



March 10, 2020

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 (STN MR0000159) and VLN[®] Menthol King (STN MR0000160) Cigarettes

Dear Sir or Madam:

22nd Century Group, Inc. (the Company or XXII) seeks to amend the Modified Risk Tobacco Product Applications (MRTPA) originally submitted on May 17, 2019 with amendments on May 23, 2019; June 25, 2019; July 18, 2019; August 7, 2018; August 28, 2019; September 13, 2019; and March 2, 2020, for VLN[®] King (STN MR0000159) and VLN[®] Menthol King (STN MR0000160) Cigarettes.

During a teleconference on March 4, 2020 between the Company and the FDA, the FDA requested the Company review Table VI.F-1 from Section VI. Environmental Assessment in order to validate the data within the table. Upon review, the Company discovered mathematical errors in Table VI.F-1, as well as in Tables VI.G-1 and VI.G-2. The purpose of this amendment is to withdraw the three erred tables and replace them with the three amended tables that accompany this amendment.

The Company appreciates the FDA's continued consideration of the MRTPAs and looks forward to working with the FDA to secure orders under Section 911(g)(2) of the FD&C Act for the subject products discussed herein and in the attached amendment.

Sincerely,

(b) (6)

Program Manager and Authorized Contact
22nd Century Group, Inc.