



June 25, 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 (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 Application (MRTPA) originally submitted on May 17, 2019 with an amendment dated May 23, 2019, for VLN™ King (STN MR0000159) and VLN™ Menthol King (STN MR0000160) Cigarettes.

The purpose of this amendment is to provide 12-month storage stability and water activity study results that have now become available from our ongoing storage stability study being conducted at Enthalpy Analytical, LLC.

The Company appreciates the FDA's continued consideration of the MRTPA 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.