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 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