Reynolds American Inc. Submits Premarket Tobacco Product Application for VUSE Products

WINSTON-SALEM, N.C., Oct. 11, 2019 /PRNewswire/ -- 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. ("RAI") is a member of the British American Tobacco Group. RAI's operating companies remain committed to responsibly marketing age-restricted tobacco products. RAI's operating companies' marketing communications are designed for, and directed to, existing adult tobacco consumers who are 21 and older. This standard is implemented in a variety of ways. First, direct interactions with consumers via e-mail, direct mail, and consumer engagements are restricted to existing 21+ adult consumers of tobacco products who have opted in to receive communications from RAI's operating companies that manufacture tobacco products. With respect to mass media (print advertising, television, online advertising), RJRVC employs strict guidelines to ensure that the audience viewership is overwhelmingly adult. In addition to restricting the dissemination of marketing communications, RAI's operating companies also impose numerous restrictions on the content of those marketing messages.

SOURCE Reynolds American Inc.

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