

**Programmatic Environmental Assessment for Marketing Order
for New Cigars Manufactured by (b) (4)**

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

January 27, 2021

Table of Contents

1.	Applicant and Manufacturer Information	3
2.	Products Information	3
3.	The Need for the Proposed Actions.....	4
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 Product.....	4
	6.1. Affected Environment.....	5
	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	7
	7.1. Affected Environment.....	7
	7.2. Air Quality.....	7
	7.3. Biological Resources	7
	7.4. Water Resources.....	8
	7.5. Solid Waste	8
	7.6. Socioeconomics and Environmental Justice.....	8
	7.7. Impacts of the No-Action Alternative	8
8.	List of Preparers	9
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. First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigar Use in the United States Projected to be Attributed to the New Products	13

1. Applicant and Manufacturer Information

Applicant Name:	Altadis U.S.A LLC.	
Applicant Address:	5900 N. Andrews Avenue Suite 600 Fort Lauderdale, FL 33309	
Manufacturer Name:	(b) (4)	
Product Manufacturing Location:	(b) (4)	

2. Products Information

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

New Product Names	STNs	Original Product Names	STNs
H. Upmann Petite Corona	EX0001269/PD5	H. Upmann Petite Corona	GF1806358
Trinidad Maduro Belicoso	EX0001269/PD7	Trinidad Maduro Belicoso	GF1805647
Romeo y Julieta Reserva Real Petite Robusto	EX0001269/PD9	Romeo y Julieta Reserva Real Petite Robusto	GF1804185
Blender's Gold Dominican Maduro Churchill	EX0001269/PD11	Blender's Gold Dominican Maduro Churchill	GF1805269
H. Upmann Petite Corona	EX0001269/PD15	H. Upmann Petite Corona	GF1806358
Montecristo Classic Collection Toro	EX0001269/PD17	Montecristo Classic Collection Toro	GF1703489
Romeo y Julieta Vintage Vintage II	EX0001270/PD15	Romeo y Julieta Vintage Vintage II	GF1804205
Trinidad Maduro Toro	EX0001270/PD17	Trinidad Maduro Toro	GF1805633
Montecristo Corona Grande	EX0001271/PD3	Montecristo Corona Grande	GF1906561
Romeo y Julieta Vintage Vintage IV	EX0001271/PD5	Romeo y Julieta Vintage Vintage IV	GF1804216
Trinidad Fundador	EX0001271/PD7	Trinidad Fundador	GF1907639
Romeo y Julieta 1875 Exhibicion #1	EX0001271/PD9	Romeo y Julieta 1875 Exhibicion #1	GF1602085
Romeo y Julieta 1875 Cedro Deluxe #1	EX0001271-PD11	Romeo y Julieta 1875 Cedro Deluxe #1	GF1804173
Seijas' Signature Series Toro	EX0001271-PD13	Seijas' Signature Series Toro	GF1908832
VegaFina Lonsdale	EX0001271-PD17	VegaFina Lonsdale	GF1907649

Product Identification

Product Category:	Cigars
Product Subcategory:	Leaf-Wrapped, Cigar
Product Number per Retail Unit:	EX0001269/PD5, PD7, PD17; EX0001270/PD15; EX0001271/PD13 –20 individually wrapped cigars per box EX0001269/PD9, PD11 –five individually wrapped cigars per package EX0001269/PD15 –27 individually wrapped cigars per box EX0001270/PD17 –10 individually wrapped cigars per box

	EX0001271/PD3, PD9, PD11, PD17 –20 individually wrapped cigars per package EX0001271/PD5, PD7 –50 individually wrapped cigars per package
Product Package:	The individual packaging material consist of cellophane cigar wrap and the external package consist of a wooden box with cellophane wrap or a cellophane wrap, inside a cardboard box.

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 15 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. 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 tobacco products would be simultaneously marketed. The new products differ from the corresponding original products by eliminating or adding a flavor or additive, a change in the amount of product units per package, or both (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco 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 the manufacturing facility complies with all applicable environmental regulations. In addition, the applicant included an environmental permit for the operation of the manufacturing facility issued by the Ministry of the Environment and Natural Resources from (b) (4)

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

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 current and projected market volumes (Confidential Appendix 2) for the new tobacco 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 would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Air Quality

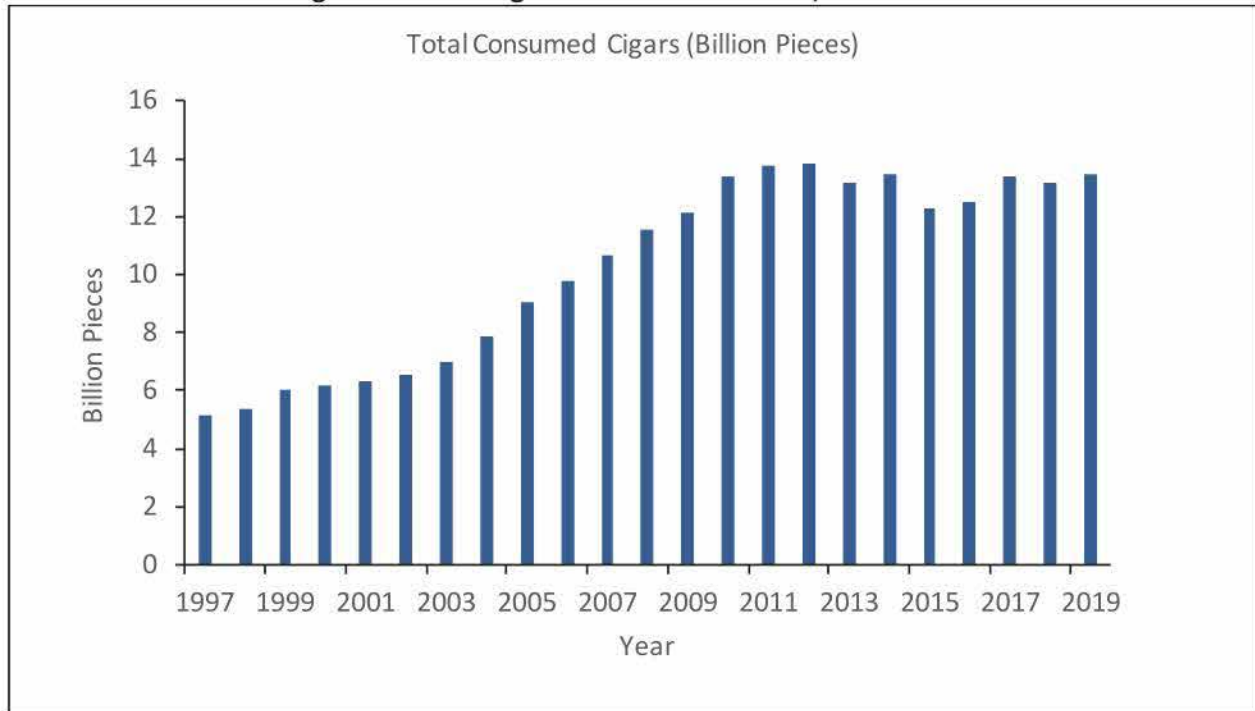
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment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

There is no safe level of exposure to SHS (DHHS, 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% (DHHS, 2006a and 2006b).
- 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 (DHHS, 2006a and 2006b).
- SHS causes more than 40,000 deaths per year (DHHS, 2014).

The consumption of cigars in the United States increased significantly during 1997 to 2011. Since 2011 through 2019, 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 2).¹ 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; other studies). 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. 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 (Yao et al., 2016).

¹ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtm> Accessed January 21, 2021.

Figure 2. Use of Cigars in the United States, 1984 – 2019

As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are also 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.

6.3. Environmental Justice

No new emissions are expected due to use of the new tobacco products. 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 tobacco products would 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 would allow for the applicant to distribute and sell the new tobacco 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 would 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 tobacco products. The chemicals in the new tobacco products are commonly used in other currently marketed cigars. Because the new tobacco products are anticipated to compete with or replace other currently marketed cigars, the butt waste generated from the new tobacco products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new tobacco 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 tobacco products would 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 waste (U.S. Environmental Protection Agency, 2019) per FDA's experience in evaluating the packaging waste generated from tobacco products.

7.3. Biological Resources

The applicant stated that 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,² the disposal of the new tobacco products is not expected to change the fire frequency because (1) the disposal of the new tobacco products would be similar to 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 as the new tobacco products are anticipated to replace similar marketed cigars.

² National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials>. Accessed January 21, 2021.

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 tobacco products because chemicals in the new tobacco products would be the same or similar to the chemicals in currently marketed cigars. Additionally, the new product would compete with or replace other cigars currently on the market.

7.5. Solid Waste

The use of the new tobacco products may impact the environment through littering of discarded cigar butts. The environmental impacts from cigar butt litter is not well studied, and potentially pose similar environmental risk as cigarette butts, which can persist in the environment for more than 18 months (Novotny and Zhao, 1999; Kurmus and Mohajerani, 2019).

Like cigarettes, compounds in cigar butts can leach out into water, potentially threatening human health and the environment, especially aquatic and marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigar butts due to air emissions is not well studied. Airborne emissions from cigar butts are likely to resemble those emissions from cigarette butts. Airborne emissions after disposal of cigarette butts depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the brand, length, filter material, types of tobacco, ingredients in the tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.³

The Agency does not foresee the introduction of the new tobacco products would notably affect the current cigar butt waste generated from all cigars. The waste generated due to disposal of the new tobacco products would 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 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 tobacco products. The waste generated due to disposal of the new tobacco 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 tobacco 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 tobacco products would continue to be disposed of in the United States.

³ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed January 25, 2021.

8. List of Preparers

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

Preparer:

Hermes Reyes Caballero, Ph.D., Center for Tobacco Products
 Education: Ph.D. in Biochemistry
 Experience: Twenty years in various scientific activities
 Expertise: Environmental toxicology, tobacco toxicology

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
 Education: Ph.D. in Environmental Science and Management
 Experience: Five 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.

10. References

American Lung Association. 2020. Smokefree Air Laws. Available at: <http://www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html> (updated December 10, 2020). Accessed January 21, 2021.

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*. 2011;119(2):A70-A74.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*. 2015;64(4):103-108.

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destailats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*. 2011;119(9):1218-1226.

Novotny TE, Zhao F. Consumption and production waste: Another externality of tobacco use. *Tobacco Control*. 1999;8(1):75-80.

Kurmus H, Mohajerani A. The toxicity and valorization options of cigarette butts. *Waste Management*. 2020;104:104-118.

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Environmental Protection Agency. (2019). Advancing Sustainable Materials Management: 2017 Fact Sheet. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. November 2019.

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;131:357-366.

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

STN	Modification
EX0001269/PD5	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Elimination of the adhesive (b) (4) from the binder • Addition of the complex adhesive (b) (4) to the binder • Decreased number of cigars per package
EX0001269/PD7	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Elimination of the additive (b) (4) from the wrapper • Elimination of the adhesive (b) (4) from the binder • Addition of the complex adhesive (b) (4) to the binder
EX0001269/PD9	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Deletion of wooden box package • Addition of cellophane package • Decreased number of cigars per package
EX0001269/PD11	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper
EX0001269/PD15	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Increased number of cigars per package
EX0001269/PD17	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper
EX0001270/PD15	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Decreased number of cigars per package
EX0001270/PD17	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Decreased number of cigars per package
EX0001271/PD3	<ul style="list-style-type: none"> • Addition of the additive (b) (4) in the wrapper • Increased number of cigars per package • Deletion of wooden box package • Addition of cellophane package
EX0001271/PD5	<ul style="list-style-type: none"> • Addition of the additive (b) (4) from the wrapper • Addition of the additive (b) (4) from the wrapper • Increased number of cigars per package • Deletion of wooden box package • Addition of cellophane package
EX0001271/PD7	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Elimination of the additive (b) (4) from the wrapper • Increased number of cigars per package • Deletion of wooden box package • Addition of cellophane package

EX0001271/PD9	<ul style="list-style-type: none"> • Addition of the additive (b) (4) from the wrapper • Deletion of wooden box package • Addition of cellophane package
EX0001271/PD11	<ul style="list-style-type: none"> • Addition of the additive (b) (4) from the wrapper • Decreased number of cigars per package • Deletion of wooden box package • Addition of cellophane package
EX0001271/PD13	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Elimination of the additive (b) (4) from the wrapper • Elimination of the additive (b) (4) from the wrapper • Decreased number of cigars per package
EX0001271/PD17	<ul style="list-style-type: none"> • Elimination of the additive (b) (4) from the wrapper • Decreased number of cigars per package • Deletion of wooden box package • Addition of cellophane package

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigar Use in the United States Projected to be Attributed to the New 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.⁴ 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 they would market the original product and that the new products simultaneously. In addition, the applicant stated that the original and new tobacco products would compete with similar tobacco products currently on the market.

STN	Market Volume				
	Current Year	Projected Volume			
		First Year		Fifth Year	
	Tobacco Product (Cigars)	Product (Cigars)	Product as a Percent of Total Cigars Used ⁵	Product (Cigars)	Product as a Percent of Total Cigars Used ⁶
EX0001269/PD5	(b) (4)				
Predicate to EX0001269/PD5 (GF1806358)	(b) (4)				
EX0001269/PD7	(b) (4)				
Predicate to EX0001269/PD7 (GF1805647)	(b) (4)				
EX0001269/PD9	(b) (4)				
Predicate to EX0001269/PD9 (GF1804185)	(b) (4)				
EX0001269/PD11	(b) (4)				
Predicate to EX0001269/PD11 (GF1805269)	(b) (4)				
EX0001269/PD15	(b) (4)				
Predicate to EX0001269/PD15 (GF1806358)					
EX0001269/PD17	(b) (4)				
Predicate to EX0001269/PD17 (GF1703489)	(b) (4)				
EX0001270/PD15	(b) (4)				

⁴ The Agency used historical data regarding total use of cigars from 1997 to 2019 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 13.51 billion cigars in the first year and 12.89 billion cigars in the fifth year of marketing the new products.

⁵ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$

⁶ Ibid.

Predicate to EX0001270/PD15 (GF1804205)	b) (4)
EX0001270/PD17	
Predicate to EX0001270/PD17 (GF1805633)	
EX0001271/PD3	
Predicate to EX0001271/PD3 (GF1906561)	
EX0001271/PD5	
Predicate to EX0001271/PD5 (GF1804216)	
EX0001271/PD7	
Predicate to EX0001271/PD7 (GF1907639)	
EX0001271/PD9	
Predicate to EX0001271/PD9 (GF1602085)	
EX0001271-PD11	
Predicate to EX0001271-PD11 (GF1804173)	
EX0001271-PD13	
Predicate to EX0001271-PD13 (GF1908832)	
EX0001271-PD17	
Predicate to EX0001271-PD17 (GF1907649)	
Total	