



## PMTA Coversheet: Environmental Science

SUBMISSION INFORMATION			
<b>Applicant</b>	22nd Century Group, Inc.		
<b>Product Manufacturer</b>	NASCO Products, LLC		
<b>Submission Date</b>	December 4, 2018	<b>FDA Receipt Date</b>	December 4, 2018
<b>Cross-referenced Submission<sup>1</sup></b>	<b>Cross-referenced STN</b>	<b>Primary STN(s)</b>	
	(b)(4)	Applies to all STNs	
<b>Amendments</b>	<b>Amendment STN</b>	<b>Primary STN</b>	<b>FDA Receipt Date</b>
	PM0000493	Applies to all STNs	December 11, 2018
	PM0000497	Applies to all STNs	January 10, 2019
	PM0000499	Applies to all STNs	February 11, 2019
	PM0000502	Applies to all STNs	February 25, 2019
	PM0000506	Applies to all STNs	March 14, 2019
	PM0000507	Applies to all STNs	March 15, 2019
	PM0000508	Applies to all STNs	March 15, 2019
	PM0000509	Applies to all STNs	March 20, 2019
	PM0000511	Applies to all STNs	April 3, 2019
	PM0000514	Applies to all STNs	June 27, 2019
	PM0000519	Applies to all STNs	July 18, 2019
	PM0000524	Applies to all STNs	August 7, 2019
	PM0000544	Applies to all STNs	September 13, 2019
PM0000549	Applies to all STNs	October 2, 2019	

NEW TOBACCO PRODUCTS	
<b>PM0000491: Moonlight<sup>®2</sup></b>	
<b>Product Category</b>	Cigarettes
<b>Product Sub-Category</b>	Combusted, Filtered
<b>Package Type</b>	Hard pack
<b>Package Quantity</b>	20 per pack
<b>Characterizing Flavor</b>	None
<b>Length</b>	83 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	13%

<sup>1</sup> The application contains a valid and active cross-reference, which contains appropriate authorization for the applicant to reference the entire file or certain sections thereof.

<sup>2</sup> On December 4, 2018, FDA received original PMTAs for VLN™ King and VLN™ Menthol. On October 2, 2019, the applicant submitted a proposed name change for the products to Moonlight and Moonlight Menthol, respectively. The scientific reviews reflect the proposed names (VLN™ and VLN™ Menthol) in the original PMTA submissions.

STN PM0000491-PM0000492

<b>PM0000491: Moonlight® Menthol<sup>2</sup></b>	
<b>Product Category</b>	Cigarettes
<b>Product Sub-Category</b>	Combusted, Filtered
<b>Package Type</b>	Hard pack
<b>Package Quantity</b>	20 per pack
<b>Characterizing Flavor</b>	Menthol
<b>Length</b>	83 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	13%

## **FINDING OF NO SIGNIFICANT IMPACT**

### **Marketing Orders for VLN™ King and VLN™ Menthol King Cigarettes (Collectively “VLN™ Cigarettes”)**

#### **Marketed by 22<sup>nd</sup> Century Group, Inc.**

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of these actions and has concluded that these actions will not have significant effects on the quality of the human environment. Therefore, environmental impact statements are not required.

22<sup>nd</sup> Century Group, Inc. wishes to introduce two very low nicotine cigarettes into interstate commerce for commercial distribution in the United States and submitted to FDA premarket tobacco product applications to obtain marketing orders under the provisions of section 910 of the Federal Food, Drug, and Cosmetic Act.

FDA prepared the programmatic environmental assessment (PEA), dated October 29, 2019, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500–1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40). The PEA concluded that the marketing orders would have no significant impact and is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing the new products are anticipated. FDA does not foresee that use of the new products would result in new or different environmental impacts. FDA believes that the disposal of the new products is the same as the disposal conditions of other combusted, filtered cigarettes that are currently marketed in the United States. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

Approved by

Digitally signed by Kimberly A. Benson -S  
Date: 2019.10.29 12:32:45 -04'00'

---

Kimberly Benson, Ph.D.  
Director  
Division of Nonclinical Science  
Office of Science  
Center for Tobacco Products  
U.S. Food and Drug Administration