Decision on FDA's PMTA Review of VUSE SOLO

Reynolds PMTA Update

On October 12, 2021 VUSE SOLO received the first of its kind U.S. Food and Drug Administration (FDA) marketing authorization for vapor products, and FDA's orders confirm that the marketing of VUSE SOLO products are appropriate for the protection of the public health, underscoring years of scientific study and research dedicated to ensuring that adult nicotine consumers (ANCs) age 21+ have access to innovative and potentially less harmful alternatives to traditional tobacco products. The first FDA Marketing Order has been granted for 3 VUSE products – the VUSE SOLO Power Unit, VUSE SOLO Replacement Cartridge Original (Tobacco) 4.8% G1, and VUSE SOLO Replacement Cartridge Original (Tobacco) 4.8% G2.

Background on PMTA

The FDA requires a Pre-Market Tobacco Application (PMTA) submission be filed for any new-to-market tobacco product before it can be sold in the U.S. This process evaluates vapor and modern oral products against the FDA's high standard as considered appropriate for the protection of public health. Once a PMTA submission is approved, a Marketing Order is issued by the FDA authorizing the products for sale. Products which have already submitted a PMTA prior to the September 9, 2021 deadline but have not received a denial are considered under review and may remain on the market at FDA enforcement discretion.

Frequently Asked Questions

Q: How will Reynolds let us know if a product's application has been denied or approved?
Your Reynolds Marketing Services representative will continue to communicate with you on a regular basis and will keep you informed as we receive further updates from the FDA. The FDA posts marketing order updates on their website as well.

Q: Can Reynolds VUSE and VELO products continue to be sold beyond September 9, 2021 if there is no FDA decision on the PMTA by this date?
Yes, it is our understanding that we are able to lawfully sell products for which we have submitted PMTAs, subject to ongoing enforcement discretion by the FDA. We have not received a decision on our VUSE SOLO menthol flavor or our other VUSE and VELO products, meaning all currently marketed VUSE and VELO products can remain on the market subject to further review by the FDA.

Q: Will the PMTA change anything about your product marketing?
Responsible marketing already underscores everything we execute at Reynolds, and we believe new category nicotine products can be produced, marketed and sold responsibly to adult nicotine consumers with only that group in mind. Marketing Orders are subject to review and can be suspended or revoked after being granted, and the FDA has established post-market surveillance requirements and reporting for these products, including monitoring potential youth uptake.

Q: What will happen with products that receive a marketing denial order from FDA?
The FDA issued Marketing Denial Orders for five VUSE SOLO flavors (not tobacco or menthol) that are not currently on the market. Regarding the FDA's limited concerns on those applications not currently on the market, we are carefully studying the agency analysis and decision. We will continue to assess the impact of the agency's decision as it relates to existing VUSE SOLO availability at reputable retailers across the country. Should Reynolds need to remove any of its existing products from the market in the future, we will coordinate directly with retailers to ensure compliance with applicable regulations.

To learn more about the PMTA process and Reynolds product innovations, visit RJRVapor.com/PMTA. Please direct any further questions to your designated Trade Marketing representative.