

**Programmatic Environmental Assessment for Marketing
Orders for New Cigars
Marketed by
Joseph Anderson dba Smokin Joes**

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

October 11, 2022

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1. Applicant and Manufacturer Information

Applicant Name:	Joseph Anderson dba Smokin Joes
Applicant Address:	4900 Indian Hill Road Lewiston, New York 14092
Manufacturer Name:	Joseph Anderson dba Smokin Joes
Product Manufacturing Location:	4900 Indian Hill Road Lewiston, New York 14092

2. Product Information

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

New Product Names	STNs	Original Product Names
Exacta Filtered Cigars Menthol	EX0002050.PD1	Smokin Time Filtered Cigars Menthol
Bogar Filtered Cigars Cherry	EX0002051.PD1	Smokin Time Filtered Cigars Cherry
No Limit Filtered Cigars Grape	EX0002052.PD1	Smokin Time Filtered Cigars Grape
No Limit Filtered Cigars Ultra Smooth	EX0002053.PD1	Smokin Time Filtered Cigars Ultra Light
No Limit Filtered Cigars Full Flavor	EX0002056.PD1	Smokin Time Filtered Cigars Full Flavor
No Limit Filtered Cigars Vanilla	EX0002058.PD1	Smokin Time Filtered Cigars Vanilla
Bogar Filtered Cigar Smooth	EX0002059.PD1	Smokin Time Filtered Cigar Light

Product Identification

Product Category:	Cigar
Product Subcategory:	Filtered, Sheet-Wrapped
Product Number per Retail Unit:	20 cigars in a soft pack and 10 soft packs in a carton
Product Package:	The packaging materials consist of a foil inner liner, inner frame paper, paperboard box wrapped in cellophane film, and cardboard carton

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 seven filtered, sheet-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 new products differ from the corresponding original products by a change in the tipping paper. (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

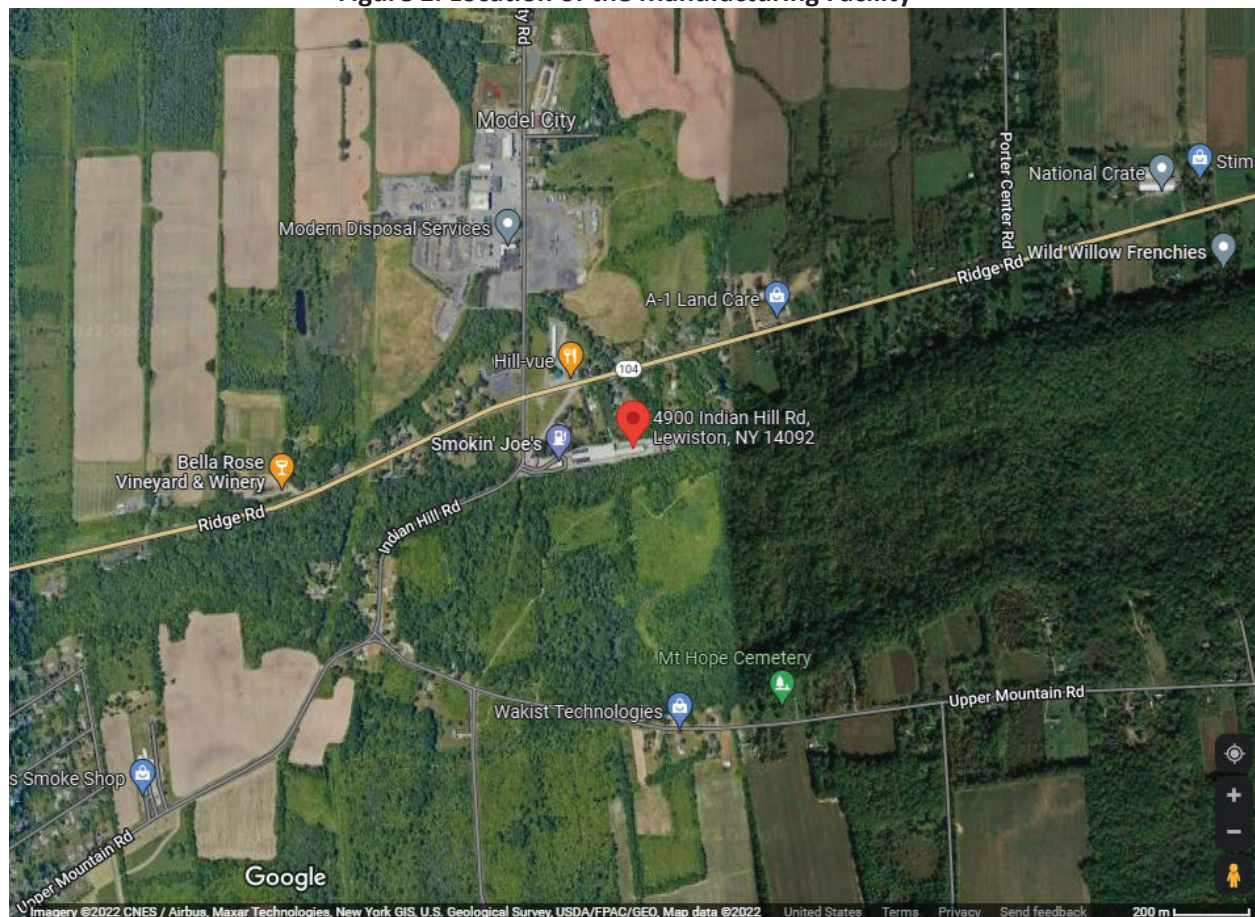
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- No facility expansion is expected due to manufacturing the new products.
- No new environmental controls will be needed due to manufacturing the new products.
- No new emissions will be expected due to manufacturing the new products.
- No new air or wastewater permits will be needed due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new products will be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility ¹



The manufacturing facility is located in a rural area of the Tuscarora Nation Indian Territory, within Niagara County, NY. There is a waste management facility to the north, a vineyard and winery to the west, and woodland area to the south and east of the facility.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products will cause the release of any new chemicals or new type of emissions into the environment. The applicant stated that no new compounds or increased amounts of compounds will be emitted due to manufacturing the new products.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into the water. The new products are intended to replace similar tobacco products currently manufactured at the facility. Additionally, the applicant stated that no new compounds or increased amounts of compounds will be emitted due to the manufacturing of the new products.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that there will be no expected facility expansion due to manufacturing the new products. Therefore, there will be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products will 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 manufacturing the new products will not require expansion of the manufacturing facility.

According to the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps², the facility is not within or near a critical habitat, or endangered animal or plant species. The U.S. FWS³ identifies the Northern Long-eared Bat (*Myotis septentrionalis*) as a threatened species present in the Niagara County. However, because the proposed actions do not require expansion of the manufacturing facility, and the listed species is not found in the immediate vicinity of the facility, the Agency does not expect any impacts to protected species or their potential habitat due to manufacturing the new products.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The Agency's search for the manufacturing facility in the Environmental Protection Agency's Enforcement and Compliance History Online database⁴ showed that, although the facility is listed, no detailed data is available.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.

Although the manufacturing facility is on Native Indian Land, no changes in impacts on minority populations are expected due to manufacturing the new products because no new chemical releases to the environment from manufacturing the new products were identified, and no facility expansion will occur as a result of manufacturing the new products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products will notably affect the current manufacturing waste generated from the facility production of all filtered cigars. The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility.

5.9 Floodplains, Wetlands, and Coastal Zones

There will be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance. Therefore, there will be no effects on floodplains, wetlands, or coastal zones.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of manufacturing cigars at the listed facility, as many similar tobacco products will continue to be manufactured.

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

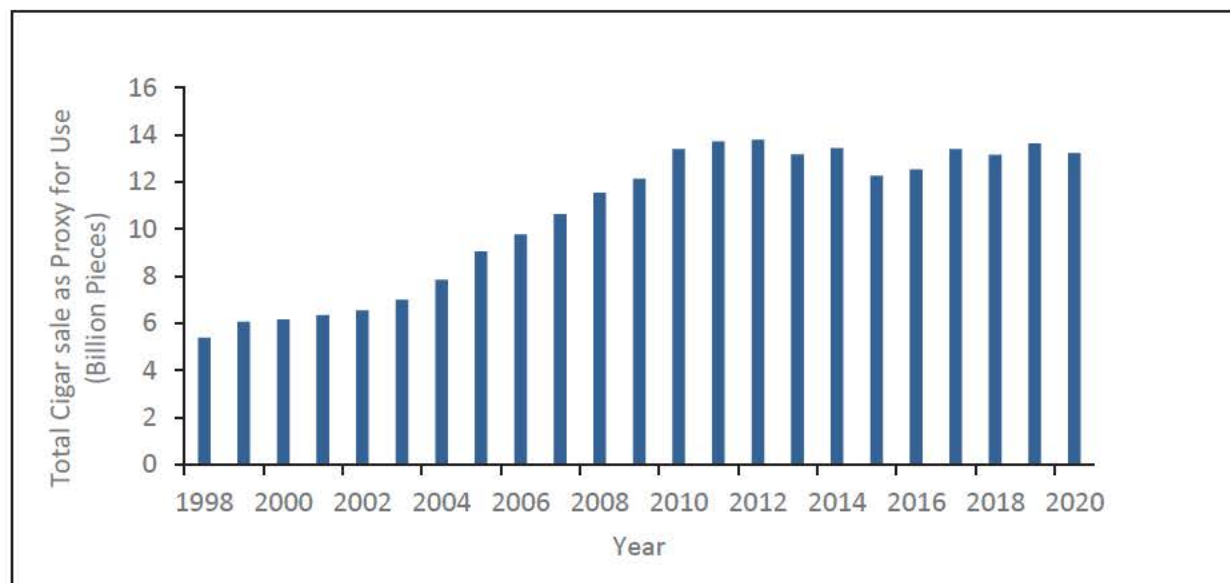
The impact from use of combusted tobacco products includes exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos, and pipes. Particles emitted by smoking might remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in a mixture in the environment alongside SHS.^{5, 6} THS can lead to exposure to carcinogens from tobacco and nicotine through dust inhalation and dermal uptake that may exceed health risk guideline levels.⁷

There is no safe level of exposure to SHS.^{8, 9} 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%.¹⁰
- 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.^{8, 9}
- SHS causes more than 40,000 deaths a year.¹⁰

Cigar sales 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).¹¹ 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.^{12, 13} 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 2013-2014.¹⁴ However, no change in exposure occurred between 2011–2012 and 2013–2014.¹⁴ 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 2010.¹³

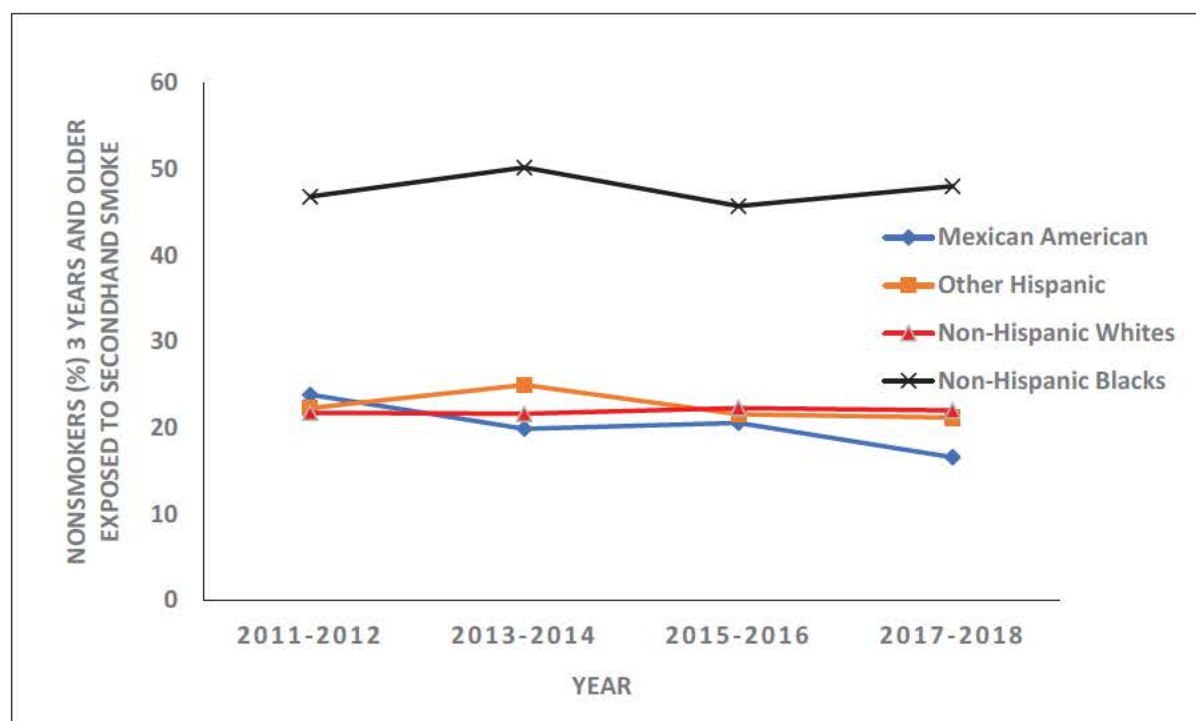
Figure 1. Total Cigar Sale as Proxy for Use in the United States, 1997 – 2020.



However, in recent years, a stagnation in reduction in rate of SHS exposure has been reported (Figure 2).¹⁵

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

Figure 2. Trends in the Exposure of Nonsmokers to Secondhand Smoke ¹⁵



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws. ¹⁶ 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 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 ¹⁷ 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, ¹⁸ 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) the Agency does not expect an increase in the 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.¹⁹ Like cigarettes, compounds in cigar butts can leach into water, potentially threatening human health and the environment, especially in aquatic and marine ecosystems.²⁰ 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.²¹

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:

Carla Figueroa, M.S., Center for Tobacco Products

Education: M.S. in Biotechnology

Experience: Six years in various scientific activities

Expertise: Water quality, wastewater treatment, 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
EX0002050.PD1, EX0002051.PD1, EX0002052.PD1, EX0002053.PD1, EX0002056.PD1, EX0002058.PD1, EX0002059.PD1	Change in tipping paper from (b) (4) . The new products' tipping paper contains different additives compared to the original products' tipping paper.

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for 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.[†] 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 Projection			
	First-Year (Cigars)	Product as a Percent of Total Cigars Used ^{†,‡}	Fifth-Year (Cigars)	Product as a Percent of Total Cigars Used ^{†,‡}
EX0002050.PD1	(b) (4)			
EX0002051.PD1				
EX0002052.PD1 [§]				
EX0002053.PD1				
EX0002056.PD1				
EX0002058.PD1				
EX0002059.PD1				
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 (%)=

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

(b) (4)