

Amendment

Section VI. Environmental Assessment

This amendment replaces three Tables in Section VI. Environmental Assessment for STNs MR0000159 and MR0000160; Table VI.F-1, Table VI.G-1 and Table VI.G-2.

Reason for Amendment:

During a teleconference on March 4, 2020, the FDA requested validation of the data in Table VI.F-1 *Current and Projected Sales (Cigarettes)* of Section VI. Environmental Assessment. Upon review of the table, mathematical errors were found in the fifth-year projected distribution of VLN® King and VLN® Menthol King products. These errors also carried over to the data in Tables VI.G-1 *Estimated Pack Waste Going to MSW* and VI.G-2 *Estimated Shipping Waste Going to MSW*. 22nd Century Group, Inc. seeks to withdraw Table VI.F-1, Table VI.G-1 and Table VI.G-2 from Section VI Environmental Assessment and replace those tables with the tables in this amendment. The amended tables provide corrected mathematical calculations, as well as additional notes to provide further clarification on the data represented therein. In addition to the tables presented below, this amendment also provides the Tables in Excel format with included filename, “2020-03-10_SectionVIEA-3AmendedTablesF1G1G2.xlsx”

Confidentiality: A version with proposed redactions is also being submitted.

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VI. Environmental Assessment

F. Environmental Introduction as a Result of Use Due to the Proposed Action

Table VI.F-1. Current and Projected Sales (Cigarettes)

<u>Product</u>	<u>2016</u>	<u>2017</u>	<u>2018*</u>	<u>First Full Year 2020**</u>	<u>Fifth Full Year 2024**</u>
NASCO's Current Taxable and Non-taxable Cigarette Distribution (Sticks)***	(b) (4)				
VLN™ King (Sticks)					
VLN™ Menthol King (Sticks)					
Total NASCO (Sticks)					
Total US Cigarette Sales (Sticks)	250,000,000,000	233,000,000,000	222,000,000,000	198,000,000,000	157,000,000,000
NASCO's % of Total US Cigarette Sales	(b) (4)				
VLN™'s % of Total US Cigarette Sales					

*Projected Sales as of October 2018

** Projected sales for full year of national distribution, based on current understanding of the market, subject to proposed rule on nicotine.

***These figures do not include VLN™

G. Environmental Introduction as a Result of Disposal After Use

1. Disposal of Packaging Material

Table VI.G-1. Estimated Pack Waste Going to MSW

<u>Packaging Component</u>	<u>Weight per Pack (mg)</u>	<u># Packs</u>	<u>First Year</u>		<u># Packs</u>	<u>Fifth Year</u>	
			<u>Weight of Component (Tons - US Short)</u>	<u>34.6 % Recycled (Tons - US Short)</u>		<u>Weight of Component (Tons - US Short)</u>	<u>34.6 % Recycled (Tons - US Short)</u>
Flip-Top Box (cardboard)	(b)	(4)					
Inner Frame (cardboard)							
Aluminum paper (aluminized paper)							
Cellophane (regenerated cellulose)							
Tear Tape							
Total Pack Waste							
Total Pack Waste Not Recycled							
Total MSW in 2014			169,060,000			169,060,000	
Pack Waste as a % of Total MSW			0.0000%			0.0012%	

Table VI.G-2 Estimated Shipping Waste Going to MSW

Packaging Component	Weight per Pack (mg)	First Full Year			Fifth Full Year		
		# Packs	<u>Weight of Component</u> (Tons - US Short)	67.7 % Recycled (Tons - US Short)	# Packs	<u>Weight of Component</u> (Tons - US Short)	67.7 % Recycled (Tons - US Short)
Carton (cardboard)	(b) (4)						
Case (cardboard)							
Total Shipping Waste							
Total Shipping Waste Not Recycled							
Total MSW in 2014			169,060,000			169,060,000	
Shipping Waste as a % of Total MSW			0.0000%			0.0002%	