FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Tobacco Products Scientific Advisory Committee (TPSAC)
FDA White Oak Conference Center
Building 31, Room 1503, 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 13-14, 2018

On September 13-14, 2018, the Committee will discuss modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company for six products, MR0000068: Camel Snus Frost, MR0000069: Camel Snus Frost Large, MR0000070: Camel Snus Mellow, MR0000071: Camel Snus Mint, MR0000072: Camel Snus Robust, MR0000073: Camel Snus Winterchill.

September 13, 2018

8:30 AM	Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
8:35 AM	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
8:40 AM	Introduction of Committee Members	Robin J. Mermelstein, PhD Chair, TPSAC
8:45 AM	Opening Remarks	Matthew R. Holman, PhD Director Office of Science, FDA/CTP
9:00 AM	Modified Risk Tobacco Product Applications	Deirdre Lawrence Kittner, PhD, MPH Deputy Director, Division of Population Health Science Office of Science, FDA/CTP
9:15 AM	Toxic and Carcinogenic Constituents in Camel Snus and Other Smokeless Tobacco Products Marketed in the U.S.	Irina Stepanov, PhD Associate Professor University of Minnesota
9:45 AM	**Break**	
10:00 AM	*R.J. Reynolds Presentations:*	
	Introduction	Michael Ogden, PhD Senior Vice President, Scientific & Regulatory Affairs, RAI Services Company
	Epidemiology	Kristin Marano, MPH, PhD, CPH Director, Scientific & Regulatory Affairs, RAI Services Company

	Clinical and Preclinical Research	Elaine Round, PhD Senior Director, Scientific & Regulatory Affairs, RAI Services Company
	Risk Perceptions, Comprehension, and Likelihood of Use	Saul Shiffman, PhD Senior Scientific Advisor, Pinney Associates Professor of Psychology, Psychiatry, Pharmaceutical Sciences and Clinical Translational Science, University of Pittsburgh
	Population Health Benefit for Camel Snus with Modified-Risk Advertising	Geoffrey Curtin, PhD Senior Director, Scientific & Regulatory Affairs, RAI Services Company
	Conclusions	Michael Ogden, PhD Senior Vice President, Scientific & Regulatory Affairs, RAI Services Company
12:00 PM	**Lunch**	
1:00 PM	*FDA Presentations:*	
	Evidence Related to Substantiation of the Modified Risk Information	Mimy Young, PhD Division of Product Science Office of Science, FDA/CTP Catherine Corey, MSPH Division of Population Health Science Office of Science, FDA/CTP
	Use and Consumer Perceptions of the Proposed MRTPs	Erin Keely O'Brien, PhD Division of Population Health Science Office of Science, FDA/CTP
3:00 PM	**Break**	
3:15 PM	Committee Discussion	
5:00 PM	Adjourn	

September 14, 2018

8:00 AM	Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
8:05 AM	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
8:10 AM	Introduction of Committee Members	Robin J. Mermelstein, PhD Chair, TPSAC
8:15 AM	Open Public Hearing Session	
9:30 AM	**Break**	
9:45 AM	FDA's Questions to TPSAC on RJRT's Camel Snus MRTPAs	Deirdre Lawrence Kittner, PhD, MPH Deputy Director, Division of Population Health Science Office of Science, FDA/CTP
10:00 AM	Committee Discussion of the Questions	
12:00 PM	**Lunch**	
1:00 PM	Committee Discussion *(continued)*	
3:00 PM	Adjourn	