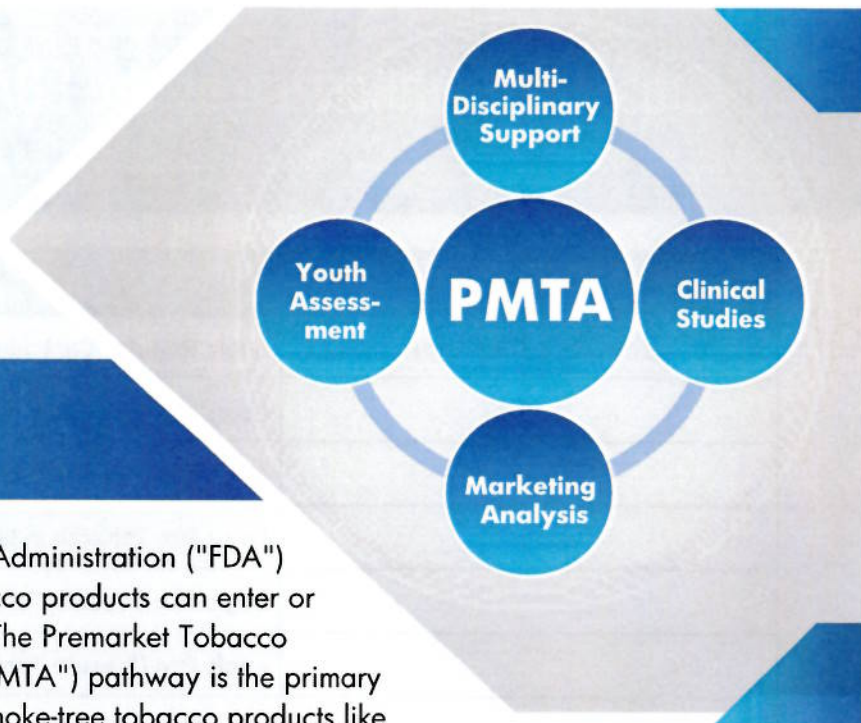
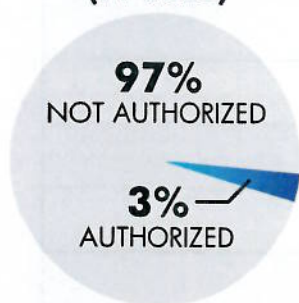


The Premarket Tobacco Product Application (PMTA)

A Science and Evidence-Based Product Review by FDA



Estimated Total E-Vapor Category Volume (FY 2022)



The U.S. Food & Drug Administration ("FDA") determines which tobacco products can enter or remain on the market. The Premarket Tobacco Product Application ("PMTA") pathway is the primary avenue to market for smoke-free tobacco products like e-vapor, heated tobacco ("heat-not-burn"), and nicotine pouches products.

The PMTA pathway offers promise as a comprehensive science and evidence-based examination of new tobacco products. To enter the market, manufacturers must demonstrate that the entry of each new tobacco product "is appropriate for the protection of the public health." (1)



PMTA submission requirements include: (2)

- Assessment of the impact of the product on tobacco use initiation by non-users, including youth
- The pharmacological profile of the product, including the impact of nicotine in clinical studies
- Studies of consumer perception and intent to use it
- Toxicological profile of the product which may include preclinical testing for genotoxicity, carcinogenicity, and reproductive toxicity
- Information about how consumers actually use the product and switch from more harmful tobacco products



Products

- Detailed description of manufacturing
- Youth Assessment
- Multi- Disciplinary Support
- PMTA
- Marketing Analysis
- Clinical Studies

For context, the PMTA application for on!® nicotine pouches was over 65,000 pages and included 6 original studies.

Even following authorization, FDA has stringent post-market surveillance authority and may revoke authorization.

1 FDCA 910(c)(4).

2 See, e.g., Premarket Tobacco Product Applications and Recordkeeping Requirements 84 Fed. Reg. 50,566, Sept. 25, 2019, <https://www.govinfo.gov/content/pkg/FR-2019-09-25/pdf/2019-20315.pdf>

E-Cigarettes Authorized by the FDA

As of Jan. 2024, these are the only e-cigarettes authorized to be sold in the U.S.



Manufacturer	Product Name
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package
	Logic Vapeleaf Cartridge/Capsule Package
	Logic Vapeleaf Tobacco Vapor System
	Logic Pro Tobacco e-Liquid Package
	Logic Pro Capsule Tank System (1)
	Logic Pro Capsule Tank System (2)
	Logic Power Tobacco e-Liquid Package
	Logic Power Rechargeable Kit
	NJOY LLC
NJOY DAILY EXTRA Rich Tobacco 6%	
NJOY ACE Device	
NJOY ACE POD Classic Tobacco 2.4%	
NJOY ACE POD Classic Tobacco 5%	
NJOY ACE POD Rich Tobacco 5%	
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)
	Vuse Vibe Tank Original 3.0%
	Vuse Vibe Power Unit (2)
	Vuse Ciro Power Unit (1)
	Vuse Ciro Cartridge Original 1.5%
	Vuse Ciro Power Unit (2)
	Vuse Solo Power Unit
	Vuse Replacement Cartridge Original 4.8% G1
	Vuse Replacement Cartridge Original 4.8% G2

For the most up-to-date list of authorized e-cigarettes, visit the [Premarket Tobacco Product Marketing Granted Orders webpage](#).

While these products are authorized to be sold in the U.S., it does not mean these products are safe nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.



Facts, Figures, and Statistics Supporting a Ban

- **It is well-established that e-cigarettes are not safe for kids.** Their use poses a significant - and unavoidable - health risk to young people in the United States.⁵ Risks include increasing the possibility of:
 - Addiction
 - Harm to brain development
 - Harm to respiratory health
 - Use of other harmful tobacco products
- **Flavors lure young people into using e-cigarettes.**
 - Of youth who have tried tobacco, 75% first tried it using vape products.⁶
 - 11.2% of 6-12th graders have vaped nicotine and 17.5% of 12th graders.⁶
 - Greater than 90% of all kids start with flavored tobacco products.
 - Flavor makes vape juice more toxic and damaging to the lungs. The chemicals used to flavor e-cigarettes contain harmful toxins.
- **Teens are more likely to develop a lifetime addiction with flavored vape use.** This has been found when teens start vaping with sweet flavors like cotton candy or mango.⁹
- **The American Lung Association strongly supports clearing all flavored products from the market, including menthol.**
- **Permitting the sale of all varieties of flavored e-cigarettes in specialty tobacco shops creates the illusion of protection but in reality, creates an underground channel of distribution to anyone under 21 years old.** The majority of youth (51.6%) borrow vape products from someone else, give someone money to buy them, or receive them from a person over 18 years old.
- **Vaping is more popular with Utah teens than adults.** 9.7% of Utah high school students reported they had vaped compared to 6.8% of adults.¹⁰
- **There is public support for bans:** 57% of Americans support a policy prohibiting the sale of all tobacco products.
- **Cost burden is high -** \$630 million annual health care costs in Utah directly caused by tobacco products.

References:

1. Tobacco Sales - Utah Tobacco Laws
2. FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint | FDA
3. China e-cigarette titan behind 'Elf Bar' floods the U.S. with illegal vapes (cnbc.com)
4. U.S. Supreme Court lets California ban flavored tobacco products | Reuters
5. Know the Risks: E-cigarettes & Young People | U.S. Surgeon General's Report
6. SHARP
7. Harrell MB, Loukas A, Jackson CD, Marti CN, Perry CL. Flavored Tobacco Product Use among Youth and Young Adults: What if Flavors Didn't Exist? *Tob Regul Sci.* 2017 Apr;3(2):168-173. doi: 10.18001/TRS.3.2.4. PMID: 28775996; PMCID: PMC5536860.
8. Chandra, D., Bogdanoff, R.F., Bowler, R.P. et al. Electronic cigarette menthol flavoring is associated with increased inhaled micro and sub-micron particles and worse lung function in combustion cigarette smokers. *Respir Res* 24, 108 (2023). <https://doi.org/10.1186/s12931-023-02410-9>
9. The American Lung Association
10. (Utah BRFSS 2020)

Flavors vaped most often by Utah youth, grades 8, 10, 12, SHARP PNA 2023

