Reynolds Completes 2020 PMTA Submissions with Vuse Alto E-Cigarette Applications

Grouped Alto applications are final FDA submission for deemed products, representing both Vuse and VELO portfolios
-- Reynolds completes 2020 deemed product PMTA submissions for one of the broadest portfolios in the industry
-- Reynolds has provided the FDA with more than 530,000 pages of scientific data for review as part of all PMTA applications submitted
-- More than 8,600 scientific documents were submitted as part of the six grouped filings made

WINSTON-SALEM, N.C., Sept. 4, 2020 /PRNewswire/ -- Reynolds American Inc. ("Reynolds") announces today its final submission of a group of Premarket Tobacco Product Applications ("PMTAs") to the U.S. Food and Drug Administration ("FDA") through R.J. Reynolds Vapor Company ("RJRV"), seeking orders authorizing the marketing of Vuse Alto electronic nicotine delivery systems ("ENDS") under Section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act.

Today's group of applications concludes a multi-year application process launched in advance of FDA's September 9, 2020 deadline for PMTAs. Reynolds first submitted a PMTA application in October of 2019 for Vuse Solo, and submitted additional applications for its Vuse Ciro and Vuse Vibe vapor products in April of 2020. Applications for VELO lozenge and pouch products submitted in August of this year. The VELO product PMTAs have been accepted by the FDA after their August filing, while the Vuse products are currently in substantive scientific review by the FDA.

"Completing our 2020 PMTA submissions is a key milestone for us as we continue creating innovative products responsibly –so adult tobacco consumers have a choice available when they are ready for an alternative to combustible tobacco products," noted Guy Meldrum, the CEO of Reynolds American. "Today marks completion of a critical hurdle of submitting PMTAs for every newly-deemed tobacco product offered by Reynolds for one of the broadest portfolios of products in the industry."

Thirteen Vuse Alto ENDS products are included in the Vuse Alto PMTAs, comprised of an ENDS component (the Vuse Alto Power Unit) and 12 closed e-liquid cartridges. Vuse Alto Cartridges are available in four flavors, each in three nicotine levels. The Vuse Alto Power Unit works in combination with all 12 closed e-liquid cartridges.

Vuse Alto currently offers flavor pods in Menthol, Rich Tobacco and Golden Tobacco via www.vusevapor.com and retailers nationwide. A PMTA was also submitted for Mixed Berry flavor pods. If the Vuse Alto PMTAs receive a marketing order from the FDA, adult consumers would have four flavor options in a variety of nicotine levels to suit their preferences.

The Vuse brand offers innovative vapor products for adult tobacco consumers' evolving preferences – reflecting a longstanding commitment to transform the tobacco industry by developing products that are innovative, consumer-acceptable and responsibly marketed.

Dr. James Figlar, Reynolds' Executive Vice President and Head of Scientific & Regulatory Affairs, noted "In order to provide regulators with confidence in knowing how these important products are made, marketed and regulated, we sought to build a package of the available best science to describe product analyses, information on human health risks, and assessments showing that these Vuse Alto products are appropriate for the protection of public health – including assessments on users and nonusers of tobacco products."

Dr. Figlar continued: "Additionally, we are heartened by the FDA's recent enforcement actions against illegally marketed tobacco products, as well as their recent decision to make public a list of legally sold tobacco products for which PMTAs were submitted by the deadline, which will make it easier for retailers to identify illegal products that should be pulled from shelves after September 9. This sort of regulatory enforcement ensures consumers have up-to-date, reliable information available on these highly-regulated products."

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 commercially proprietary applications include relative risk information based on FDA guidance, the marketing orders sought do not make modified risk claims regarding Vuse or VELO products.

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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