



August 7, 2019

SUBMITTED VIA CTP PORTAL UPLOAD ONLY

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: AMENDMENT for VLN™ King (STNs PM0000491 and MR0000159) and VLN™ Menthol King (STNs PM0000492 and MR0000160) Cigarettes

Dear Sir or Madam:

22nd Century Group, Inc. (the Company or XXII) seeks to amend the Premarket Tobacco Product Application (PMTA) originally submitted on December 4, 2018 and amended on January 8, 2019, February 11, 2019, February 25, 2019, March 13, 2019, March 14, 2019, March 15, 2019, March 20, 2019, April 3, 2019, June 27, 2019, and July 18, 2019 and the Modified Risk Tobacco Product Application (MRTPA) originally submitted on May 17, 2019 with amendments submitted May 23, 2019, June 25, 2019, and July 18, 2019 for the following products:

PM0000491 and MR0000159: VLN™ King Cigarettes

PM0000492 and MR0000160: VLN™ Menthol King Cigarettes

The purpose of this amendment is to provide additional medical information on the serious adverse event that was reported in the study sponsored by 22nd Century Group, Inc, titled, “A *Longitudinal Ambulatory Study to Assess Changes in Cigarette Consumption Behavior and Biomarkers of Exposure during a 6-Week Switch to Very Low Nicotine Cigarettes.*” This study used the VLN™ King and VLN™ Menthol King Cigarettes.

The Company appreciates the FDA’s continued consideration of the PMTA and MRTPA and looks forward to working with the FDA to secure orders under Section 910(c)(1)(A)(i) and 911(g)(2) of the FD&C Act for the subject products discussed herein and in the attached amendment.

Sincerely,

(b) (6)

22nd Century Group, Inc.