RJ Reynolds Newsroom

Reynolds Submits First VELO Dissolvable Nicotine Lozenge Premarket Tobacco Product Applications

FDA applications are a first for VELO's dissolvable nicotine lozenges

WINSTON-SALEM, N.C., Aug. 24, 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 dissolvable nicotine lozenges. A grant of these marketing orders would allow these products to remain on the market after the FDA's September 9, 2020 deadline for PMTAs.

VELO Lozenges – formerly sold under the REVEL brand – were reintroduced under the VELO brand in 2020 by Reynolds subsidiary R.J. Reynolds Vapor Company. VELO is the group's brand for modern oral products. VELO Lozenges are designed to provide adult tobacco consumers with innovative alternatives to traditional combustible and smokeless tobacco products. VELO's dissolvable oral nicotine lozenge products are available in hard and soft forms and four flavor variants Dark Mint, Mint, Berry, and Crema. VELO Lozenges are manufactured using tobacco-derived nicotine.

Although the applications contain confidential commercial information, broadly, the PMTAs for VELO Lozenges highlight key evidence demonstrating that the continued marketing of these products is appropriate for the protection of the public health. The applications include a range of scientific studies using established methodologies for the comparative assessment of tobacco products and associated health risks, including product analyses, information on human health risks, and assessments showing the impact of VELO Lozenges on the health of the population as a whole—including users and nonusers of tobacco products.

"VELO is an award-winning brand bringing consistently innovative products to adult tobacco users, and a potential marketing order for PMTA submission would help to ensure adult tobacco consumers have access to FDA-regulated, consumer-acceptable product alternatives to combustible tobacco," noted Reynolds' Executive Vice President and Head of Scientific and Regulatory Affairs, Dr. James Figlar. "As we've noted in the past, we're hopeful that as our group of PMTAs move forward, the FDA continues to enforce against illegally marketed tobacco products introduced after August 8, 2016."

The PMTAs for VELO lozenges are part of Reynolds' ongoing submissions to the FDA seeking marketing orders, following applications for Vuse Vibe, Ciro and Solo electronic nicotine delivery devices. 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 are not statements 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.

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