WARNING LETTER

VIA UPS

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 correct these violations may lead to federal enforcement actions, 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 you or your employee sold an e-liquid product to a minor and failed to check identification to verify purchaser's age for a purchaser under the age of 27.

This inspection revealed that the establishment sells, distributes, and/or advertises tobacco products, including e-liquid 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. A minor was able to buy a JUUL e-liquid product on XX/XX/XXXX, at approximately XX:XX AM/PM in the establishment.

   A retailer must NOT sell covered tobacco products, such as e-liquid products, to a person younger than 18 years of age. Doing so violates 21 C.F.R. § 1140.14(b)(1) (2016).

2. No one in the establishment checked the minor’s identification before the sale of a JUUL e-liquid product on XX/XX/XXXX, at approximately XX:XX AM/PM.

   A retailer MUST check a photographic identification that includes a date of birth for any person under the age of 27 who attempts to purchase covered tobacco products, such as e-liquid products. Failure to do so violates 21 C.F.R. § 1140.14(b)(2)(i) (2016).

The listed violations cause your e-liquid product to be “misbranded” under 903 of the FD&C Act (21 U.S.C. § 387c).

You should immediately correct the violations listed above. Failure to correct the violations may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalty, no-tobacco-sale order, seizure, and/or injunction.

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* (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252758.htm)
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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* (http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499353.htm).

You have 15 working days from the date you receive this letter to respond. In your response, explain your plan for correcting the listed violations and preventing future violations. 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