

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Tobacco Products Scientific Advisory Committee (TPSAC)
FDA White Oak Campus, Building 31, Great Room
Silver Spring, MD
February 14, 2020
AGENDA

Meeting Link:

<https://collaboration.fda.gov/tpsac021420/>

Topic: The committee will meet in open session to discuss the modified risk tobacco product applications (MRTPAs) submitted by 22nd Century Group Inc. for the following cigarette tobacco products; MR0000159: VLN™ King, and MR0000160: VLN™ Menthol King

Note: Committee members are participating in person.

Time	Presentation/Presenter
8:30 AM	<p><u>Opening Remarks: Call to Order, Introduction of Committee</u> Robin Mermelstein, Ph.D. Chair, TPSAC</p> <p><u>Administrative Announcements, Conflict of Interest Statement</u> Serina Hunter-Thomas, M.S.A., R.N. Designated Federal Officer, TPSAC CTP, FDA</p>
8:45 AM	<p>22nd Century Group Inc. Modified Risk Tobacco Products Applications (MRTPAs) (15 min) Cindy Tworek, Ph.D., M.P.H. Technical Project Lead, 22nd Century Group Inc. MRTPs Branch Chief Division of Population Health Science Office of Science Center for Tobacco Products (CTP)</p>
9:00 AM	22nd Century Group, Inc. Presentation (60 min)
10:00 AM	Break (25 min)
10:25 AM	Open Public Hearing (60 min allotted)
10:48 AM	<p>Evaluating VLN™ Cigarettes as MRTPs: Considerations of Morbidity, Mortality, and Population Health (30 min) Mollie Miller, Ph.D. Pharmacologist Division of Individual Health Science Office of Science Center for Tobacco Products</p>
11:09 PM	Discussion of Questions # 1 and 2

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12:00 PM	Lunch (30 min)
12:34 PM	Discussion of Question # 3
12:51 PM	<p>Investigating and Addressing the Perceived Risk of Nicotine and Very Low Nicotine Content Cigarettes (45 min) Justin Byron, Ph.D. Assistant Professor, Family Medicine School of Medicine Adjunct Assistant Professor, Health Behavior Gillings School of Global Public Health University of North Carolina at Chapel Hill</p> <p>Consumer Understanding of the Modified Risk Information Alexander Persoskie, Ph.D. Social Scientist Division of Population Health Science Office of Science Center for Tobacco Products</p>
1:37 PM	Discussion of Question # 4
2:35 PM	Adjourn Meeting