WARNING LETTER

[Retail Establishment Name]
Attn: Site Manager
[Retailer Address]
[City, State] [Zip Code]

Re: **FDA Warning Letter Regarding Tobacco Retailer Inspection Violation**
Reference Number: **[Assignment ##]**

Dear Sir or Madam:

This Warning Letter is notification from the United States Food and Drug Administration (FDA) advising you that **[Retail Establishment Name]** was observed to be in violation of federal tobacco laws and regulations. Failure to address this violation may result in FDA initiating regulatory or legal action, including monetary penalties. Your response is requested in 15 working days.

New Tobacco Products Without Required Marketing Authorization are Adulterated and Misbranded

On **[Inspection Date]**, an inspector representing the FDA completed an inspection of the establishment located at **[Retailer Address]**, **[City, State] [Zip Code]**. During this inspection, the establishment was in violation because your establishment offered for sale an electronic nicotine delivery system (ENDS) product that lacks the required marketing authorization.

This inspection revealed that the establishment sells and/or distributes tobacco products, including ENDS products, which requires that the establishment and its owners comply with federal laws and regulations governing the sale, distribution, and/or advertising of such products. The violation observed during the **[Inspection Date]**, inspection includes the following:

1. The establishment offered for sale tobacco products that are required to have, but lack, premarket authorization. Specifically, on **[Inspection Date]**, the establishment offered for sale a **[Brand Name]** ENDS product.

   Generally, to be legally marketed in the United States, the FD&C Act requires "new tobacco products" to have a premarket authorization order in effect. A "new tobacco product" is any tobacco product that was not commercially marketed in the United States as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007 (Section 910(a) of the FD&C Act; 21 U.S.C. § 387j(a)). Generally, a marketing authorization order under

Section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. § 387j(c)(1)(A)(i)) is required for a new tobacco product unless (1) the manufacturer of the product submitted a report under Section 905(j) of the FD&C Act (21 U.S.C. § 387e(j)) and FDA issues an order finding the product substantially equivalent to a predicate tobacco product (Section 910(a)(2)(A) of the FD&C Act) or (2) the manufacturer submitted a report under Section 905(j)(1)(A)(ii) of the FD&C Act (21 U.S.C. § 387e(j)(1)(A)(ii)) and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA under Section 905(j)(3) of the FD&C Act (21 U.S.C. § 387e(j)(3)).

The ENDS product listed above is a new tobacco product because it was not commercially marketed in the United States as of February 15, 2007. This product does not have an FDA marketing authorization order in effect under Section 910(c)(1)(A)(i) of the FD&C Act and is not otherwise exempt from the marketing authorization requirement. Therefore, this product is adulterated under Section 902(6)(A) of the FD&C Act (21 U.S.C. § 387b(6)(A)). In addition, it is misbranded under Section 903(a)(6) of the FD&C Act (21 U.S.C. § 387c(a)(6)) because a notice or other information respecting this product was not provided as required by section 905(j) of the FD&C Act (21 U.S.C. § 387e(j)).

The listed violation causes the ENDS product you offer for sale or distribution in the United States to be "adulterated" and "misbranded" under Sections 902 and 903 of the FD&C Act.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), this product is a tobacco product because it is made or derived from tobacco or contains nicotine from any source, and is intended for human consumption. Certain tobacco products, including ENDS products, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1, and are required to be in compliance with the requirements in the FD&C Act.

On March 15, 2022, the President signed legislation to amend the FD&C Act to extend FDA's jurisdiction to products "containing nicotine from any source," not just nicotine derived from tobacco. *See* Consolidated Appropriations Act, 2022, Public Law 117-103, Division P, Subtitle B. Specifically, this legislation expanded the definition of "tobacco product" under 21 U.S.C. § 321(rr) to include products containing nicotine from any source. Tobacco products, including ENDS products, containing nicotine from any source, must be in compliance with the FD&C Act and its implementing regulations. For more information, please see, https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14.

As of April 14, 2022, it is illegal for a retailer to sell any tobacco product, containing nicotine from any source – including cigarettes, smokeless tobacco, cigars, and e-cigarettes – to anyone under 21.

Please be aware that the FD&C Act requires “new tobacco products” to have premarket authorization. A “new tobacco product” is any tobacco product that was not commercially marketed in the United States as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007. *See* Section 910(a) of the FD&C Act.

Conclusion and Requested Actions

FDA has determined that your establishment markets new tobacco products lacking premarket authorization in the United States. All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA’s discretion.

For a list of products that received marketing granted orders, please visit our website: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#PMTAView%20all%20marketing%20granted.

You should take prompt action to address the violation listed above. Failure to address any violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., Chapter IX, relating to tobacco products including the tobacco regulations in 21 C.F.R. Parts 1140, 1141, and 1143, may result in FDA initiating regulatory or legal action. These actions may include, but are not limited to, civil money penalty, no-tobacco-sale order, seizure, and/or injunction. However, this Warning Letter does not constitute "written notice" for purposes of Section 303(f)(9)(B)(i)(II) of the FD&C Act.

Please note that this warning letter does not constitute final agency action, but if you have evidence or information that you believe demonstrates that this notice was issued in error, you should preserve any evidence or information relevant to this warning letter in the event FDA initiates regulatory or legal action at a later date.

Your establishment may have previously received a Warning Letter, Civil Monetary Penalty, or No-Tobacco-Sale Order from FDA. Although this Warning Letter includes violation(s) of Sections 902 and 903 of the FD&C Act, please remember your ongoing obligation to comply with the regulations in 21 C.F.R. Part 1140.

The violation indicated in this letter may not be a complete list of violations at the establishment.

We will periodically inspect your establishment and review your promotional activities (e.g., website(s)) related to FDA-regulated tobacco products to assess your compliance with all applicable laws and regulations, including access, marketing, labeling, and advertising restrictions.

For more information on these requirements, helpful resources for retailers, a database of inspections, and retailer education materials, visit our website at

http://www.fda.gov/TobaccoProducts. The following Guidance documents provide additional information on compliance with retailer responsibilities:

> *Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance)
>
> *Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements* (https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance)
>
> *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance).

You have 15 working days from the date you receive this letter to respond. In your written response, explain your plan for addressing the listed violation and preventing future violations. Include a telephone number and address. Note your reference number of **[Assignment #]** in your response and mail it to:

> Food and Drug Administration
> Center for Tobacco Products
> Document Control Center
> Building 71, Room G335
> 10903 New Hampshire Avenue
> Silver Spring, MD 20993-0002

If you have any questions, contact the Center for Tobacco Products via email at CTP-WL@fda.hhs.gov or via phone at 1-877-CTP-1373. Have your reference number ready when you call and include it with any email communications.

Sincerely,

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products