

**Programmatic Environmental Assessment for Marketing
Orders for New Cigars Manufactured by
Empresas Victor Sinclair Dominicana, S.A.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

February 14, 2022

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1. Applicant and Manufacturer Information

Applicant Name:	Empresas Victor Sinclair
Applicant Address:	Carretera Luperon KM 4.5 Gurabo, Santiago 51000 Dominican Republic
Manufacturer Name:	Empresas Victor Sinclair Dominicana, S.A.
Product Manufacturing Location:	Carretera Luperon KM 4.5, Gurabo, Santiago 51000, Dominican Republic

2. Product Information

New Product (STNs), New Product Names, and Original Product Name

New Product STN	New Product Name	Original Product Name
EX0001310-PD25	POINT BREAK FLAVORS BLUEBERRY CORONA TUBO	SMOKIN ASS KONA COFFEE CORONA TUBO
EX0001310-PD31	POINT BREAK FLAVORS CINNAMON CORONA TUBO	
EX0001310-PD33	POINT BREAK FLAVORS GRAPE CORONA TUBO	
EX0001310-PD37	POINT BREAK FLAVORS KEY LIME PIE CORONA TUBO	

Product Identification

Product Category:	Cigar
Product Subcategory:	Unfiltered, leaf-wrapped
Product Number per Retail Unit:	1 wrapped cigar, 5 cigars per box or 5 cigars per bundle
Product Package:	The packaging materials consist of individual cigars wrapped in cellophane and co-packaged in a wooden box with cellophane overwrap or co-bundled in an outer cellophane overwrap.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for four unfiltered, leaf-wrapped cigars. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if: (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report.

The new products are made by modifying the corresponding original products. The modifications are to the package quantity (Appendix 1) and added ingredients (Confidential appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new products.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The new products would be manufactured outside of the United States at the address listed in section 1 of this document. However, the applicant stated that manufacturing the new products would not (i) require an expansion of the manufacturing facility, (ii) require additional environmental controls, or (iii) lead to changes in air emissions or wastewater discharges. The applicant also stated that the manufacturing facility is not located in a protected area that include any endangered species. Because this facility is located outside the United States, environmental impacts associated with manufacturing the new products will not be evaluated.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products (Confidential Appendix 2).

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new products to be sold to consumers in the United States.

6.2. Air Quality

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned products, including cigars. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

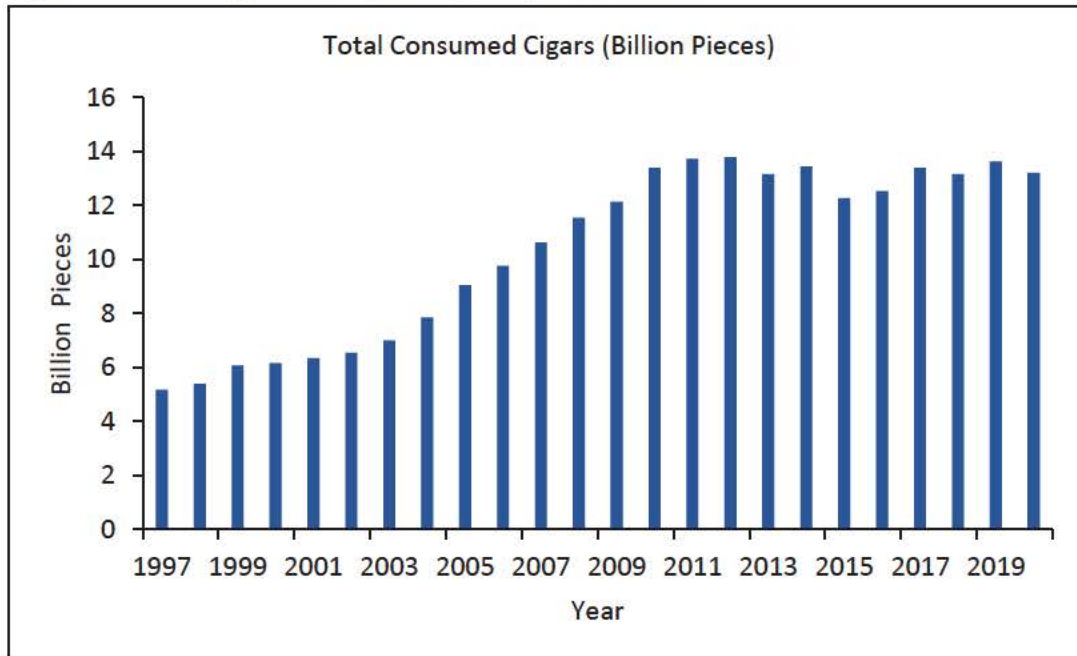
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing,

wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).

- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

The consumption of cigars in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar use has stabilized with a minor overall decrease, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1; U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021). In combination with declines in use of other tobacco products, this likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 1. Use of Cigars in the United States, 1997 – 2020



As of December 10, 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2022). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

6.3. Environmental Justice

Because new products are not expected to increase overall cigar consumption, no new emissions are expected. Therefore, there would be no disproportionate impacts on minority or low-income populations.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigars, as many similar products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. Based on the documented use of cigars in the United States and the projected market volumes for the new products, the agency found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new products to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the new products. The fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other cigars disposed of in the United States.

No changes in air quality from disposal of the packaging materials of the new products would be expected because (1) the paper and cellophane components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste (U.S. Environmental Protection Agency, 2020) per FDA's experience in evaluating the packaging waste generated from cigars.

7.3. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA because (1) the disposal of the new products would be the same as the disposal of cigars that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigars being disposed of because the new products are anticipated to compete with, or replace, other currently marketed.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the cigar butts from the new products because the chemicals in the new products would be used in currently marketed cigars. Furthermore, the new products would replace other cigars currently on the market.

7.5. Solid Waste

The Agency does not foresee the introduction of the new products would notably affect the current cigar and packaging waste generated from all cigars. The waste generated due to disposal of the new products would be released to the environment and disposed of and handled in the same manner as any other waste generated from any other cigars disposed of in the United States. The number of cigars generated is equivalent to the market projections (Confidential Appendix 1) and a portion of those would be littered.

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other cigars in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of cigars and cigar packaging, as many other similar products would continue to be disposed of in the United States.

8. A listing of Agencies and Persons Consulted

Not applicable.

9. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Thomas E. Creaven, Ph.D., Center for Tobacco Products
Education: B.S. in Chemistry/Biology, Ph.D. in Biology/Neuroscience
Experience: Ten years in science education and four years in NEPA Review
Expertise: Physics, Chemistry, Biology education and NEPA Review

Reviewer:

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Education: Ph.D. in Plant Molecular Biology and Virology
Experience: Forty-four years in various scientific activities including ten years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

10. References

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Appendix 1. Modification in the Package Quantity of the New Products as Compared with the Original Product.

The packaging materials consist of individual cigars wrapped in cellophane and co-packaged in a wooden box with cellophane overwrap or co-bundled in an outer cellophane overwrap.

New Product STN	Outer Package Quantity	
	New Product	Original Product
EX0001310-PD25 EX0001310-PD31 EX0001310-PD33 EX0001310-PD37	5 cigars per box or bundle	25 cigars per box or bundle

Confidential Appendix 1. Modifications in the New Products as Compared with the Original Product

New Product STN	Modification
EX0001310-PD25	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4)
EX0001310-PD31	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4)
EX0001310-PD33	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4)
EX0001310-PD37	<ul style="list-style-type: none"> • Deletion of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4)

Confidential Appendix 2. Market Volumes for the New and Original Products and Percentage of Cigar Used in the United States Projected to be Attributed to the New and Original Products.

First- and fifth-year market volume projections of the new products were compared to the total forecasted use of cigars in the United States.¹ The projected use of the new products in the first and fifth year of marketing after marketing orders are issued account for about (b) (4) and (b) (4) respectively, of the forecasted cigar use in the United States. (b) (4)

New Product STN	Tobacco Product	Market Volume					
		Current Year		New and Original Products Projected Market Volumes			
		Individual Cigars	Product as a Percent of Total Cigars ²	First Year		Fifth Year	
				Individual Cigars	Product as a Percent of Total Cigars ³	Individual Cigars	Product as a Percent of Total Cigars ⁴
EX0001310-PD25	New	(b) (4)					
	Original						
EX0001310-PD31	New						
	Original						
EX0001310-PD33	New						
	Original						
EX0001310-PD37	New						
	Original						
Total	New						
	Original						

¹ The Agency used historical data regarding total use of cigars from 1997 to 2020 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R2 value of 0.926, the forecasted number of cigars that would be used in the United States is estimated at 13.42 billion cigars in the first year and 12.75 billion cigars in the fifth year of marketing the new products.

² $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

³ Ibid

⁴ Ibid