Environmental Assessment for Marketing Order for a New Cigar Manufactured by John Middleton Co.

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

November 22, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Altria Client Services LLC
Applicant Address:	2325 Bells Road Richmond, VA 23234
Manufacturer Name:	John Middleton Co.
Product Manufacturing Location:	John Middleton Co. (JMC) Bay 8 Building 2211 Bells Road Richmond, VA 23234

A subcontracted manufacturer would also produce the new product in a foreign country. Information regarding this manufacturer is in Confidential Appendix 1.

2. Product Information

Submission Tracking Number (STN), New Product and Predicate Product Names

STN	New Product Name	Predicate Product Name
SE0015410	Black & Mild® Wine Shorts	Black & Mild Wine

Product Identification

Product Category	Cigar
Product Subcategory	Unfiltered, sheet wrapped
Tip Property	Plastic tip
Product Number per Retail Unit	Sold individually, 25 individually wrapped cigars per pack and 30 packs per shipping case.
Product Package	The packaging materials consist of a polypropylene cigar overwrap, paperboard pack, polypropylene pack overwrap, polypropylene tear tape, and corrugated board shipping case.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) report to obtain marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product. The predicate product was previously found substantially equivalent (SE0015142).

The new product differs from the predicate product in the cigar dimensions, and ingredients in tobacco filler, cigar binder and cigar wrapper (Confidential Appendix 2).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue marketing order for the new tobacco product in the United States.

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

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

- The ingredients in the new product are commonly used or are similar to ingredients used in other cigars manufactured at the facility.
- No facility expansion is expected due to manufacturing the new product.
- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new product.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new product would be manufactured at 2211 Bells Road, Richmond, VA 23234 (Figure 1).

Figure 1. Location of the Manufacturing Facility

The manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping

station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.[1]

The facility is located in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area of the commonwealth of Virginia.[2,3] Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.[4]

5.2 Air Quality

The Agency does not anticipate that any new chemicals would be released into the environment due to manufacturing the new product. The applicant stated that manufacturing the new product is not expected to result in changes in air emissions. Accordingly, the applicant concluded that manufacturing the new product would not require any additional environmental controls for air emissions or a new air permit.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new product would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new product is not expected to result in changes in wastewater discharges and, therefore, would not require any additional environmental controls or a new water discharge permit.

5.4 Soil, Land Use, and Zoning

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

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new product would 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 reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps,

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[1] Google. 2018. Map of 2211 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. May 30, 2019.

[2] A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall, See https://water.usgs.gov/edu/watershed.html and http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf.

[3] Virginia Department of Environmental Quality. Available at: http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf. Accessed May 30, 2019

[4] Ibid

three threatened species (two flowering plants and one northern long-eared bat) and one endangered freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties).[5,6] However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided detailed information for the following air emission and wastewater permits issued for Philip Morris USA Inc. (PMUSA) manufacturing center, which includes JMC Bay 8 manufacturing facility:

(1) Air permit contained in the federal operating permit issued by the Virginia Department of Environmental Quality (VA DEQ) under Permit No. PRO52608.

(2) Wastewater discharge permit number 2149 issued by the Division of Wastewater Treatment, City of Richmond. The permit requires compliance with the relevant effluent limitations (40 CFR 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the publicly owned treatment works facility. The applicant stated that the facility complies with the requirements of this permit and submits regular discharge monitoring reports to VA DEQ.

The Agency's search for the manufacturing facility in the EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.[7] The applicant stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.7 Socioeconomics and Environmental Justice

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

No changes in impacts on environmental justice are anticipated. The applicant stated that the projections of future cigar production at the facility, including for the new product, are within the existing permitted manufacturing capacity and would not require facility expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new product. Thus, though 2010 U.S. Census and American Community Survey data show that 80% of the population within three miles of the manufacturing facility is minority with 46% under the poverty

[5] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed February 19, 2019.

[6] Critical habitat maps available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449.

[7] EPA ECHO Detailed Facility Report: John Middleton Co., Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110070005247. Accessed September 27, 2019.

line,[8] no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new product. In addition, the facility is not located within Native American lands.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new product would notably affect the current manufacturing waste generated from the facility production of all unfiltered cigars. The Agency anticipates that the waste generated due to manufacturing the new product would 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. The applicant stated that manufacturing the new product would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

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

5.10 Cumulative Impacts

The Agency does not anticipate the proposed action would incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. JMC is a wholly owned subsidiary of PMUSA and the JMC Bay 8 facility is located in the PMUSA manufacturing center. Therefore, production-related releases from the JMC manufacturing facility are included in PMUSA's toxic release data reported in the EPA's Toxic Release Inventory (TRI) database. A search in the EPA's TRI database showed that in 2017, PMUSA manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air (Table 1).[9] Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts, have known adverse developmental effects.[10] The TRI database search did not show that the PMUSA manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

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[8] Ibid.

[9] U.S. Environmental Protection Agency (EPA). TRI Data Form R & A Download. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on February 19, 2019.

[10] EPA. myRight-to-Know, available at: https://myrtk.epa.gov/info. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed February 19, 2019.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2017

Production-Related Waste Managed or Released		Chemical Mass (Pounds)
Recycled		126,020
Energy Recovery		0
Treated		104,427
Subtotal Waste Managed		*230,447*
On-Site Release	Ammonia	18,713
	Nicotine and Nicotine Salts	10,683
Off-Site Release		60,822
Subtotal Waste Released		*90,218*
Total Production-Related Waste		**320,665**

The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and, therefore, a new or revised air permit, storm water permit, or waste water permit would not be required.

5.11 Impacts of the No-Action Alternative

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

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

The Agency considered potential impacts to resources in the environment that could be affected by use of the new product 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 for the new product (Confidential Appendix 3) 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 order would allow for the new tobacco product to be sold to consumers in the United States.

6.2 Air Quality

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new 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 product would be released in the same manner as the combustion products of any other marketed cigars, (2) the new product is expected to compete with or replace other currently marketed cigars, and (3) the ingredients in the new 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 would be no new disproportionate impacts on minority or low-income populations.

6.4 Cumulative Impacts

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).

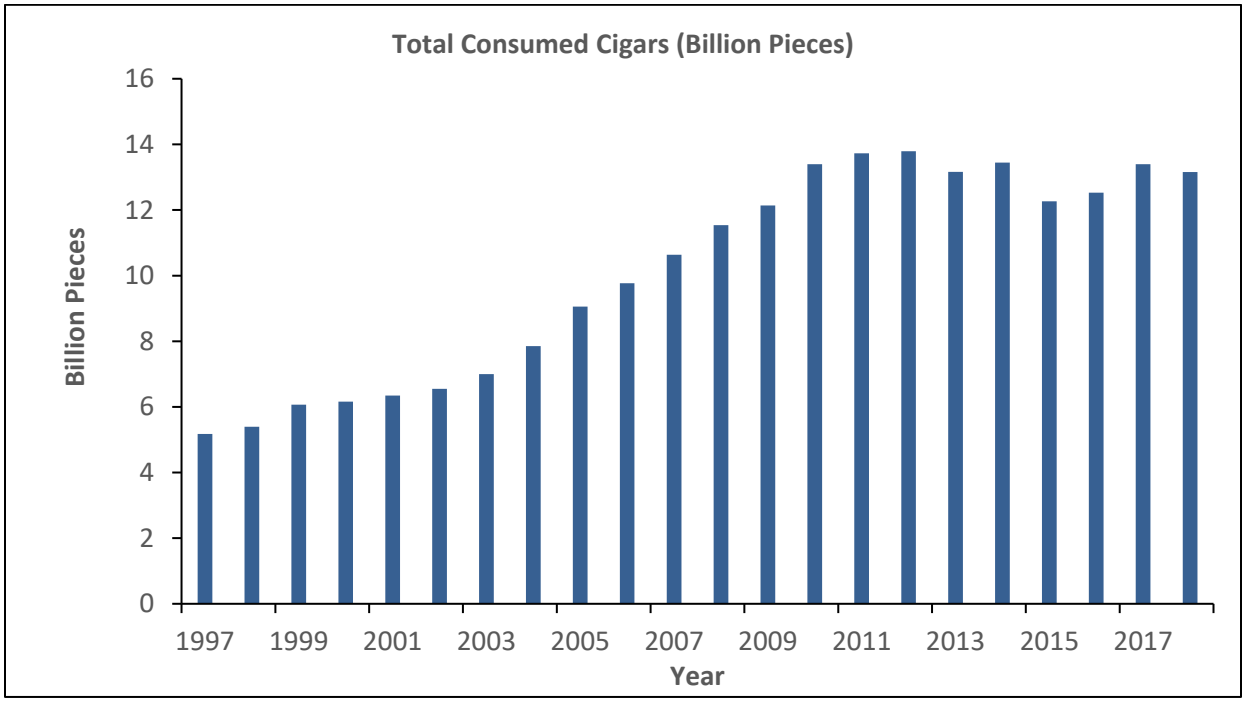
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- 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 (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

The consumption of cigars in the United States increased significantly from 1997 to 2011. From 2011 through 2018, the trend of cigar use has stabilized with minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[11] 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). 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).

[11] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 7, 2018

Figure 2. Use of Cigars in the United States, 1997 – 2018



As of March 2019, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2018). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

6.5 Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of use of cigars, as similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Action and the Alternatives – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product. 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 product (Confidential Appendix 3), 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 would allow for the applicant to distribute and sell the new tobacco product to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate that disposal of the new product 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 cigars and cigar tips of the new product. The chemicals in the new product and cigar tips are commonly used in other currently marketed cigars. Because the new product is anticipated to compete with or replace other currently marketed cigars, the tip waste generated from the new product would replace the same type of waste. 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 packaging materials in the new product would 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 per FDA's experience in evaluating the packaging waste generated from tobacco products.

7.3 Water Resources

No changes in any impacts on water resources are expected due to disposal of the unburned cigars and cigar tips from the new product because the chemicals in the new product would be the same or similar as in currently marketed cigars and the new product would compete with or replace other cigars currently on the market.

7.4 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. ESA because (1) the disposal of the new product 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 product is anticipated to replace similar marketed cigars.

7.5 Solid Waste

The Agency does not foresee the introduction of the new product would notably affect the current cigar tip waste generated from all cigars. The waste generated due to disposal of the new product 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 tips generated is equivalent to the market projections (Confidential Appendix 3); 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 product. The waste generated due to disposal of the new product 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 product; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

The use of the new product may impact the environment through littering of discarded non-combusted cigar and cigar tips. The environmental impacts from cigar tip litter is not well studied, and potentially pose similar environmental risk as cigarette butts (Novotny and Zhao, 1999).

Like cigarettes, compounds in cigar tips 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 tips due to air emissions is not well studied. Airborne emissions from plastic cigar tips would likely include different chemicals than the emissions from cigarette butts. However, the fate of those emissions is likely to be similar and cigarette butt emissions have been studied more than cigar tip emissions. For cigarette butts, the airborne emissions after disposal 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 cigarette tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[12]

However, the cumulative impacts from cigar tips are not of concern as TTB data shows relatively stable rate of cigar use in the United States since 2011 and the proposed action is unlikely to change that.

7.8 Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of disposal of cigars and cigar packaging, as similar tobacco products would 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:

Dilip Venugopal, Ph.D., Center for Tobacco Products
- Education: M.S. in Ecology and Ph.D. in Entomology
- Experience: Seventeen years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
- Education: M.S. in Environmental Science and Ph.D. in Biochemistry
- Experience: 11 years in FDA-related NEPA review
- Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

[12] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed August 16, 2018.

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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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

Comparison of the New Product to the Predicate Product

STN	Component	Change from Predicate Product
SE0015410	Cigar rod	Decreased target rod length, and weight
	Cigar tobacco filler	Decreased tobacco filler weight and the target values of all other ingredients reduced
	Cigar wrapper	Reduction in (b) (4) [redacted]
	Cigar binder	Reduction in tobacco content, (b) (4) [redacted]

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New and Predicate Products and Percentage of Cigar Use in the United States Projected to be Attributed to the New and Predicate Products

The applicant intends to simultaneously market both the new and predicate products and provided their first-and fifth-year market volumes. First- and fifth-year market volume projections for the new and predicate products were compared to the total forecasted use of cigars in the United States.[13] The new and predicate products account for a fraction of a percent of the forecasted cigar use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used[14]	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used[15]
SE0015410 (New product)	(b) (4)	[redacted]	[redacted]	[redacted]
SE0015142 (Predicate product)	(b) (4)	[redacted]	[redacted]	[redacted]
Total	(b) (4)	[redacted]	[redacted]	[redacted]

[13] The Agency used historical data regarding total use of cigars from 1997 to 2018 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 0.92, the forecasted number of cigars that would be used in the United States is estimated at 13.664 billion cigars in the first year and 13.429 billion cigars in the fifth year of marketing the new product.

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

[15] Ibid.