

**Programmatic Environmental Assessment for Marketing
Orders for New Cigars Marketed by Empresas Victor Sinclair
Dominicana**

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

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Table of Contents

- 1. Applicant and Manufacturer Information 3**
- 2. Products Information 3**
- 3. The Need for the Proposed Actions..... 3**
- 4. Alternative to the Proposed Actions 4**
- 5. Potential Environmental Impacts of the Proposed Actions and Alternative – Manufacturing the New Products 4**
- 6. Potential Environmental Impacts of the Proposed Actions and Alternative – Use of the New Products 4**
 - 6.1. Affected Environment 4
 - 6.2. Air Quality 5
 - 6.3. Environmental Justice..... 6
 - 6.4. Impacts of the No-Action Alternative..... 6
- 7. Potential Environmental Impacts of the Proposed Actions and Alternative – Disposal of the New Products 6**
 - 7.1. Affected Environment 7
 - 7.2. Air Quality 7
 - 7.3. Biological Resources 7
 - 7.4. Water Resources 7
 - 7.5. Solid Waste 7
 - 7.6. Socioeconomics and Environmental Justice 8
 - 7.7. Impacts of the No-Action Alternative..... 8
- 8. List of Preparers 8**
- 9. A Listing of Agencies and Persons Consulted..... 9**
- 10. References..... 9**
- CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products..... 11**
- CONFIDENTIAL APPENDIX 2. Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products 12**

1. Applicant and Manufacturer Information

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

2. Products Information

New Product Names, Submission Tracking Numbers (STNs), and Original Product Names

New Product Names	STNs	Original Product Names
Tabanero Coffee Liqueur Mini	EX0001309/PD37	Cuban Delights Flavors Amaretto Mini
Café Latte Belicoso	EX0001309/PD39	Big Dog Sweet Tip Torpedo
Point Break Flavors Key Lime Pie Torpedo	EX0001309/PD45	Big Dog Sweet Tip Torpedo

Product Identification

Product Category:	Cigars	
Product Subcategory:	Unfiltered, Leaf-Wrapped	
Product Number per Retail Unit:	EX0001309/PD45	10 individually wrapped cigars per box
	EX0001309/PD39	20 individually wrapped cigars per box
	EX0001309/PD37	50 individually wrapped cigars per box
Product Package:	EX0001309/PD37 EX0001309/PD39	Each individual cigar is in a cellophane wrap and then packaged in either a box with a cellophane overwrap, or only a cellophane overwrap if in a “bundle” packaging format.
	EX0001309/PD45	Each individual cigar is in a Crystal Tube wrap and then packaged in either a box with a cellophane overwrap, or only a cellophane overwrap if in a “bundle” packaging format and cardboard shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the 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 three 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 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. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The applicant stated that the new and original products will be simultaneously marketed. The new products differ from the corresponding original products by a change in the outer co-package product quantity and/or the deletion of an additive and the addition of a different additive (Confidential Appendix 1).

4. Alternative 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 Alternative – Manufacturing the New Products

The manufacturing facility is located outside the United States. The applicant stated that manufacturing the new products is not expected to result in any new or additional adverse environmental impacts, and thus will not jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations.

6. Potential Environmental Impacts of the Proposed Actions and Alternative – 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 (Confidential Appendix 2) for the new products and the documented cigar use in the United States.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will 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 cigars, cigarettes, cigarillos and pipes. 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 a mixture in the environment alongside SHS. ^{1,2}

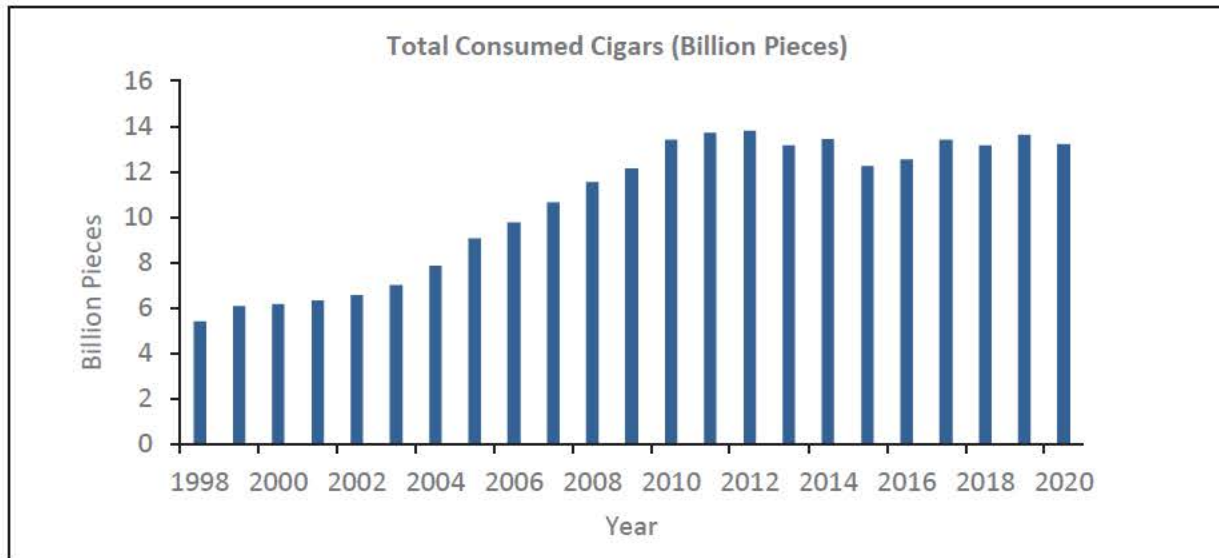
There is no safe level of exposure to SHS. ^{3,4} Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30%. ^{3,4}
- 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. Such exposure can cause coughing, wheezing, phlegm, and breathlessness. ^{3,4}
- SHS causes more than 40,000 deaths per year. ⁵

The consumption of cigars in the United States increased significantly during 1997 to 2011. Since 2011 through 2020 the trend of cigar usage has stabilized with minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1). ⁶ 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. ^{7,8}

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. ⁷ There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS 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. ⁸

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



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws.⁹ Such laws are expected to reduce the levels of non-users' exposure to SHS and THS.

The Agency does not anticipate that new chemicals will be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other cigars already on the market because (1) the combustion products from the new products will be released in the same manner as the combustion products of the original products and any other marketed cigars, (2) the new products are expected to compete with, or replace, other currently marketed cigars, and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there will 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 will not change the existing condition of use of cigars, as many similar tobacco products will continue to be used in the United States.

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on TTB data, which shows relatively stable rates of cigar use in the United States since 2010, and the applicant's submitted information, including market volume projections 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 will allow for the applicant to distribute and sell the new products to consumers in the United States.

7.2. Air Quality

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

No changes in air quality are anticipated from disposal of the unburned cigar butts of the new products. The chemicals in the new products are commonly used in other currently marketed cigars. Because the new products are anticipated to compete with or replace other currently marketed cigars, the butt waste generated from the new products will replace the same type of waste. Therefore, 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 in the new products will be expected because (1) the paper, wood, and plastic 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 waste¹⁰ per FDA's experience in evaluating the packaging waste generated from tobacco products.

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. Although disposal of smoldering tobacco products like cigars and cigarettes has been implicated in many fire incidents,¹¹ the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products will be similar to the disposal of cigars that are currently marketed in the United States, and (2) there will be no anticipated increase in number of cigars being disposed of as the new products are anticipated to compete with or replace similar marketed cigars.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the unburned cigars and cigar butts from the new products because chemicals in the new products will be the same or similar to the chemicals in currently marketed cigars. Additionally, the new products will compete with or replace other cigars currently on the market.

7.5. Solid Waste

Environmental impacts from cigar litter are not well studied and potentially pose similar environmental risks as cigarette butts, which can persist in the environment.¹² Like cigarettes, compounds in cigar butts can leach into water, potentially threatening human health and the environment, especially in

aquatic and marine ecosystems.¹³ The environmental toxicity of air emissions from cigar butts is not well studied, but emissions might resemble those from cigarette butts that are influenced by environmental conditions, chemicals in the butts, brand, length, filter material, types of tobacco, ingredients in the cigarette tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹⁴

The Agency does not foresee the introduction of the new products will notably affect the current cigar butt waste generated from all cigars. The waste generated due to disposal of the new products will be handled in the same manner as any other waste generated from any other cigars disposed of in the United States. The number of cigar butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those will 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 will 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 will 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 will not change the existing condition of disposal of cigars and cigar packaging, as many other similar tobacco products will continue to be disposed of in the United States.

8. List of Preparers

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

Preparer:

Chad Baisden, MS, Center for Tobacco Products

Education: MS in Natural Resources

Experience: Six years in various scientific activities

Expertise: Environmental risk assessment, public risk assessment, regulatory compliance

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Six years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products

STN	Modification
EX0001309/PD37	- Deletion of additive (b) (4) [REDACTED], and the addition of additive (b) (4) [REDACTED]
EX0001309/PD39	- Deletion of additive (b) (4) [REDACTED], and the addition of additive (b) (4) [REDACTED] - Decrease in the outer co-package product quantity
EX0001309/PD45	- Deletion of additive (b) (4) [REDACTED], and the addition of additive (b) (4) [REDACTED] - Decrease in the outer co-package product quantity

CONFIDENTIAL APPENDIX 2. Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products

Current year market volume and first- and fifth-year market volume projections of the new and original products were compared to the total forecasted use of cigars in the United States.* 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) %, respectively, of the forecasted cigar use in the United States. (b) (4)

STN	Market Volume				
	Current Year	Projected Volume			
		First Year		Fifth Year	
	Tobacco Product (Cigars)	Product (Cigars)	Product as a Percent of Total Cigars Used †	Product (Cigars)	Product as a Percent of Total Cigars Used †
EX0001309-PD37	(b) (4)				
Original Product: CUBAN DELIGHTS FLAVORS AMARETTO MINI					
EX0001309-PD39					
Original Product: BIG DOG SWEET TIP TORPEDO					
EX0001309-PD45					
Original Product: BIG DOG SWEET TIP TORPEDO					
Total					

* The Agency used historical data about total cigar use from 1997 to 2020 (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021) to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R² value of 0.9287, the forecasted number of cigars 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 product.

† Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$