
- Heats small particles of nicotine, metal and other substances. Not WATER VAPOR. (https://www.ncbi.nlm.nih.gov/books/NBK507163/?utm_)
- Produces chemicals which can cause lung and heart disease, including formaldehyde and acrolein. (<https://www.cdc.gov/tobacco/e-cigarettes/health-effects.html>)
- High nicotine levels and inaccurate labeling of actual amount of nicotine – can result in nicotine poisoning. (<https://pubmed.ncbi.nlm.nih.gov/38378209>)
- Ultrafine particles are inhaled deep into lungs, sometimes resulting in EVALI, using either nicotine or THC. (CDC)
- Secondhand emissions contain nicotine, ultrafine particles, diacetyl, which is linked to lung disease, and benzene and heavy metals, found in car exhaust. (https://www.heart.org/en/news/2022/05/31/in-secondhand-vape-scientists-smell-risk?utm_)

WHERE DOES THAT LEAVE HEALTH INSPECTORS?

“NEW” FLAVORED PRODUCTS FOUND EVERY DAY IN STORES

SNIFF/TASTE TEST

BUT, NOT AUTHORIZED BY FDA



508) 532-5470
health@framinghamma.gov
www.framinghamma.gov

CITY OF FRAMINGHAM
Public Health Department



188 Concord Street
Room 102
Framingham, MA 01702

July 16, 2025

NOTICE TO TOBACCO PERMIT HOLDERS

At their meeting on July 15, 2025, the City of Framingham Board of Health assessed the following tobacco/nicotine delivery products and determined that they are "flavored tobacco products" under the definition outlined in Massachusetts General Law Chapter 270, Section 28, 105 CMR 665.000 Minimum Standards for Retail Sale of Tobacco and Electronic Nicotine Delivery Systems, and "An Act to Modernize Tobacco Control". These products are prohibited from being sold in retail establishments that are not licensed smoking bars. The list of nicotine delivery products determined to have flavor include:

VAPE

- CRAVE MAX 2500
- NU CLEAR 2500
- SPACE ULTRA CLEAR
- CRAVE CLEAR BC7000
- CRAVE MEGA CLEAR 5500
- BRIXZ CLEAR UNFLAVORED
- OXBAR 35K

NICOTINE POUCH

- BRIXZYN WHITE
- BRIXZYN FRESH
- BRIXZYN CLEAR
- CRAVE CHILL

You are hereby notified the following:

1. These products must not be sold in Framingham after September 1st, 2025;
2. You must confirm by email that you have complied with this notice;
3. Failure to comply will result in a fine of \$1000 per 105 CMR 665.045 (A)(1);
4. Additional enforcement action including fines, permit suspension, or permit revocation, if necessary

The items listed is not final. Additional items may be added as determined by the Framingham Board of Health.

If you have any questions, please contact Parivallal Thillaigovindan pthillaigovindan@framinghamma.gov

Sincerely,

Parivallal Thillaigovindan
Tobacco Control Program Manager
Framingham Public Health Department
188 Concord St Room 102
Framingham MA 01702

LETTER FROM U.S. FOOD & DRUG ADMINISTRATION DATED 12/5/2025



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

12/5/2025

VIA ELECTRONIC MAIL

Joan E. Hamlett, Director
Boards of Health Tobacco Control Alliance
Email: leominsterbohtca@hotmail.com

Dear Director Hamlett:

This correspondence is to follow up on our email and telephone conversations regarding new tobacco products that can be lawfully marketed in the U.S.

A new tobacco product must have FDA authorization before it can be legally marketed in the United States, and generally, products without authorization are at risk of enforcement action.

Public resources are available to determine which products can be lawfully marketed in the U.S. These resources include:

1: [E-Cigarettes, “Vapes” and Other Electronic Nicotine Delivery Systems \(ENDS\) Authorized by the FDA | FDA](#)

To date, FDA has issued marketing granted orders for 39 tobacco- and menthol-flavored e-cigarette products and devices. These are the only e-cigarette products that may be



U.S. Food & Drug Administration
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To date, FDA has issued marketing granted orders for 39 tobacco- and menthol-flavored e-cigarette products and devices. These are the only e-cigarette products that may be lawfully marketed in the U.S. at this time.

2: [Nicotine Pouch Products Authorized by the FDA | FDA](#)

To date, FDA has authorized 20 nicotine pouch products; these are the only nicotine pouch products that may be lawfully marketed in the U.S.

3: [Searchable Tobacco Products Database](#)

FDA's Searchable Tobacco Products Database provides entries for tobacco products that may be legally marketed because they are 1) new tobacco products authorized through one of [three pathways to market](#), 2) established through a voluntary determination program as [pre-existing tobacco products](#) (commercially marketed as of Feb. 15, 2007), or 3) provisional tobacco products that were [removed from review](#).

FDA has not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization. The pendency of an application does not create a legal safe

harbor to sell that product. (this information can likewise be found online, at [Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products | FDA](#))

I trust this information is useful to your organization in enforcing the requirements of the Commonwealth of Massachusetts.

If you have any questions regarding this letter, you may contact me directly at John.Verbeten@fda.hhs.gov or contact CTP at CTPCompliance@fda.hhs.gov.

Sincerely,

John Verbeten
Director, Office of Compliance and Enforcement
Center for Tobacco Products

cc: Ms. Cheryl Sbarra, Massachusetts Association of Health Boards
sbarra@mahb.org

HIGHLIGHTS FROM LETTER

- “A new tobacco product must have FDA authorization before it can be legally marketed in the United States . . .”
- Only products with Marketing Granted Orders can be sold in the United States.
- “Public resources are available to determine which products can be lawfully marketed in the U.S.”
- “The pendency of an application does not create a legal safe harbor to sell that product.”
- “I trust this information is useful to your organization in enforcing the requirements of the Commonwealth of Massachusetts.”
- Signed by John Verbeten, Director, Office of Compliance and Enforcement, Center for Tobacco Products as the FDA.
- Directed to Joan Hamlett, Director, Boards of Health Tobacco Control Alliance.
- Cc” Cheryl Sbarra, Massachusetts Association of Health Boards

Searchable Tobacco Products Database

This database provides entries for tobacco products that may be legally marketed because they are 1) new tobacco products authorized through one of [three pathways to market](#), 2) established through a voluntary determination program as [pre-existing tobacco products](#) (commercially marketed as of Feb. 15, 2007), or 3) provisional tobacco products that were [removed from review](#). For more information on database terminology and Q&A, visit [Searchable Tobacco Products Database - Additional Information](#).

FDA also maintains a [printable flyer of authorized e-cigarettes](#).

No tobacco product is safe, and it is illegal to sell tobacco products to anyone under 21. Products in this database may be the subject of agency action for other reasons.

[Download All Records](#) 📄

Search the Database ?

Search Company, Product Name, STN, MRTPT, Additional Information

Category

Select options

Sub-Category

Select options

Submission Type - Marketing Authority

Select options

Date of Action From

mm/dd/yyyy



Date of Action To

mm/dd/yyyy



Search 🔍

Reset ↺

Company	Product Name	Category	Sub-Category	Submission Type - Marketing Authority	Date of Action	Order Letter	Decision Summary	Environmental Assessment	FONSI	STN	Associated MRTPT	Additional Information
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Search the Database ?

Search Company, Product Name, STN, MRTP, Additional Information

Category

Other

☒ Check all ☒ Uncheck all

☐ E-Cigarette

☐ Cigar

☐ Pipe

☐ Waterpipe/Hookah

☐ Heated Tobacco Product

☒ Other

Sub-Category

Select options

Date of Action To

mm/dd/yyyy

[Search](#) 🔍[Reset](#) ↺

Submission Type - Marketing Authority

Select options

Submission Type -
Marketing Authority

Date of Action

Order Letter

Decision Summary

Environmental
Assessment

FONSI

STN

Associated
MRTP

Additional
Information

Company ⇅	Product Name ⇅	Category ⇅	Sub-Category ⇅	Submission Type - Marketing Authority ⇅	Date of Action ▼	Order Letter	Decision Summary	Environmental Assessment	FONSI	STN ⇅	Associated MRTP	Additional Information
Helix Innovations LLC	on! PLUS nicotine pouches 6 mg Mint	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD10		
Helix Innovations LLC	on! PLUS nicotine pouches 9 mg Mint	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD11		
Helix Innovations LLC	on! PLUS nicotine pouches 6 mg Tobacco	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD13		
Helix Innovations LLC	on! PLUS nicotine pouches 9 mg Tobacco	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD14		
Helix Innovations LLC	on! PLUS nicotine pouches 6 mg Wintergreen	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD16		
Helix Innovations LLC	on! PLUS nicotine pouches 9 mg Wintergreen	Other	Other	PMTA - Marketing Granted Order	12/19/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0009121.PD17		
Swedish Match USA, Inc.	ZYN Cool Mint 3 mg	Other	Other	PMTA - Marketing Granted Order	01/16/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0000593.PD1		This product is commonly referred to as a nicotine pouch.
Swedish Match USA, Inc.	ZYN Cool Mint 6 mg	Other	Other	PMTA - Marketing Granted Order	01/16/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0000594.PD1		This product is commonly referred to as a nicotine pouch.
Swedish Match USA, Inc.	ZYN Peppermint 3 mg	Other	Other	PMTA - Marketing Granted Order	01/16/2025	Order Letter	Decision Summary	Environmental Assessment	FONSI	PM0000595.PD1		This product is commonly referred to as a nicotine pouch.

PRODUCTS WITH MARKETING GRANTED ORDERS

AS OF 12/19/2025

- 39 vapes:
 - Vuse
 - Juul
 - NJOY
 - Logic
- Some are just the tanks and accessories.
- At least 6 are flavored and cannot be sold in MA
- 30 pouches:
 - on!
 - VERVE
 - ZYN
- 2 of them are labeled “tobacco” flavored. (on!)

ENFORCEMENT STRATEGY MOVING FORWARD

- MA local tobacco sales regulations require applicants to sign a statement affirming their responsibility to comply with all federal, state and local laws.
- Marketing Granted Orders are one such federal requirement.
- FDA currently mandates that only products with Marketing Granted Orders may be sold in the U.S.
- We are not enforcing the FDA mandate, but rather we are enforcing one part of the local regulation that says applicants must comply with all federal, state and local requirements.
- Remember that MA local tobacco sales regulations are more comprehensive than FDA requirements. For example, MA prohibits flavored nicotine products.
- **Review this with your municipal attorney!** Vapor Tech. Ass'n v. Wooten Docket No. 25CV00076-M-RJ, (E.D. NC 6/27/15 7/3/25)

NEXT STEPS

- Template Guidance Document to share with Health Departments, Tobacco Control Collaboratives, municipal attorneys.
 - Suggested protocol
 - Notice to retailers
 - Written template drafted
 - Educational visits
 - Request removal of products without Marketing Granted Orders
 - Document products without Marketing Granted Orders if not removed at next visit
 - Report products without orders to the FDA illegal tobacco products portal
 - Report findings to board of health

QUESTIONS AND CONTACT INFORMATION

- Cheryl Sbarra, Esq., Executive Director and Senior Staff Attorney, Massachusetts Association of Health Boards, sbarra@mahb.org
- Christopher Banthin, Esq., Program Manager, Public Health Advocacy Institute, chrisbanthin@phaionline.org
- Lisa Stevens-Goodnight, Esq., Tobacco Control Director, Massachusetts Municipal Association, lstevensgoodnight@mma.org
- Sarah McColgan, Tobacco Control Director, Massachusetts Health Officers Association, smccolgan@mhoa.com