VELO Pouch Premarket Tobacco Applications Submitted to FDA for Review by Reynolds

VELO pouch is second group of PMTAs for VELO products, and completes current VELO brand PMTA submissions

WINSTON-SALEM, N.C., Sept. 1, 2020 /PRNewswire/ -- Reynolds American Inc. ("Reynolds") announces today the submission of a group of Premarket Tobacco Product Applications ("PMTAs") to the U.S. Food and Drug Administration ("FDA") seeking orders authorizing the marketing of VELO pouches. A grant of these marketing orders would allow these products to remain on the market after FDA review.

VELO is the group's brand for modern oral products, designed to provide adult tobacco consumers with innovative alternatives to traditional combustible and smokeless tobacco products. The VELO pouch, which is made with nicotine derived from tobacco but contains no tobacco leaf, is a small, white pouch that is placed between an adult tobacco consumer's gum and lip. Unlike traditional dip, there is no need to spit the product and no lingering smell. The submitted group of applications includes varying nicotine strength levels and two flavors for VELO pouch products.

As with prior PMTA submissions, these commercially-proprietary applications provide FDA with product analyses, information on human health risks, and assessments showing that these VELO Pouches are appropriate for the protection of public health – including assessments on users and nonusers of tobacco products.

"VELO represents an innovative space for us to identify what adult tobacco consumers want next – thus submitting the final group of VELO brand PMTAs was a great next step to help ensure adult tobacco consumers have consumer-acceptable products available that provide them with lifestyle choices and varying nicotine levels that make sense," stated Reynolds' Executive Vice President and Head of Scientific & Regulatory Affairs, Dr. James Figlar. "As the FDA begins evaluation of our industry's collective PMTAs after the September 9 deadline, it is critical that our chief regulatory agency continues to enforce against illegally marketed tobacco products introduced after August 8, 2016."

The PMTAs for VELO pouches are part of Reynolds' ongoing submissions to the FDA seeking marketing orders, following applications for VELO lozenges and Vuse Vibe, Ciro and Solo electronic nicotine delivery systems. The PMTA process allows the FDA to evaluate whether these products should remain on the market as part of the FDA's public health mission. While these applications include relative risk information, it should be noted that the marketing orders sought make no claims of modified risk.

About Reynolds American Inc.
Reynolds American Inc. is an indirect, wholly owned subsidiary of British American Tobacco p.l.c., and the U.S. parent company of R. J. Reynolds Tobacco Company; Santa Fe Natural Tobacco Company, Inc.; American Snuff Company, LLC; R. J. Reynolds Vapor Company; and Kentucky BioProcessing, Inc.

- R. J. Reynolds Tobacco Company (RJRT) is the second-largest U.S. tobacco company. RJRT's brands include Newport, Camel and Pall Mall.
- Santa Fe Natural Tobacco Company, Inc. manufactures and markets Natural American Spirit products in the United States.
- American Snuff Company, LLC is the nation's second-largest manufacturer of smokeless tobacco products. Its leading brands are Grizzly and Kodiak.
- R. J. Reynolds Vapor Company (RJRV) markets vapor products and modern oral products, including VUSE, VELO and REVEL.
- Kentucky BioProcessing, Inc. conducts research and development related to protein expression and extraction from tobacco plants.

To learn more about Reynolds American Inc. and its operating companies, please visit www.reynoldsamerican.com.

Engage Socially

Twitter: https://www.twitter.com/RAI_News
LinkedIn: https://www.linkedin.com/company/rj-reynolds/
Facebook: https://www.facebook.com/ReynoldsAmericanInc/

SOURCE Reynolds American Inc.

For further information: Kaelan Hollon, 202-421-4921, hollonn@rjrt.com

---

https://rjvapor.thecampaignroom.com/2020-09-01-VELO-Pouch-Premarket-Tobacco-Applications-Submitted-to-FDA-for-Review-by-Reynolds