WARNING LETTER

Name of Establishment
Attn: Site Manager
Address
City, State Zip Code

Re: **FDA Warning Letter Regarding Tobacco Retailer Inspection Violations**
Reference Number: [Inspection No.]

Dear Sir or Madam:

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

On XX/XX/XXXX, an inspector representing the FDA completed an inspection of the establishment located at Address, City, State Zip Code. During this inspection, the establishment was in violation because your establishment offered for sale electronic nicotine delivery system (ENDS) products without the required marketing authorization.

This inspection revealed that the establishment sells, distributes, and/or advertises tobacco products, including electronic nicotine delivery system (ENDS) products, which requires that the establishment and its owners comply with federal laws and regulations governing such practices. The violations observed during the XX/XX/XXXX, inspection include the following:

1. The establishment offered for sale tobacco products that are required to have, but lack, premarket authorization. Specifically, on XX/XX/XXXX, an inspector observed a [product] electronic nicotine delivery system (ENDS) product and a [product] electronic nicotine delivery system (ENDS) product for sale.

   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 (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 products listed above are new tobacco products because they were not commercially marketed in the United States as of February 15, 2007. These products do not have FDA marketing authorization orders in effect under section 910(c)(1)(A)(i) of the FD&C Act and are not otherwise exempt from the marketing authorization requirement. Therefore, these products are adulterated under section 902(6)(A) of the FD&C Act. In addition, they are misbranded under section 903(a)(6) of the FD&C Act because a notice or other information respecting these products was not provided as required by section 905(j) of the FD&C Act (21 U.S.C. § 387e(j)).

The listed violations cause your tobacco products to be “adulterated” and “misbranded” under sections 902(6)(A) and 903(a)(6) of the FD&C Act.

You should take prompt action to address the violations listed above. Failure to address any violations of the type described above may result in FDA taking regulatory action. These actions may include, but are not limited to, civil money penalty, 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.

Your establishment may have previously received a Warning Letter, Civil Monetary Penalty, or No-Tobacco-Sale Order from FDA. Although this Warning Letter includes violations 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 violations 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.

Please be aware that, effective August 8, 2016, FDA deemed additional products meeting the definition of a tobacco product, except accessories to these newly deemed products, to be subject to regulation under the Act. These products include, but are not limited to, electronic nicotine delivery systems (including e-cigarettes), e-liquids, cigars, and pipe tobacco. *See* Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products

and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016), available at https://federalregister.gov/a/2016-10685.

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)
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> *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)
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> *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 correcting the listed violations and preventing future violations. If you do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. Include a telephone number and address. Note your reference number of [Inspection No.] 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, option 6. 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