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

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

July 20, 2020

Table of Contents

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

A subcontracted manufacturer would also produce the new products in a foreign country (Confidential Appendix 1).

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0015597	Black and Mild® Blues Wood Tip	Prince Albert Soft Cherry Vanilla
SE0015600	Black and Mild® Blues	

Product Identification

Product Category	Cigar
Product Subcategory	Unfiltered, sheet wrapped
Tip Property	SE0015597- Wood tip SE0015600- Plastic tip
Product Number per Retail Unit	Individually wrapped cigars or co-packaged as 5 individually wrapped cigars, 10 co-packaged cigars per display tray, and 30 display trays per shipping case.
Product Package	The packaging materials consist of individual cigar polypropylene overwrap, paperboard pack, polypropylene pack overwrap, polypropylene tear tape, paperboard display tray, and corrugated board shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. 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 single predicate product. The predicate product is a grandfathered tobacco product (GF1602193) commercially marketed in the United States as of February 15, 2007.

The new products differ from the single predicate products in ingredients, tobacco rod size, wrapper and binder composition, and tip composition (Confidential Appendix 2). In addition, the plastic tip in the predicate product is replaced by a wood tip in the new product in SE0015597.

4. Alternatives to the Proposed Actions

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

5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Tobacco 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 production of the new products will replace production of other similar tobacco products currently manufactured at the facility.
- No facility expansion 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 affected environment includes human and natural environments surrounding the manufacturing facility. 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 the new products 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 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 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 products would lead to changes in soil, land use, or zoning. The applicant stated that no facility expansion 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.

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[1] Google. 2018. Map of 2211 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. June 26, 2020.

[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 June 26, 2020.

[4] Ibid

5.5 Biological Resources

The Agency does not anticipate that 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 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 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 relevant federal, state, and local environmental regulations including the Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act. The applicant provided detailed information for the following air emission and wastewater permits issued for Philip Morris USA Inc. (PMUSA) manufacturing center, which includes John Middleton Co. (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 (POTW) 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.

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

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[5] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed June 26, 2020.

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

[7] EPA ECHO Detailed Facility Report: Philip Morris USA manufacturing center, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed June 26, 2020.

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.

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 three miles of the manufacturing facility is minority with 46% under the poverty line,[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 a Native American land.

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 that 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.

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 would incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. John Middleton Co. (JMC) is a wholly owned subsidiary of Philip Morris USA Inc. (PMUSA) and the JMC Bay 8 manufacturing facility is located in the PMUSA manufacturing center. Therefore, production-related releases from the 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 2018, PMUSA manufacturing facility in Richmond, Virginia released 10,313 pounds of nicotine and nicotine salts to air, but released no other hazardous air pollutants at reportable levels (Table 1).[9] Nicotine and nicotine salts have known adverse developmental effects.[10] The TRI database search did not show that the PMUSA manufacturing facility

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[8] See footnote #7.

[9] U.S. Environmental Protection Agency (EPA). TRI Data Available at: https://enviro.epa.gov/facts/tri/ef-facilities/#/Waste/23234PHLLP3601C. Accessed June 26, 2020.

[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 June 26, 2020.

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 2018

Production-Related Waste Managed or Released		Chemical Mass (Pounds)
Recycled		122,530
Energy Recovery		0
Treated		94,266
Subtotal Waste Managed		*216,796*
On-Site Release	Ammonia	0
	Nicotine and Nicotine Salts	10,313
Off-Site Release		35,528
Subtotal Waste Released		*45,841*
Total Production-Related Waste		**262,637**

The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and, therefore, a new air or wastewater permits 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 Actions and Alternatives – Use of the New Tobacco 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 for the new products (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 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 that 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 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 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 exposure to SHS can harm children and adults in many ways, including the following:

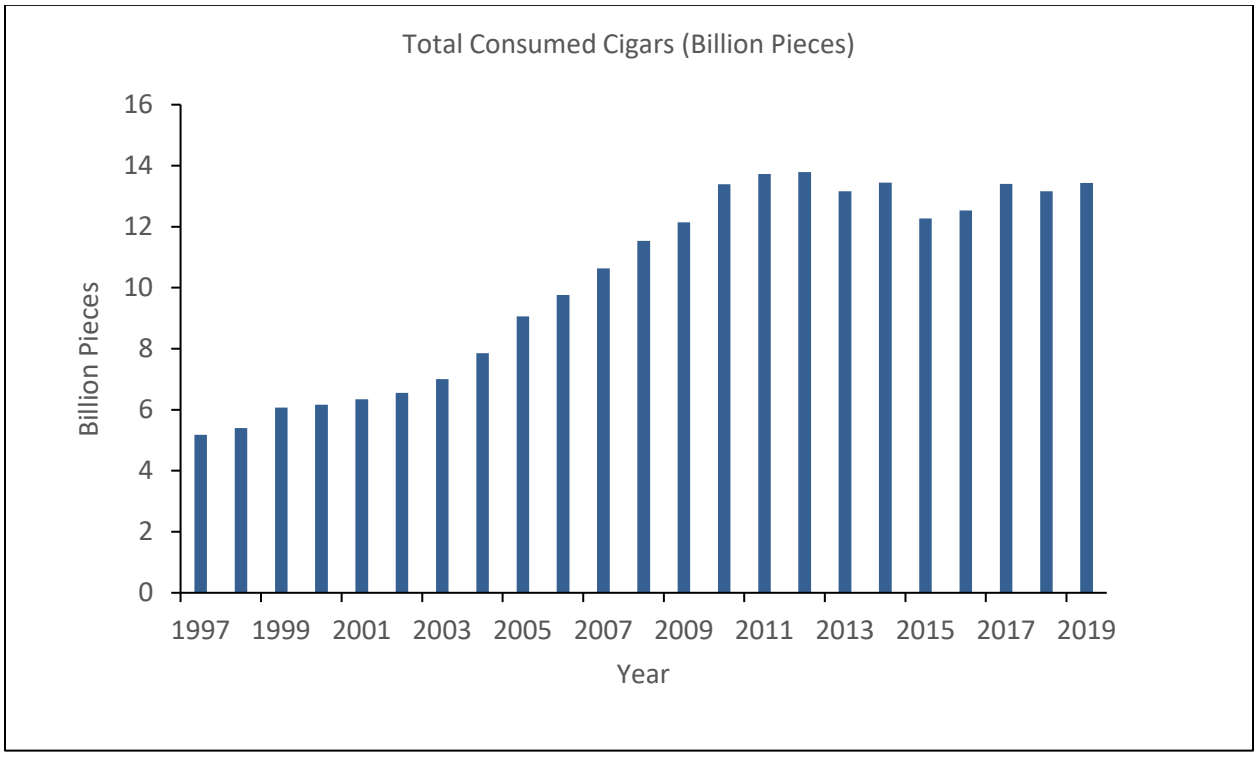
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent 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 2019, 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

[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 12, 2020.

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).

Figure 2. Use of Cigars in the United States, 1997 – 2019



As of March 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.

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 Actions and Alternatives – Disposal of the New Tobacco 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 that 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 cigars and cigar tips of the new products. The chemicals in the new products and cigar tips are commonly used in other currently marketed cigars. Because the new products are anticipated to compete with or replace other currently marketed cigars, the 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 unburned cigars and cigar tips from the new products because the chemicals in the new products would be the same or similar as in currently marketed cigars and the new products would compete with or replace other cigars currently on the market. The wood tip in SE0015597 would be biodegradable; thus, it is a relatively shorter-lasting environmental issue compared to the plastic tips in the predicate product, specifically in waterbodies and run-offs from an urban environment.

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 because (1) the disposal of the new 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 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 tip waste generated from all cigars. The waste generated due to disposal of the new 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 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 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 non-combusted cigar and cigar tips. The environmental impacts from plastic cigar tip litter is not well studied, and potentially pose similar environmental risk as cigarette butts and plastic waste.

Like cigarette butt leachate, which may cause cumulative impacts to the aquatic environment, especially marine ecosystems (Kadir and Sarani, 2015), there is likely to be some toxicity from plastic cigar tip leachate. Again, cigar tips are likely to pose similar issues as cigarette butts and may also be an acute health hazard to animals and small children who might accidentally ingest them (Novotny and Zhao, 1999). However, the wood tip in the new product in SE0015597 replaces the plastic tip in the predicate product and, therefore, may pose less risk to the aquatic environment; the wood tip is biodegradable with a relatively shorter-lasting environmental issue compared to the plastic tip, specifically in waterbodies and run-offs from an urban environment.

The environmental toxicity of plastic 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 to cigarette butt emissions, which have been studied more than plastic 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 2010 and the proposed actions are 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:

[12] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed June 26, 2020.

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Six years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

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

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

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

American Lung Association. 2018. Smokefree Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (updated March 8, 2019). Accessed August 20, 2019.

Burton B. (2011). Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*, *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 A A, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats 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.

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. 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.

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: Subcontracted Manufacturing Facility

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

The third-party manufacturing facility is located in the (b) (4), which is bounded by residential and agricultural land (Figure below). The applicant stated that the facility complies with all applicable laws and regulations and that the manufacturing contract is contingent upon the facility obtaining and maintaining all applicable permits or licenses.

(b) (4)

Confidential Appendix 2: Changes in the New Products as Compared with the Corresponding Predicate Products

STN	Component	Change from Corresponding Predicate Product
SE0015597 SE0015600	Wrapper and binder	Removal of (b) (4) and (b) (4) .
	Cigar rod	Reduction in rod length and diameter.
	Cigar tobacco filler	Removal of 88 ingredients.
SE0015600	Cigar tip	Change in composition in plastic tip with the addition of (b) (4) and a (b) (4) , and a decrease in (b) (4)

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.[13] The new products would account for about (b) (4) % and (b) (4) % of the forecasted cigar use in the United States in the first and fifth years of marketing, respectively.

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]
SE0015597	(b) (4)			
SE0015600				
Total				

The applicant does not intend to market the new and predicate products simultaneously, after receiving marketing orders for the new products.

[13] 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 R^2 value of 0.926, the forecasted number of cigars that would be used in the United States is estimated at 13.56 billion cigars in the first year and 13.11 billion cigars in the fifth year of marketing the new product.

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

[15] Ibid.