

**Environmental Assessment for a Marketing
Order for a New Cigar Manufactured by
Tabacalera de Garcia S.A.S.**

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

October 5, 2022

1. Applicant and Manufacturer Information

Applicant Name:	Tabacalera de Garcia S.A.S.
Applicant Address:	Industrial Free Zone No. 1, La Romana 22000, Dominican Republic
Manufacturer Name:	Tabacalera de Garcia S.A.S.
Product Manufacturing Address:	Industrial Free Zone No. 1, La Romana 22000, Dominican Republic

2. Product Information

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

New Product Name	STN	Original Product Name	STN
Altadis 38 x 6 1/2 Parejo	EX0002035	Romeo y Julieta 1875 Lancero	GF1804219

Product Identification

Product Category	Cigars
Product Subcategory	Leaf-Wrapped Cigars
Number of Products per Retail Unit	1 Cigar
Product Package	Each cigar individually wrapped in cellophane and placed in a 5-count bundle with a cellophane overwrap.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence (SE) reporting for a marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a leaf-wrapped cigar tobacco product. 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 product into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the product exemption 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 product for which the applicant has obtained exemption from demonstrating substantial equivalence.

(b) (4) [Redacted] The new product differs from the original product by deletion of one

additive applied to the leaf tobacco wrapper, the deletion of a type of adhesive, and an increase in the amount of another adhesive used (Confidential Appendix 1).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new product.

5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

The manufacturing facility is located outside of the United States at Industrial Free Zone No. 1, La Romana 22000, Dominican Republic. The applicant stated that manufacture of the new product would not require an expansion of the facility and that the facility is in compliance with all applicable local environmental regulations. The applicant also stated that the manufacture of the new product would not require any new environmental controls or lead to a change in air or wastewater discharges from the facility.

6. Potential Environmental Impacts of the Proposed Action and Alternative – Use of the New Product

The Agency evaluated potential impacts of the new product's use to resources in the environment and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information that the Agency considered were projected first- and fifth-year market volume for the new and original product and documented cigar use in the United States (Confidential Appendix 2 and Figure 1).

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new tobacco product 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 might 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 20-30%. ⁵
- 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 a year. ⁵

Cigar sales in the United States, a proxy for consumption, increased significantly from 1997 to 2010. From 2011 through 2020 (Figure 1), the trend of cigar sales has stabilized, per the, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports.⁶ In combination with declines in use of other tobacco products, it is likely that this 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 prevalence of SHS exposure among non-smokers from 87.5% in 1988-1991 to 25.1% in 2013-2014 with the highest prevalence of exposure among non-Hispanic black (50.3%), compared to Mexican Americans (20%) and non-Hispanic whites (21.4%) in 2013-2014.⁹ However, no change in exposure occurred between 2011–2012 and 2013–2014.⁹ There were also significant declines in SHS exposure prevalence noted in 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 However, in recent years, the decline in SHS exposure has slowed with exposure rates relatively constant from 2011 to 2018 (Figure 2).¹⁰

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

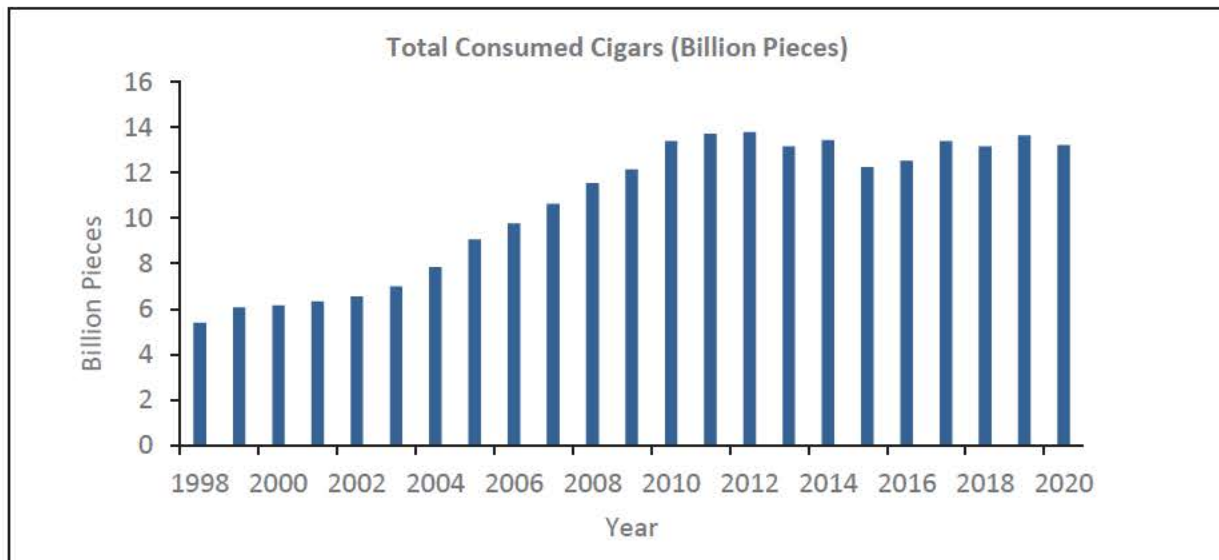
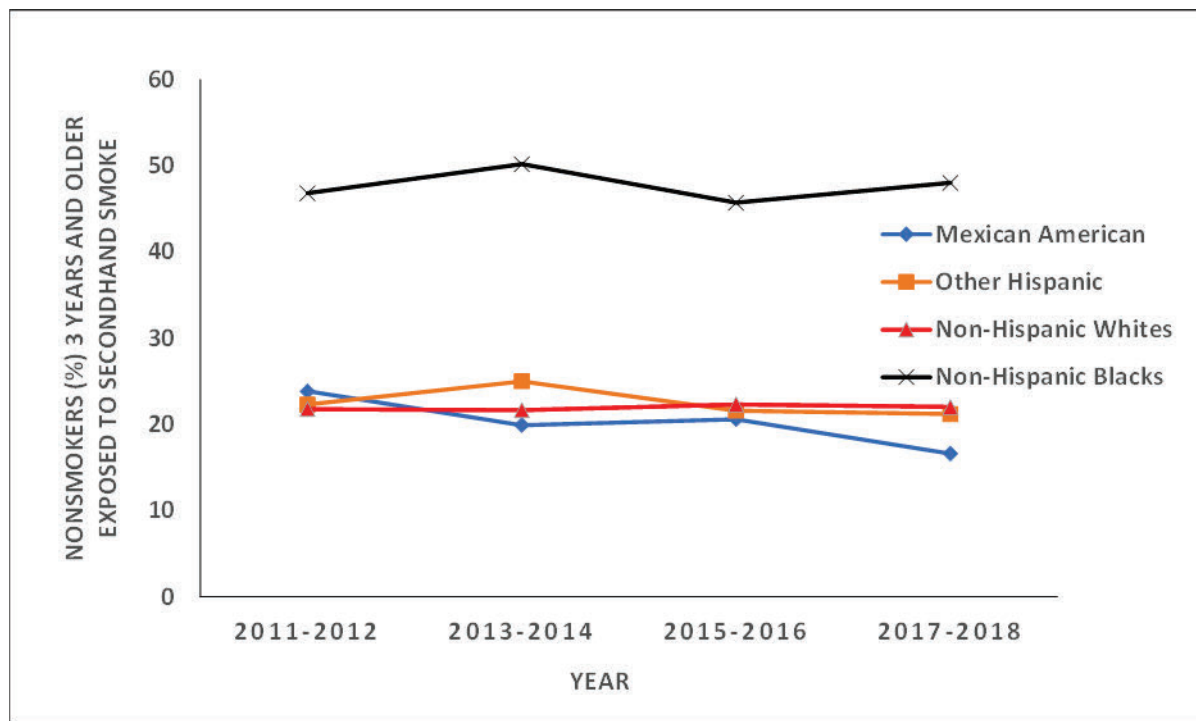


Figure 2. Trends in the Exposure of U.S. Nonsmokers to Secondhand Smoke, 2011 – 2018 by Major Ethnic and Racial Groups.



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws.¹¹ Such laws are expected to reduce the levels of non-users' exposure to SHS and THS.

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new tobacco product, 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 tobacco product would be released in the same manner as the combustion products of the original tobacco product and any other marketed cigars, (2) the new tobacco product is expected to compete with, or replace, other currently marketed cigars, and (3) the ingredients in the new tobacco product are used in other currently marketed tobacco products.

6.3 Environmental Justice

No new emissions are expected due to use of the new product. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

6.4 Impacts from 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 Alternatives – Disposal of the New Product

The Agency considered potential impacts of the new product's disposal to resources in the environment. Based on TTB data, which shows relatively stable rates of cigar use in the United States since 2010 ⁶, and the applicant's submitted information, including market volume projections for the new and original products (Confidential Appendix 2), 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 order will allow for the new product to be sold to consumers and be disposed of in the United States.

7.2 Air Quality

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

No changes in air quality are anticipated from disposal of the cigar butts of the new product. The chemicals in the new product's cigar butts are commonly used in other currently marketed cigars. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product 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 new product's package materials will be expected because the paper and plastic components of the package are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled and the waste generated due to disposal of the new product's packaging is a minuscule portion of the municipal solid waste in the United States ¹² per FDA's experience in evaluating the packaging waste generated from cigars.

7.3 Water Resources

The Agency does not anticipate any new impacts on water resources due to disposal of the cigar butts and packaging from the new product because the chemicals in the new product are used in currently marketed cigars. Furthermore, the new product will compete with other cigars currently on the market and the applicant states that the new product is expected to eventually replace the original product.

7.4 Biological Resources

The proposed action is not expected to impact any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act (ESA). Although disposal of smoldering tobacco products like cigars and cigarettes has been implicated in many fire incidents ¹³, the disposal of the new tobacco product is not expected to change the fire frequency because (1) the disposal of the new tobacco product would be similar to the disposal of cigars and cigar wrappers that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigars or cigar wrappers being disposed of as the new tobacco product is anticipated to replace similar marketed products.

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.¹⁴ Like cigarettes, compounds in cigar butts can leach into water, potentially threatening human health and the environment, especially in aquatic and marine ecosystems.¹⁵ 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.¹⁶

The Agency does not foresee the introduction of the new product will notably affect current waste generated from all cigars. The applicant stated that the waste generated due to the disposal of the new product will be handled in the same manner as waste generated from other cigars in the United States.

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 product. The waste generated due to disposal of the new product 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 product. Therefore, there will be no disproportionate impacts on minority or low-income populations.

7.7 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of disposal of cigar and cigar packaging, as many other similar 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:

Corey DeBoom, M.S., Center for Tobacco Products

Education: M.S in Natural Resources and Environmental Science

Experience: Ten years in natural resources research and management.

Expertise: Aquatic science, animal ecology, natural resources management

Reviewer:

Greg Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-nine years in environmental compliance and analysis

Expertise: Environmental toxicology and risk assessment, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

None

10. References

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Confidential Appendix 1: Modifications: New Product as Compared with the Original Product

STN	Tobacco Leaf Wrapper Additives		Adhesive Ingredients	
	New Product	Original Product	New Product	Original Product
EX0002035.PD1	None	(b) (4)		

Confidential Appendix 2: Current Market Volume for the New and Original Products, First- and Fifth-Year Market Volume Projections for the New and Original Products

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 and original products in the first and fifth year of marketing after a marketing order is issued account for (b) (4) of the forecasted cigar use in the United States. (b) (4)

STN	Current Market Volume		Projected Market Volume					
	New Product (# cigars)	Original Product (# cigars)	First Year			Fifth Year		
			New Product (# cigars)	Original Product (# cigars)	% Of Total Cigars Used [†]	New Product (# cigars)	Original Product (# cigars)	% Of Total Cigars Used [‡]
EX0002035.PD1	0	(b) (4)						

* 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 0.9287, the forecasted number of cigars that will 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 product.

[†] Projected Market Occupation of the New and Original Product in the United States (%) = $\frac{\text{Projected Market Volume of the New and Original Products (\# of cigars)}}{\text{Projected Use of Cigars in United States (\# of cigars)}} \times 100$

[‡] Ibid.