



September 13, 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 (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 Application (MRTPA) originally submitted on May 17, 2019 with amendments submitted on May 23, 2019; June 25, 2019; July 18, 2019; August 7, 2018; and August 28, 2019 for the following products:

MR0000159: VLN™ King Cigarettes
MR0000160: VLN™ Menthol King Cigarettes

(b) (4)

purpose of this amendment, along with analysis from M/A/R/C® Research, LLC, is to address the FDA's finding as it relates to the Company's MRTPA.

The Company appreciates the FDA's continued consideration of the MRTPA and looks forward to working with the FDA to secure orders under 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.

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