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VUSE Premarket Tobacco Product Application Filed for Substantive Review by the FDA
First-of-its-Kind Filing for VUSE Products

WINSTON-SALEM, N.C. – Nov. 27, 2019 – Today, Reynolds American Inc. ("RAI") announced that the recently-submitted Premarket Tobacco Product Application ("PMTA") for VUSE vapor products has been filed by the Food and Drug Administration ("FDA") for substantive scientific review, moving the application one step further through the review process.

"This is a first-of-its-kind application for VUSE products, and it puts VUSE one step closer to gaining a marketing order from the FDA. FDA will now review our scientific justification and determine the appropriateness of VUSE e-cigarette products against the public health standard," notes RAI CEO Ricardo Oberlander. "For adult tobacco consumers seeking an alternative source of nicotine, having FDA oversight of e-cigarette products is an important step to ensure those alternatives meet strict regulatory scrutiny."

The FDA's scientific review of the VUSE application – which totals more than 150,000 pages of research and data – comes just over six weeks after its initial submission to the FDA. The FDA, per its earlier-issued guidance, considers the following issues, among others:

- Risks and benefits to the population as a whole, including both users and nonusers of tobacco products;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available;
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available; and
- The methods, facilities, and controls used to manufacture, process, and pack the new tobacco product.

Dr. James Figlar, Executive Vice President within the RAI Group, explained the science behind the application, stating that "We compiled both the data and clinical information necessary for predicting the effect of continued marketing of VUSE products on the public health. We surveyed current tobacco users to understand product use behavior and demographics, conducted behavioral studies of current and non-users of tobacco to gauge consumer understanding of risks and interest in product use, and performed statistical population modeling to project the effect on the population as a whole."

He continued, "We also conducted clinical studies that looked at the abuse potential of VUSE products, which included examining nicotine pharmacokinetics, as well as conducted several studies to examine the aerosol properties of the products and the temperature during use."

"While many of the results of our studies are confidential and proprietary, we believe that our application is complete and meets the regulatory requirements laid out in FDA's guidance, and we will work with the Agency to address any questions they may have about our products throughout the review process."

The next step in the review process is the FDA evaluation of the scientific information and data in the VUSE application. The FDA will also conduct inspections of manufacturing sites, as well as sites and entities involved in clinical and nonclinical studies, as part of this review process. Thereafter, the application may receive market clearance or denial, based on the FDA's evaluation of the application and evidence.

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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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