U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

September 17, 2025

VIA UPS AND ELECTRONIC MAIL

Mr. Patrick Murphy
Vice President, Scientific & Regulatory Affairs
R.J. Reynolds Vapor Company
100 Moore RJR Drive 12
Tobaccoville, NC 27050
(b)(6) @rjrt.com

(b)(4)

Dear Mr. Murphy:

It has come to our attention that R.J. Reynolds Vapor Company (RJRV) may intend to, or may currently, sell and/or distribute new finished tobacco products to customers in the U.S., specifically Vuse One branded electronic nicotine delivery system (ENDS) products, without the required premarket authorization under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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).

To date, FDA has not issued a marketing granted order for any Vuse One branded ENDS products. (b)(4) New tobacco products marketed without the statutorily required premarket authorization are marketed unlawfully and may be subject to enforcement action at FDA's discretion, including, but not limited to, civil money penalties, seizure, and/or injunction. FDA has not adopted a broad policy of enforcement discretion regarding the marketing of new tobacco products without an authorization. We can issue, and have issued, warning letters for products subject to a pending application. As FDA has repeatedly stated, and as evidenced by the recent enforcement actions undertaken by the Agency in conjunction with U.S. Department of Justice federal partners,[1] enforcing against unauthorized tobacco products is among the Agency's highest enforcement priorities.

[1] For more information about these enforcement actions, see https://www.justice.gov/opa/video/attorney-general-bondi-hhs-secretary-kennedy-make-significant-law-enforcement.

If you are selling or distributing any Vuse One branded ENDS products in the United States, please provide information on the sale and distribution of such products, including URLs of websites that sell, distribute, and/or offer for sale and/or distribution Vuse One branded ENDS products, including the dates of initial sales and distribution of such products to U.S. customers.

Please submit the requested information within 3 business days of receipt of this letter. (b)(4) [redacted]

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[2],[3] using eSubmitter.[4] Alternatively, submissions may be mailed to:

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

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date. Deliveries must be on or before the due date; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. FDA is unable to accept regulatory submissions by e-mail.

If you have any questions regarding this letter, please contact CTP at CTPCompliance@fda.hhs.gov.

Sincerely,

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

[2]For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[3] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[4] For more information about eSubmitter, see http://www.fda.gov/ForIndustry/FDAeSubmitter.