

**Programmatic Environmental Assessment
for Marketing Orders for Six
New Cigars
Manufactured by John Middleton Co.**

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

May 15, 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:	2211 Bells Road, JMC Bay 8 Building Richmond, VA 23234

A subcontracted manufacturer would also produce the new products through a third-party manufacturer. Information regarding the third-party manufacturer and subcontracted manufacturer is in Confidential Appendix 1.

2. Product Information

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

New Product Name	STN	Predicate Product Name
Middleton's Cherry Blend	SE0015138	Middleton's Cherry Blend
Middleton's Cherry Blend	SE0015139	Middleton's Cherry Blend
Black & Mild® Wine Wood Tip	SE0015140	Black & Mild Wine
Black & Mild® Wine Wood Tip	SE0015141	Black & Mild Wine
Black & Mild® Wine	SE0015142	Black & Mild Wine
Black & Mild® Wine	SE0015143	Black & Mild Wine

Product Identification

Product Category	Cigar
Product Subcategory	Unfiltered, sheet-wrapped
Product Number per Retail Unit	SE0015138 and SE0015143: Five plastic mouth tipped cigars per pack with ten packs per paperboard display tray (which serves as a display) and shipped 30 trays per shipping case. SE0015139 and SE0015142: Twenty-five individually wrapped plastic mouth tipped cigars per pack (which serves as a display) with 30 packs per shipping case. SE0015140: Twenty-five individually wrapped wood mouth tipped cigars per pack (which serves as a display) with 30 packs per shipping case. SE0015141: Five wood mouth tipped cigars per pack with ten packs per paperboard display tray (which serves as a display) and shipped 30 trays per shipping case.
Product Package	The pack consists of a paperboard box, polypropylene outer film, and polypropylene tear tape. Individual cigars inside the box pack are wrapped in polypropylene overwrap film with a polypropylene tear tape. The paperboard display trays are wrapped in a polypropylene film and placed in a corrugated board shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the predicate products. The predicate products are grandfathered products commercially marketed in the United States as of February 15, 2007.

The new products differ from the predicate products in cigar rod length, circumference, and ingredients in the wrapper, binder and tobacco filler.

4. Alternatives to the Proposed Actions

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

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

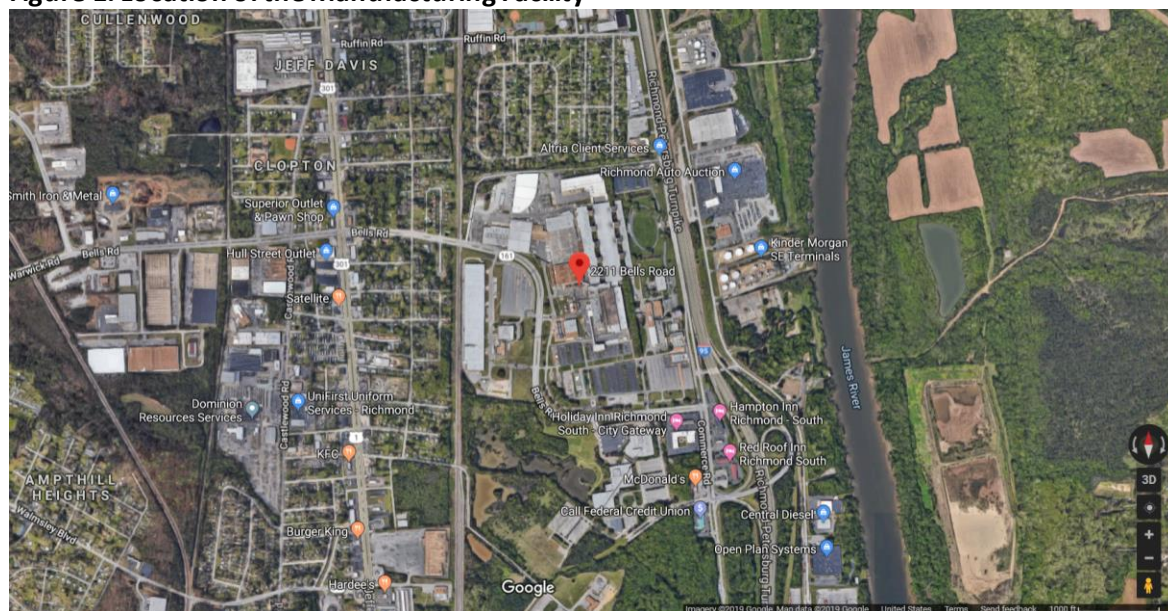
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The level of the alternative ingredients in the new products that are replacing the ingredients in the predicate products; these ingredients are each a small percentage of the total products.
- The new products are intended to replace the predicate products if marketing orders are issued.
- No facility expansion or new construction is expected due to manufacturing the new products.
- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new products.

5.1 Affected Environment

The new products would be manufactured at 2211 Bells Road, Richmond, VA 23234 (Figure 1) and the subcontracted manufacturing facility (Confidential Appendix 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 products. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing

¹ Google. 2019. Map of 2211 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. April 25, 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 April 26, 2019.

⁴ Ibid

the new products would not require any additional environmental controls or new permits for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products is not expected to result in changes in wastewater discharges; accordingly, the applicant concluded that manufacturing the new products would not require any additional environmental controls or new permits for water discharges.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated that no facility expansion or new construction due to manufacturing the new products 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 manufacturing the new products 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 stated that there are no plans of expanding the facility production beyond its current permitted level. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two flowering plants – sensitive joint-vetch and swamp pink, and one mammal - northern long-eared bat), and one endangered freshwater mussel species - James spinymussel 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, storm water, and wastewater permits:

- (1) Stationary source permit (Registration no. 52608) in accordance with provisions of the Virginia State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution, issued by the Department of Environmental Quality, Commonwealth of Virginia (VA DEQ).
- (2) Wastewater permit number 2149 issued by the Division of Wastewater Treatment, City of Richmond. The applicant stated that the facility complies with the requirements of this permit, which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting. The permit requires compliance with the relevant effluent limitations (40 CFR 400 –

⁵ U.S. Fish and Wildlife Service (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed April 26, 2019.

⁶ Critical habitat maps available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>.

699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The applicant stated that the facility 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.

The applicant also stated that the subcontracted manufacturing facility complies with all applicable laws and regulations.

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 the predicate products and similar tobacco products currently manufactured at the facility.

No changes in impacts on environmental justice are anticipated. The applicant stated that the future year projections of cigar production at the facility, including the new products, 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 products. Thus, though 2010 U.S. Census and American Community Survey data show that 80% of the population within a three-mile radius of the manufacturing facility is minority,⁸ no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products. In addition, the facility is not located within an Indian reservation.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all unfiltered cigars. The Agency anticipates the waste generated due to manufacturing the new products 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 products 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.

⁷ EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 26, 2019.

⁸ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 26, 2019.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products 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 actions to incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, Philip Morris USA manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air, (a total of 29,396 pounds), but released no other hazardous air pollutants at reportable levels (Table 1).⁹ Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts, have known adverse developmental effects.¹⁰ The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and therefore, a revised or new air permit would not be required. The TRI database search did not show that the Philip Morris USA 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.

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
<i>Subtotal Waste Managed</i>			<i>230,447</i>
On-Site Release	Air	Ammonia	18,713
		Nicotine and Nicotine Salts	10,683
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-Site Release			60,822
<i>Subtotal Waste Released</i>			<i>90,218</i>
Total Production-Related Waste			320,665

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 April 26, 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 April 26, 2019.

The other manufacturing facility in the industrial complex (Altria Compounds, LLC) which has the potential to generate and manage 2,200 pounds of monthly hazardous waste does not report to EPA's TRI database, as it is considered a minor facility.^{11,12} The Agency's search for the manufacturing facility in the 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. The applicant does not anticipate manufacturing the new products would require a revised or new storm water permit or waste water permit.

5.11 Impacts of the No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – 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 3) 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 would allow for the new tobacco products to be sold to consumers in the United States.

6.2 Air Quality

The Agency does not anticipate new chemicals would 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 would be released in the same manner as the combustion products of any other marketed cigars; (2) the new products are expected to replace the predicate products if marketing orders are issued; (3) the new products are expected to compete with, or replace, other currently marketed; and (4) 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 would be no new disproportionate impacts on minority or low-income populations.

¹¹ See footnote 7.

¹² See footnote 10.

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).

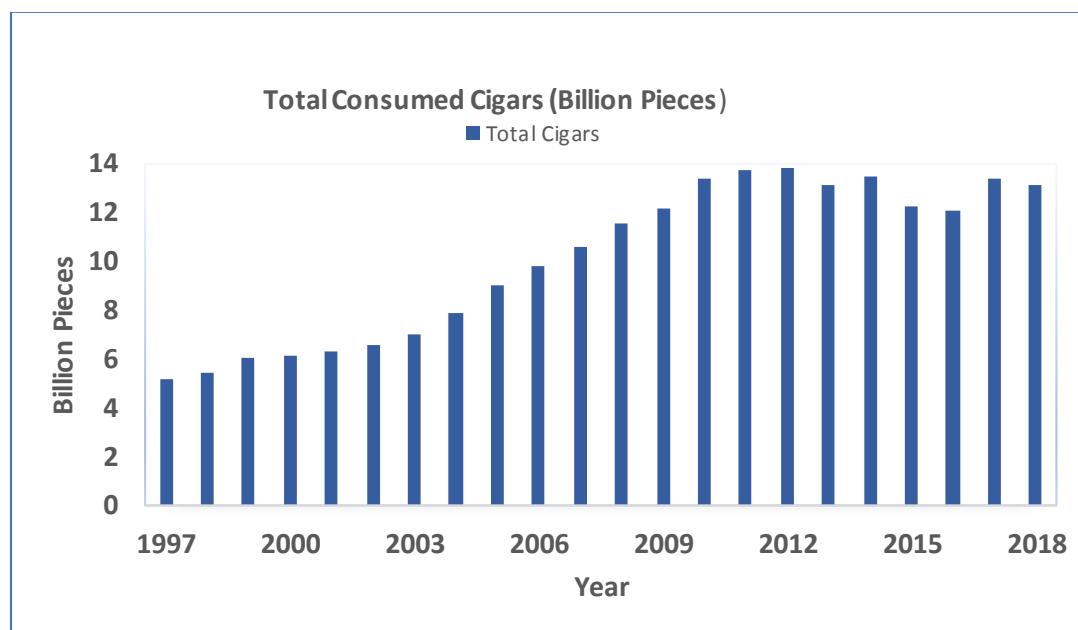
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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 during 1997 to 2011. Since 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).¹³ In combination with declines in the 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).

¹³ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed April 26, 2019.

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 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 marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – 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 material would 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 as well as plastic and wood tips of the new products. The chemicals in the cigar butts are commonly used in other currently marketed cigars. Because the new product is anticipated to compete with or replace other currently marketed cigars, the butt and tip waste generated from the new 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 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 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 cigar butts from the new products because the chemicals in the new products are like chemicals in currently marketed cigars and the new products would compete with or replace other cigars currently on the market.

7.4 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,^{14,15} the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products would be the same as 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 products are anticipated to replace similar marketed cigars.

7.5 Solid Waste

The Agency does not foresee the introduction of the new products would notably affect the current cigar butt and tip waste generated from all unfiltered, tipped, sheet-wrapped cigars. The waste generated due to disposal of the new products would be in the same manner as any other waste generated from any other unfiltered, tipped, sheet-wrapped cigars disposed of in the United States. The number of cigar butts and tips generated is equivalent to the market projections (Confidential Appendix 3); a portion of those would be littered.

¹⁴ 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 April 26, 2019.

¹⁵ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed April 26, 2019.

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 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 products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

The use of the new products may impact the environment through littering of discarded cigar wood or plastic filter tips and cigar butts. The environmental impacts from cigar butt litter is not well studied, and potentially poses similar environmental risk as cigarette butts, which can persist in the environment for more than 18 months (Novotny and Zhao, 1999).

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 and cigarette butts due to air emissions is not well studied. Airborne emissions from cigar and cigarette butts 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 cigar tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigar.¹⁶

However, the cumulative impacts from cigar butts is not of concern as TTB data shows relatively stable rate of cigar use in the United States since 2010 and the proposed actions are unlikely to change that.

7.8 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 marketed in the United States.

8. List of Preparers

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

Preparer:

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-four years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

¹⁶ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 26, 2019.

Reviewer:

Gregory Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: Thirty-six years in environmental toxicology and risk assessment

Expertise: NEPA analysis, environmental risk assessment, environmental fate and effects

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Homa, D.M., Neff, L.J., King, B.A., Caraballo, R.S., Bunnell, R.E., Babb, S.D., Garrett, B.E., Sosnoff, C.S., & Wang, L. (2015). Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*, 64(4), 103-108.

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

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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

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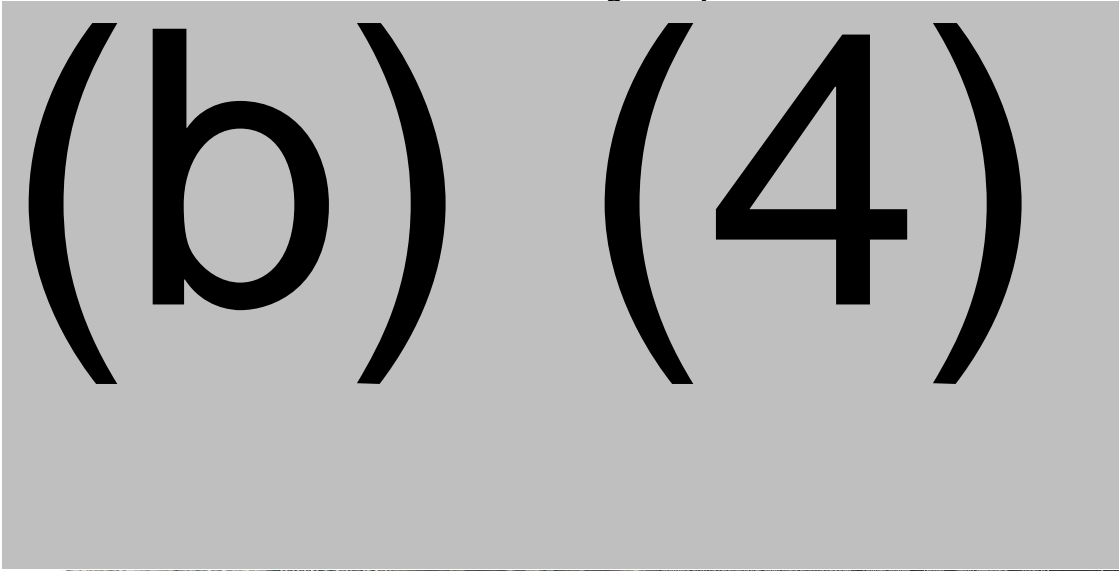
CONFIDENTIAL APPENDIX 1

Third-Party and Subcontracted Manufacturing Facility

Applicant Name:	Altria Client Services LLC
Applicant Address:	2325 Bells Road, Richmond, VA 23234
Third-Party Manufacturer Name:	(b) (4)
Third-Party Manufacturer Location:	(b) (4)
Subcontracted Manufacturer Name:	(b) (4)
Subcontracted Manufacturer Location:	(b) (4)

The subcontracted facility is located in the (b) (4) and is bounded by residential and agricultural land. The applicant stated that facility is in compliance with all applicable laws and regulations and that the manufacturing contract is contingent upon the facility obtaining and maintaining all applicable permits or licenses.¹⁷ No products are manufactured in the third-party location.

Location of the Subcontracted Manufacturing Facility



¹⁷ Google. 2019. (b) (4). Retrieved from Google Maps: www.google.com/maps. April 24, 2019.

CONFIDENTIAL APPENDIX 2

Comparison of the New Products Compared to the Predicate Products

STN	Component	Modification
SE0015138 SE0015139	Cigar Rod and circumference	Reduction in length and diameter
SE0015140 SE0015141 SE0015142 SE0015143	Cigar wrapper	Replacement of (b) (4) with a lesser quantity of (b) (4) (b) (4)
	Cigar binder	Replacement of (b) (4) with a lesser quantity of (b) (4) Replacement of (b) (4) with an equal quantity of (b) (4)
	Cigar tobacco filler	Reduction in weight

CONFIDENTIAL APPENDIX 3

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 for the new products were compared to the total forecasted use of cigars in the United States.¹⁸ The new products account for a small percentage of the forecasted cigar use in the United States. In addition, the applicant does not intend to simultaneously market the predicate and new products.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used ¹⁹	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used ²⁰
SE0015138	(b) (4)			
SE0015139				
SE0015140				
SE0015141				
SE0015142				
SE0015143				
Total				

¹⁸ 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 R² value of 0.91, the forecasted number of cigars that would be used in the United States is estimated at 13.725 billion cigars in the first year and 13.562 billion cigars in the fifth year of marketing the new product.

¹⁹ Projected Market Occupation of the New Product in the United States (%)=

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

²⁰ See footnote #18 and #19.