RJ Reynolds Newsroom

REYNOLDS SUBMITS SECOND AND THIRD COMPLETE PREMARKET TOBACCO PRODUCT APPLICATIONS

Vuse Vibe and Vuse Ciro join Reynolds' Prior Vuse Solo Submission to FDA

WINSTON-SALEM, N.C. – April 15, 2020 - Reynolds American ("Reynolds") announced today that it has submitted two new Premarket Tobacco Product Applications ("PMTAs") to the U.S. Food and Drug Administration ("FDA"). Reynolds is seeking marketing orders for their Vuse Vibe and Vuse Ciro vapor products, which would allow these products to remain on the market after the FDA's May 12, 2020 deadline for PMTA applications for Electronic Nicotine Delivery Systems ("ENDS"). The PMTAs include multiple flavor variants for each brand style.

The applications include a range of scientific studies for Vuse Vibe and Vuse Ciro using well-known methodologies, including the comparative assessment of cigarettes and associated health risks. Though the PMTA's themselves are considered commercially proprietary and are thus confidential, the data and information submitted to the FDA include the results of product analyses, nonclinical health risk information, and human health and population information, including the impact to both users and nonusers of tobacco products. The results of these studies demonstrate that the continued marketing of the Vuse Vibe and Vuse Ciro products is appropriate for the protection of the public health.

"I am incredibly proud of our diverse team of scientists, researchers and regulatory experts, who have worked tirelessly together to complete these applications well ahead of the FDA's May deadline for ENDS products," noted Reynolds' Executive Vice President and Head of Scientific and Regulatory Affairs, Dr. James Figlar. "We are optimistic that we will receive a favorable marketing order for all of our Applications, which would enable us to provide adult tobacco consumers with multiple acceptable alternatives to cigarettes and we're hopeful that as PMTAs move forward, the Agency prioritizes enforcement against illegally marketed tobacco products introduced after August 8, 2016."

The PMTAs for Vuse Vibe and Vuse Ciro are the second and third complete grouped PMTA applications submitted by Reynolds to the FDA for review, following the initial PMTA applications for Vuse Solo submitted in October 2019. The PMTA process allows the FDA to evaluate whether the marketing of certain ENDS products is appropriate for the protection of the public health.

While these applications may include relative safety 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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