

**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**

**February 6-7, 2019**  
**Agenda**

*Times are Approximate*

*On February 6-7, 2019, the Committee will convene for two sessions. The first session will convene on February 6, 2019, during which the Committee will discuss an amendment to the modified risk tobacco product applications, submitted by Swedish Match North America for the following snus smokeless tobacco products: MR0000020: General Loose; MR0000021: General Dry Mint Portion Original Mini; MR0000022: General Portion Original Large; MR0000024: General Classic Blend Portion White Large-12ct; MR0000025: General Mint Portion White Large; MR0000027: General Nordic Mint Portion White Large-12ct; MR0000028: General Portion White Large; and MR0000029: General Wintergreen Portion White Large.*

*The second session will convene after the first session has concluded, on February 6, 2019 and continue on February 7, 2019. During the second session, the Committee will discuss the modified risk tobacco product application, submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product: MR0000108: Copenhagen Snuff Fine Cut.*

**February 6, 2019**

**Session 1 – Swedish Match Amendment**

8:30 AM	Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
	Introduction of Committee Members	Robin J. Mermelstein, PhD Chair, TPSAC
8:45 AM	<i>Swedish Match USA, Inc. Modified Risk Tobacco Product Amendment</i>	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP
9:00 AM	<b><u>Applicant Presentation</u></b>	
	Swedish Match Overview Presentation	Fredrik Peyron Sr. Vice President for Regulatory Affairs & Group Communications
9:30 AM	<b><u>FDA Presentation:</u></b> <i>Swedish Match USA, Inc. Modified Risk Tobacco Product Application Amendment: Consumer Understanding and Intentions</i>	Alexander Persoskie, PhD Social Scientist, Population Health Science Office of Science, FDA/CTP
10:00 AM	Clarifying Questions	
10:15 AM	<b>Break</b>	

10:30 AM Open Public Hearing

11:00 AM Committee Questions and Discussion

12:30 PM **Lunch**

**Session 2 – Altria Client Services LLC Application on behalf of U.S. Smokeless Tobacco Company LLC**

1:30 PM	Call to Order	Robin J. Mermelstein, PhD Chair, TPSAC
	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
	Introduction of Committee	Robin J. Mermelstein, PhD Chair, TPSAC
1:45 PM	<i>U.S. Smokeless Tobacco Company LLC (USSTC) Modified Risk Tobacco Product Application</i>	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP
2:00 PM	<b><u>Applicant Presentations:</u></b>	
	Introduction	Jose Luis Murillo, JD Senior Vice President, Regulatory Affairs Altria Client Services LLC
	Scientific Evidence	Mohamadi Sarkar, MPharm, PhD, FCCP Fellow, Regulatory Affairs Altria Client Services LLC
	Health Risk	Gary Harvey Vice President and Principal Consultant William E. Wecker Associates, Inc.
	Claim Development and Testing	Stephanie Plunkett, PhD Senior Director, Perception and Behavior Research Altria Client Services LLC
	Population Impact	Ryan Black, Ph.D. Director, Regulatory Affairs Altria Client Services LLC
	Conclusion	Jose Luis Murillo, JD Senior Vice President, Regulatory Affairs Altria Client Services LLC
3:30 PM	<b>Break</b>	

- 3:45 PM ***FDA Presentation:***  
*U.S. Smokeless Tobacco Company LLC  
 (USSTC) Modified Risk Tobacco Product  
 Application: FDA Scientific Presentation* Benjamin Apelberg, PhD  
 Director, Population Health Science  
 Office of Science, FDA/CTP
- 4:45 PM Clarifying Questions
- 5:00 PM **Adjourn**

**February 7, 2019**  
**Session 2 (continued):**

- 8:00 AM Call to Order Robin J. Mermelstein, PhD  
 Chair, TPSAC
- Conflict of Interest Statement Caryn Cohen, MS  
 Designated Federal Official  
 Office of Science, FDA/CTP
- Introduction of Committee Robin J. Mermelstein, PhD  
 Chair, TPSAC
- 8:05 AM Open Public Hearing
- 8:35 AM Committee Discussion
- 10:00 AM **Break**
- 10:15 AM Committee Questions and Discussion
- 1:00 PM **Adjourn**