WARNING LETTER

Vape Hut, LLC d/b/a Vape Hut Kratom-CBD

MARCS-CMS 708451 — JUNE 05, 2025

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Delivery Method:
VIA UPS and Electronic Mail
Product:
Tobacco

Recipient:
Vape Hut, LLC d/b/a Vape Hut Kratom-CBD
2331 Eureka Road
Wyandotte, MI 48192
United States

Issuing Office:
Center for Tobacco Products
United States

June 5, 2025

WARNING LETTER

To Whom It May Concern:

The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed our inspection records and determined that Vape Hut, LLC, d/b/a Vape Hut Kratom - CBD sells and/or distributes electronic nicotine delivery system (ENDS) products to customers in the United States.

Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), these products are tobacco products because they are made or derived from tobacco or contain nicotine from any source and 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.

Please be aware that, 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, Title I, Subtitle B. Specifically, this legislation expanded the definition of "tobacco product" under section 201(rr) of the FD&C Act (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.

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)).

New Tobacco Products Without Required Marketing Authorization Are Adulterated and Misbranded

FDA has determined that you offer for sale or distribution to customers in the United States ENDS products that lack a marketing authorization order, including: North Clear 10ml 5% nicotine.

The tobacco 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.

Conclusion and Requested Actions

FDA has determined that your firm markets new tobacco products in the United States that lack premarket authorization. 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.

It is your responsibility to ensure that all tobacco products you sell and/or distribute in the United States and all related labeling and/or advertising on any websites or other media (such as e-commerce, social networking, or search engine websites), and in any retail establishments in which you advertise, comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to address any violations of the FD&C Act, 21 U.S.C. § 301 et seq. or its implementing regulations relating to tobacco products including the tobacco regulations in 21 C.F.R. Parts 1140, 1141, or 1143, may lead to regulatory action, including, but not limited to, civil money penalties, 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 tobacco products offered for import into the United States that appear to be adulterated and/or misbranded may be detained or refused admission.

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should take prompt action to address any violations that are referenced above, as well as violations that are the same as or similar to the ones stated above, and take any necessary actions to bring these tobacco products into compliance with the FD&C Act.

Please submit a written response to this letter within 15 working days from the date of receipt describing your actions to address any violations and bring these products into compliance, including the dates on which you discontinued the violative sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act. If you believe that these products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. This letter notifies you of our findings and provides you with an opportunity to address them. You can find the FD&C Act through links on FDA’s homepage at http://www.fda.gov.

Please note your reference number, ER2501205, in your response and direct your response to the following address:

DEM-WL Response, Office of Compliance and Enforcement
FDA Center for Tobacco Products
c/o Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions about the content of this letter, please contact CTPCompliance@fda.hhs.gov.

Sincerely,
/S/

John E. Verbeten
Director
Office of Compliance and Enforcement
Center for Tobacco Products