



Gate Service Station #1201
Attn: Site Manager
619 A1A North
Ponte Vedra Beach, FL 32082

OCT 06 2025

Re: Unauthorized Tobacco Product Marketing Observations: Vuse One ENDS
Reference Number: 25FL129083

To whom it may concern:

On September 15, 2025, inspectors representing the Food and Drug Administration (FDA), Center for Tobacco Products performed a tobacco retailer compliance check inspection at your establishment. During that inspection, it was observed that tobacco product marketing materials were on display for Vuse One electronic nicotine delivery system (ENDS) products. These materials indicated that the product was new or coming soon.

Vuse One ENDS products lack the required premarket authorization (PMTA) under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). To be legally marketed in the United States, the FD&C Act requires “new tobacco products” to have a PMTA 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).

Since these products do not have a marketing granted order at this time, Vuse One ENDS products are marketed unlawfully and may be subject to enforcement action at FDA’s discretion.

If FDA finds evidence of PMTA violations during a future inspection, your establishment may be subject to a warning letter or enforcement actions at FDA’s discretion, including, but not limited to: civil money penalties, seizure, and/or injunction.

FDA maintains a list of products that may be legally marketed. The ‘Searchable Tobacco Products Database’ is available at: www.fda.gov/searchtobacco. This is a user-friendly list of tobacco products—including e-cigarettes—that may be legally marketed in the United States. This website also contains a link to a printable flyer of authorized e-cigarettes.

FDA encourages you to contact R.J. Reynolds Vapor Company (RJR) to discuss possible options for any such products that you may have in your current inventory.

Sincerely,

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