

**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<br>Chair, TPSAC  |
| 8:35 AM  | Conflict of Interest Statement  | Caryn Cohen, MS<br>Designated Federal Official<br>Office of Science, FDA/CTP   |
| 8:40 AM  | Introduction of Committee Members   | Robin J. Mermelstein, PhD<br>Chair, TPSAC  |
| 8:45 AM  | Opening Remarks   | Matthew R. Holman, PhD<br>Director<br>Office of Science, FDA/CTP   |
| 9:00 AM  | Modified Risk Tobacco Product Applications  | Deirdre Lawrence Kittner, PhD, MPH<br>Deputy Director, Division of Population Health Science<br>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<br>Associate Professor<br>University of Minnesota  |
| 9:45 AM  | <b>Break</b>  |  |
| 10:00 AM | <u><i>R.J. Reynolds Presentations:</i></u>  |  |
|          | Introduction  | Michael Ogden, PhD<br>Senior Vice President, Scientific & Regulatory Affairs, RAI Services Company                         |
|          | Epidemiology  | Kristin Marano, MPH, PhD, CPH<br>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**

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