

**Programmatic Environmental Assessment for Marketing
Orders for New Cigars Manufactured by
Tabacalera de Garcia S.A.S.**

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

June 1, 2022

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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

1. Product Information

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

STN	New Product Name	Original Product Name
EX0002089.PD1	Blender's Gold Dominican Maduro Churchill	Blender's Gold Dominican Maduro Churchill
EX0002090.PD1	Altadis 28 x 4 7/8 Parejo	Romeo y Julieta 1875 Julieta
EX0002091.PD1	Altadis 36 x 6 1/2 Parejo	Blenders Gold Dominican Panetella
EX0002143.PD1	Altadis 43 x 6 1/16 Parejo	Blenders Gold Dominican Lonsdale
EX0002144.PD1	Altadis 36 x 7 Parejo	Romeo y Julieta Reserva Real Porto Real
EX0002146.PD1	Altadis 42 x 5 5/8 Parejo	Montecristo No. 10
EX0002147.PD1	Altadis 38 x 6 7/8 Parejo	Montecristo No. 20

Product Identification

Product Category	Cigars
Product Subcategory	Unfiltered, Leaf-Wrapped Cigar
Number of Products per Retail Unit	1 Cigar EX0002089.PD1, EX0002143.PD1: 4 cigars/bundle EX0002090.PD1, EX0002091.PD1: 10 cigars/box EX0002144.PD1: 20 cigars/box EX0002146.PD1, EX0002147.PD1: 25 cigars/box
Product Package	The packaging materials consist of individual cigars wrapped in cellophane and placed in a cellophane-wrapped bundle or wooden box.

2. 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 14 unfiltered, leaf-wrapped tobacco products. 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.

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

3. Alternatives to the Proposed Actions

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

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

The manufacturing facility is located outside of the United States at the address listed in Section 1 of this document. The applicant stated that manufacture of the new products 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 products would not require any new environmental controls or lead to a change in air or wastewater discharges from the facility. Furthermore, the applicant stated that the new products are intended to eventually replace the original product. Therefore, the Agency does not expect adverse environmental effects due to manufacturing the new products.

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

The Agency evaluated potential impacts to resources in the environment due to 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 that the Agency considered were projected first- and fifth-year market volumes for the new and original products as proxy for use (Confidential Appendix 2).

5.1 Affected Environment

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

5.2 Air Quality

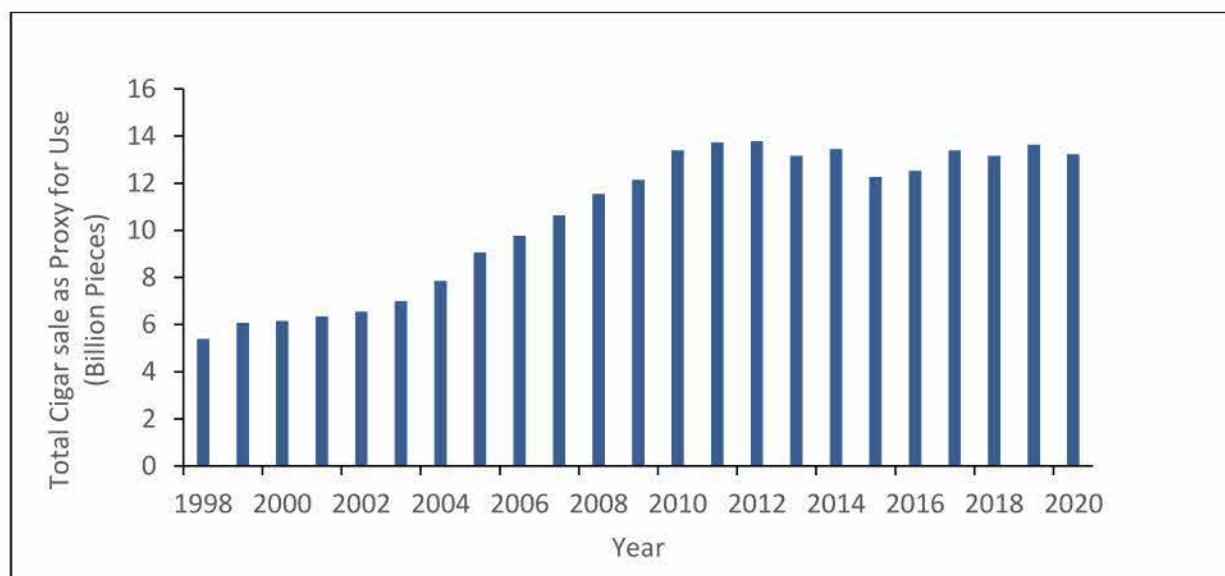
The impact from use of combusted tobacco products includes exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos, and pipes. Particles emitted by smoking might remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the 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 sale as proxy for consumption in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar use* has stabilized with a 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, 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

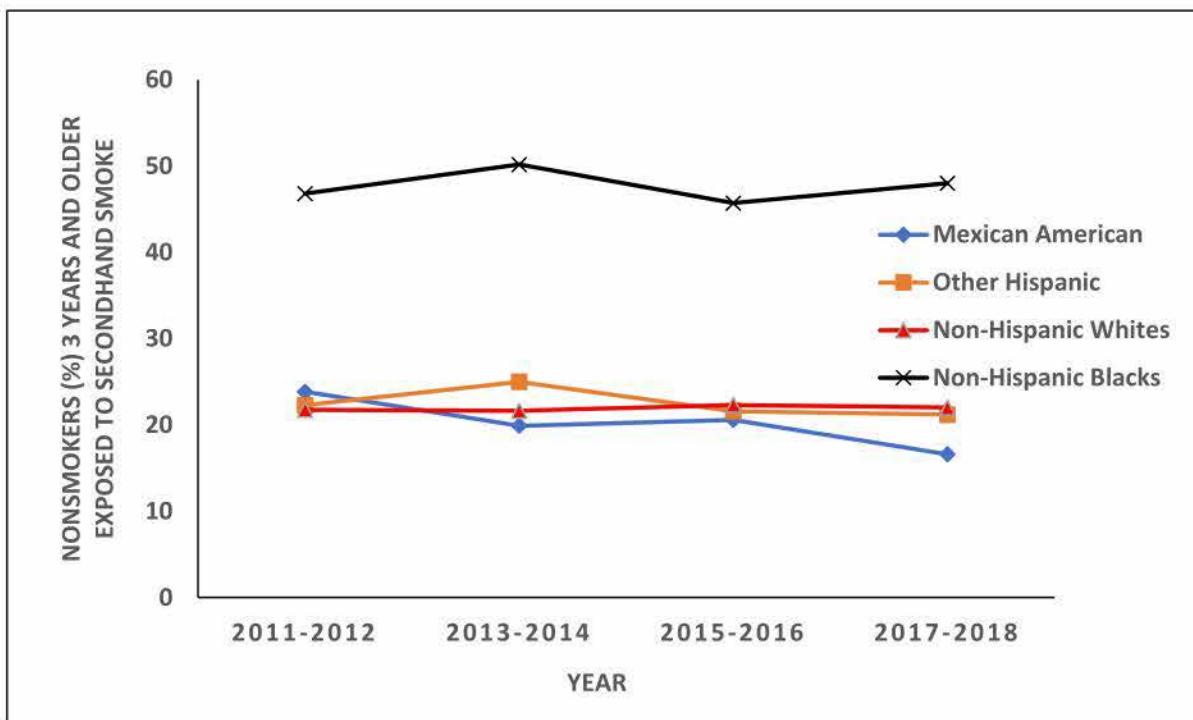
Figure 1. Total Cigar Sale as Proxy for Use in the United States, 1997 – 2020.



* Cigar sale data reported in TTB tobacco statistical reports is used as proxy for use.

However, in recent years, a stagnation in reduction in rate of SHS exposure has been reported (Figure 2).¹⁰

Figure 2. Trends in the Exposure of Nonsmokers to Secondhand Smoke¹⁰



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 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 tobacco products would be released in the same manner as the combustion products of the original tobacco products and any other marketed cigars, (2) the new tobacco products are expected to compete with, or replace, other currently marketed cigars, and (3) the ingredients in the new tobacco products are used in other currently marketed tobacco products.

5.3 Environmental Justice

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

5.4 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.

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

The Agency considered potential impacts of the new products' disposal to resources in the environment. Based on TTB data, which shows relatively stable rates of cigar use in the United States since 2010⁶, and the applicant's submitted information, including market volume projections as proxy for use of the new and original products (Confidential Appendix 2); the Agency found no significant impacts.

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 and be disposed of in the United States.

6.2 Air Quality

The Agency does not anticipate disposal of the new products 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 products. The chemicals in the new products' 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 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 new products' package materials will be expected because the paper 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 and the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States¹² per FDA's experience in evaluating the packaging waste generated from cigars.

6.3 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 products because the chemicals in the new products are used in currently marketed cigars. Furthermore, the new products will compete with other cigars currently on the market and the applicant states that the new products are expected to eventually replace the original products.

6.4 Biological Resources

The proposed action is 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. Endangered Species Act (ESA) because: (1) disposal of new products will be similar to other currently marketed cigar products in the United States, and (2) there will be no anticipated increase in cigar disposal because the new products are anticipated to compete with similar products.

6.5 Solid Waste

The Agency does not foresee the introduction of the new products will notably affect current waste generated from all cigars. The waste generated due to the disposal of the new products will be released to

the environment and disposed of in the same manner as other waste generated from any other cigars disposed of in the United States.

6.6 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.

6.7 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.

7. List of Preparers

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

Preparer:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science

Experience: Ten years in various scientific activities including five years in NEPA practice

Expertise: NEPA analysis; fate, transport, and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Reviewer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-three 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

8. A Listing of Agencies and Persons Consulted

None

9. References

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2. Matt GE, Quintana PJE, Destaillats H, et al. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environ Health Perspect*. 2011;119(9):1218-1226.
3. U.S. Department of Health and Human Services. *The health consequences of involuntary exposure to tobacco smoke: a report of the Surgeon General*. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2006a.
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Confidential Appendix 1: Modifications in the New Products as Compared with the Corresponding Original Products

STN	Tobacco Leaf Wrapper Additives	Adhesive Ingredients
EX0002089.PD1	<ul style="list-style-type: none"> • Deletion of (b)(4) (b)(4) 	<ul style="list-style-type: none"> • Deletion of (b)(4) (part of a complex ingredient, specific amount not provided) • Deletion of (b)(4) • Addition of (b)(4)
EX0002090.PD1 EX0002091.PD1 EX0002143.PD1		<ul style="list-style-type: none"> • Deletion of (b)(4) (part of a complex ingredient, specific amount not provided) • Deletion of (b)(4) • Addition of (b)(4)
EX0002144.PD1 EX0002146.PD1 EX0002147.PD1	<ul style="list-style-type: none"> • Deletion of (b)(4) 	<ul style="list-style-type: none"> • Deletion of (b)(4) • Increase in amount of (b)(4)

Confidential Appendix 2: Market Volumes and Percentage of Cigar Use in the United States Projected to be Attributed to 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 marketing orders are issued account for about (b)(4) and (b)(4) respectively, of the forecasted cigar use in the United States.[‡] The applicant stated that the new products will be commercially marketed simultaneously with the original products until the original tobacco products' inventories are depleted and the new tobacco products replace the original tobacco products.

STN (New Product)	Market Volumes							
	Current Market Volume		Projected Market Volume					
	New Product (# cigars)	Original Product (# cigars)	New Product (# cigars)	Original Product (# cigars)	% Of Total Cigars Used [§]	New Product (# cigars)	Original Product (# cigars)	% Of Total Cigars Used ^{**}
EX0002089.PD1	(b)(4)							
EX0002090.PD1								
EX0002091.PD1								
EX0002143.PD1								
EX0002144.PD1								
EX0002146.PD1								
EX0002147.PD1								
Total								

[†] 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 R^2 value of 0.9287, the forecasted number of cigars that will be used in the United States is estimated at 13.32 billion cigars in the first year and 12.48 billion cigars in the fifth year of marketing the new products.

[‡] Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

[§] Projected Market Occupation of the New and Original Products 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