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Reynolds American Inc. submits Premarket Tobacco Product Application for VUSE products

WINSTON-SALEM, N.C. – Oct. 11, 2019 - Reynolds American Inc. ("Reynolds") today announced submission of a Premarket Tobacco Product Application ("PMTA") through one of its subsidiaries to the U.S. Food and Drug Administration (FDA) seeking orders authorizing the marketing of VUSE Electronic Nicotine Delivery Systems (ENDS) products. VUSE products offer a cartridge-based vapor system intended for adult tobacco consumers, and the application highlights key evidence demonstrating that the continued marketing of VUSE products is appropriate for the protection of the public health.

FDA has issued guidance explaining criteria for PMTA submissions, which make clear that manufacturers must provide not only information on the composition, design and manufacturing process associated with the product, but also chemistry, toxicological and behavioral studies that demonstrate the product − when used − is appropriate for the protection of the public health. To support the applications and meet this guidance, Reynolds' submission to FDA includes more than 150,000 pages of documentation.

"Today's application marks the culmination of years of hard work across multiple teams, involving more than 100 individuals, including dozens of Ph.D. team members collaborating every day, with a substantial financial investment," noted Dr. James Figlar, Executive Vice President of Scientific and Regulatory Affairs at Reynolds. "This is an important first step in a long process for the millions of adult cigarette smokers who may want a legal alternative to combustible cigarettes, thus we look forward to working with the agency as the process moves forward."

"We have long worked to build a broad portfolio of competitive options for the adult tobacco consumer, and today's application is a strong next step for us in that journey. We continue to support the FDA's efforts to create, implement and enforce a science and rule-based regulatory regime to protect the public health," stated Ricardo Oberlander, CEO of Reynolds. "Our regulatory applications, including those submitted for Camel Snus along with other future submissions for products in our Modern Oral Portfolio like VELO, are positioned to transform the market through a range of dynamic alternatives to traditional combustible cigarettes."

Reynolds now awaits FDA's review of the applications to determine whether they are accepted for filing and substantive review.

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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