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FDA accepts and files modified risk tobacco product applications for Camel Snus

WINSTON-SALEM, N.C. – December 18, 2017 – Reynolds American Inc. today announced that the U.S. Food and Drug Administration (FDA) accepted, and filed for substantive review, 18 Modified Risk Tobacco Product (MRTP) applications covering 6 styles of Camel Snus. R.J. Reynolds Tobacco Company (RJRT) introduced the premium pouched, smokefree tobacco product in 2006 and markets it nationwide.

“FDA’s acceptance and filing for review of these MRTP applications for Camel Snus is an important step forward in fulfilling RAI’s commitment to collaborative leadership in the transformation of the tobacco industry,” said Dr. James Figlar, senior vice president, scientific & regulatory affairs for RAI Services Company.

The applications request FDA authorization to market Camel Snus as a modified risk tobacco product with advertising information that would, if approved by FDA, indicate a differential in risk for smokers who switch completely to Camel Snus from cigarette smoking.

The application(s) will now undergo a substantive review process by FDA that is expected to be completed within a year. The process will include the receipt of public comments and review by the Tobacco Products Scientific Advisory Committee (TPSAC).

“We look forward to working closely with the FDA and the TPSAC in their review of what we feel are comprehensive scientific applications,” Figlar adds. “We believe the science and our proposed advertising to be compelling and accurate. FDA must now critically evaluate all of the information to establish that this type of modified risk advertising is appropriate and will benefit public health.”

During FDA’s substantive review process, a redacted version of the applications will be made publicly available.

ABOUT US

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; Nicovum USA, Inc.; Nicovum AB; and R.J. Reynolds Vapor Company.

- R.J. Reynolds Tobacco Company is the second-largest U.S. tobacco company. R.J. Reynolds’ 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.
- Nicovum USA, Inc. and Nicovum AB market innovative nicotine replacement therapy products in the United States and Sweden, respectively, under the ZONNIC brand name.
- R.J. Reynolds Vapor Company is a marketer of digital vapor cigarettes under the VUSE brand name in the United States.

To learn more about RAI and its operating companies, please visit RAI's website at www.reynoldsamerican.com. RAI also uses Twitter to publicly disseminate company news via [@RAI_News](https://twitter.com/RAI_News).

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