



August 28, 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 amendments submitted May 23, 2019, June 25, 2019, July 18, 2019, and August 6, 2018 for the following products:

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

The purpose of this amendment is to provide clarifying information and supporting documentation in response to a clarifying question asked by the FDA via email from Project Manager (b) (6) on August 26, 2018. The FDA asked that XXII clarify what pack stimuli participants viewed in the VLN Control condition (also referred to in the Study Report and Protocol as the VLN No Messaging, Control 1, and No Claims Messaging condition) in the M/A/R/C Research 2018, “Quantitative Study to Evaluate VLN Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users”; Protocol Number: 5180080-VLN-B2; Principal Investigator: Randall Wahl.

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)

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