

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

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

December 21, 2018

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### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	Altria Client Services LLC
<b>Applicant Address:</b>	2325 Bells Road Richmond, VA 23234
<b>Manufacturer Name:</b>	John Middleton Co.
<b>Address Where the Products are Manufactured:</b>	2211 Bells Road, JMC Bay 8 Building Richmond, VA 23234

A subcontracted manufacturer will also produce the new product. Information regarding this manufacturer is in Confidential Appendix 1.

### 2. Product Information

#### New Product Names, Submission Tracking Numbers (STN), and Original Product Names

STN	New Product Name	Original Product Name	Amendments
EX0000297	Gold & Mild	Gold & Mild	N/A
EX0000298	Gold & Mild	Gold & Mild	N/A
EX0000299	Black & Mild Select	Black & Mild Select	N/A
EX0000300	Black & Mild Select	Black & Mild Select	N/A

#### Product Identification

<b>Product Category</b>	Cigars
<b>Product Subcategory</b>	Unfiltered sheet-wrapped
<b>Tip</b>	Plastic
<b>Quantity per Retail Sale Unit</b>	Sold as a pack of five individually wrapped cigars at retail.
<b>Product Package</b>	The pack of five is overwrapped with polypropylene film. The pack contains a single strip of tear tape. Ten five-packs are packed in a paperboard tray. Thirty display trays are placed in a shipping case.

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for 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 four combusted, non-filtered cigars. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if: (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products are made by modifying the corresponding original products. These modifications are to remove two ingredients and replacing them with equal quantities of alternate ingredients (Confidential Appendix 1).

#### **4. Alternatives to the Proposed Actions**

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

#### **5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products**

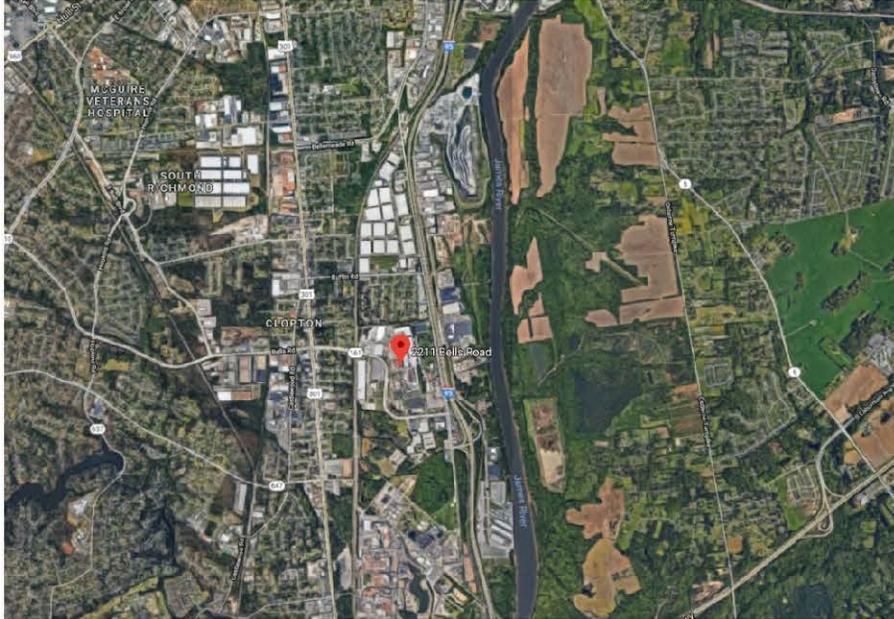
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on Agency-gathered information and the following information submitted by the applicant:

- Replacing the two alternative ingredients in the tobacco filler and cigar wrapper is a small percentage change.
- The new products are intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

##### **5.1 Affected Environment**

The new product would be manufactured at the address listed in section 1 of this document (Figure 1) and the subcontracted manufacturing facility (Confidential Appendix 1).

**Figure 1. Location of the Manufacturing Facility**



The manufacturing facility is in Richmond County, VA in Falling Creek-James River watershed, hydrologic unit code 02080206, in proximity to the James River in the east.<sup>1,2</sup> The facility is surrounded by residential and commercial areas in the western portion in proximity to the community of Clapton, VA and mixed natural areas and agricultural land to the east.

## 5.2 Air Quality

The Agency does not anticipate any new chemicals would be emitted 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 revised or new air permits.

## 5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would 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. The applicant stated that manufacturing the new products is not expected to result in changes in wastewater discharge and therefore, would not require revised or new wastewater discharge permits.

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<sup>1</sup> 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>.

<sup>2</sup> USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed November 20, 2018.

## 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. 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 Services' (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two flowering plants, the sensitive joint-vetch and the swamp pink, as well as the 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).<sup>3,4</sup> 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, including the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. The manufacturing facility is registered for waste generation under EPA ID# VAD000819466. The applicant provided detailed information for the following air emission and wastewater permits:

- (1) Air permits: Stationary Source Permit number 52608, issued in accordance with applicable U.S. Environmental Protection Agency (EPA) and Virginia Department of Environmental Quality (VA DEQ) regulations.
- (2) Wastewater permit: Industrial User Permit number 2149 from the local publicly owned treatment works (POTW) in the City of Richmond. The permit requires compliance with the relevant effluent limitations (40 CFR. parts 400 – 699) to control discharge of pollutants in the wastewater, ensuring 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.<sup>5</sup> The applicant stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

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<sup>3</sup> U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed August 16, 2018.

<sup>4</sup> Critical habitat maps available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>.

<sup>5</sup> EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed August 16, 2018.

## 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 a three-mile radius of the manufacturing facility is minority,<sup>6</sup> 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 an Indian reservation.

## 5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, unfiltered cigars. 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. The applicant stated that the volume and nature of the waste would not require new or expanded disposal, treatment, recycle capacity or resources, such as waste treatment or recycle facilities.

## 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 EPA's Toxic Release Inventory (TRI) database showed that in 2017, the Philip Morris USA manufacturing facility in Richmond, VA released 18,713 pounds of ammonia and 10,6813 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).<sup>7</sup> Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts, have known adverse developmental effects.<sup>8</sup> 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

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<sup>6</sup> EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed August 14, 2018.

<sup>7</sup> 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](https://www3.epa.gov/enviro/facts/tri/form_ra_download.html). Searched on August 14, 2018.

<sup>8</sup> 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 August 14, 2018.

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>	
<b>Total Production-Related Waste</b>		<b>320,665</b>	

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 Toxic Release Inventory database, as it is considered a minor facility.<sup>7,10</sup> EPA’s Enforcement and Compliance History Online 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 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 marketed in the United States.

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

The Agency evaluated potential impacts to resources in the environment that may 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 and that the documented trend of cigar usage has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2), 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 other marketed cigars; (2) the new products are expected to compete with or replace other currently marketed cigars, so the Agency does not expect that new or increased air emissions would be associated with use of the new products (Confidential Appendix 2); 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).

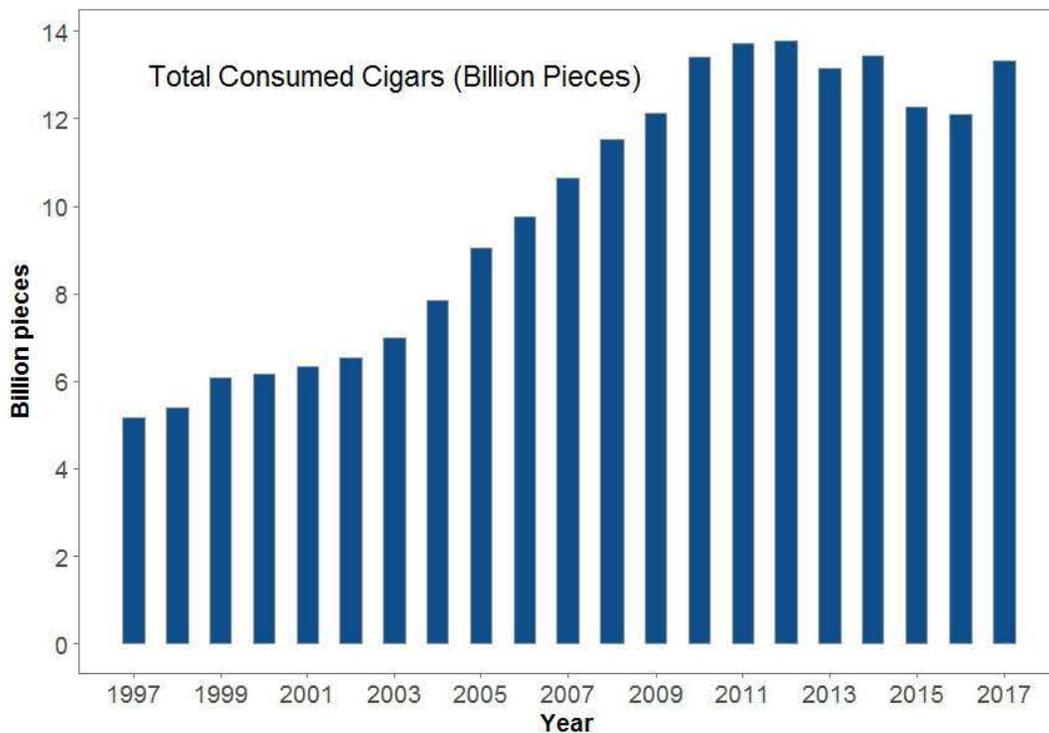
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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 2017, the trend of cigar usage has stabilized with minor decrease overall, per the U.S. Alcohol

and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).<sup>9</sup> In combination with declines in use of other tobacco products, this likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016; other studies). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

**Figure 2. Use of Cigars in the United States, 1997 – 2017**



<sup>9</sup> 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.

As of December 2015, 26 states and the District of Columbia had implemented comprehensive smoke-free laws (Tynan, et al., 2016). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

## **6.5 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 Product**

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available information such as the documented minor decline in use of cigars in the United States since 2010, and the applicant's submitted information, including the projected market volumes for the new products.

### **7.1 Affected Environment**

The affected environment includes human and natural environments in the entire United States. The marketing orders would allow for the new tobacco products to be sold to consumers throughout 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 and plastic filter tips of the new products. The chemicals in the cigar butts 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 and filter tips generated from the new products would replace the same type of waste (Confidential Appendix 3). 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 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 the same or similar to chemicals in the currently marketed cigars. The new products would replace similar products 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 have been implicated in many fire incidents,<sup>10, 11</sup> 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 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 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 cigars disposed of in the United States. The number of cigar butts and tips generated is equivalent to the market projections (Confidential Appendix 2) and an unspecified 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 is expected to be handled in the same manner as the waste generated from other cigars in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no new disproportionate impacts on minority or low-income populations.

#### **7.7 Cumulative Impacts**

The cumulative impacts are unlikely to exist because the unfiltered cigar butts of the new products are likely to disintegrate after disposal from use and they are unlikely to accumulate in the environment.

#### **7.8 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):

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<sup>10</sup> 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 August 16, 2018.

<sup>11</sup> UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed August 16, 2018.

**Preparer:**

Mehran Niazi, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Sciences

Experience: Twelve years in environmental fate and transport and environmental modeling

Expertise: water quality modeling, environmental fate and transport modeling

**Reviewer:**

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

**9. A Listing of Agencies and Persons Consulted**

Not applicable.

**10. References**

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

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

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

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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*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General: What it Means to You. *Consumer Booklet*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

U.S. Environmental Protection Agency. 2016. *Advancing Sustainable Materials Management: 2014 Fact Sheet*. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. November 2016.

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.

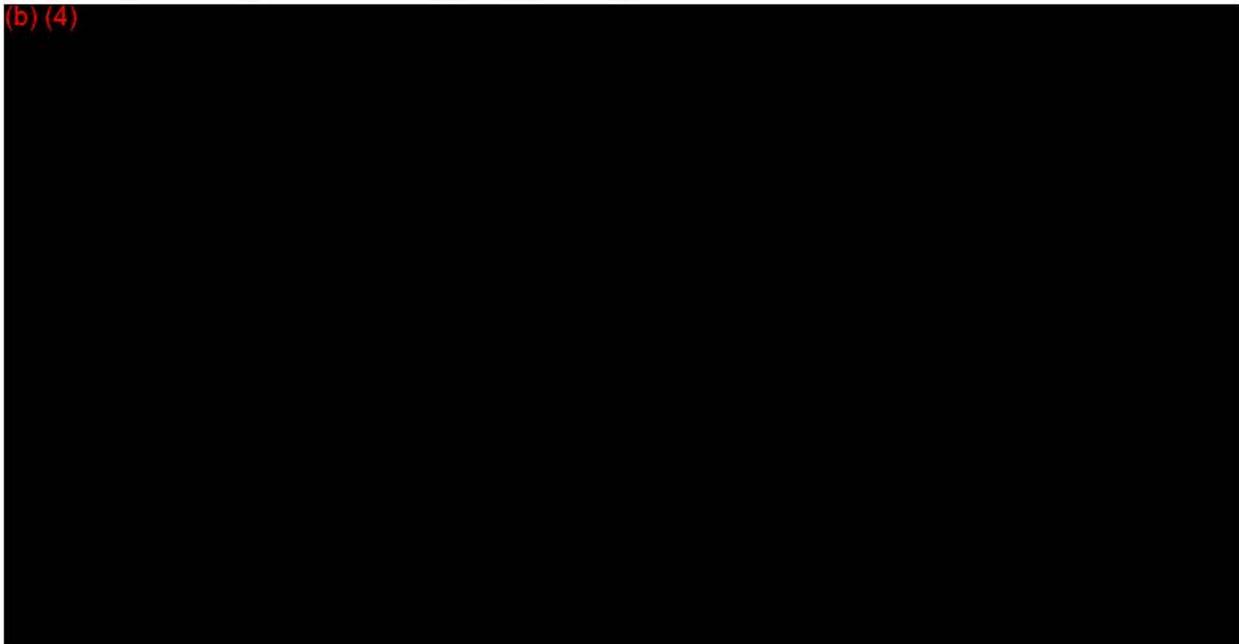
Confidential Appendix 1

Subcontracted Manufacturing Facility

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

The facility is located in the (b) (4) industrial park 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.

(b) (4)



**Confidential Appendix 2**

**Modifications: New Products as Compared to the Corresponding Original Products**

STN	Modification
EX0000297 EX0000298	Removal of (b) (4) [REDACTED]
EX0000299 EX0000300	Removal of (b) (4) [REDACTED]

**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.<sup>12</sup> The new products account for (b) (4) of a percent of the forecasted cigar use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Products (# of Cigars)	New Products as a Percent of Total Cigars Used <sup>13</sup>	New Products (# of Cigars)	New Products as a Percent of Total Cigars Used <sup>14</sup>
EX0000297	(b) (4)			
EX0000298				
EX0000299				
EX0000300				
Total				

<sup>12</sup> The Agency used historical data regarding total use of cigars from 1997 to 2017 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R<sup>2</sup> value of 0.91, the forecasted number of cigarettes that would be used in the United States is estimated at 13.67 billion cigars in the first year and 13.66 billion cigarettes in the fifth year of marketing the new product.

<sup>13</sup> Projected Market Occupation of the New Products in the United States (%) =  $\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$

<sup>14</sup> See footnote # 16.