

**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**

February 7, 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 Company
Product Manufacturing Location:	2211 Bells Road, JMC Bay 8, Building, Richmond, VA 23234

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

2. Product Information

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

New Product Name	STN	Original Product Name
Middleton's Cherry Blend	EX0000343	Middleton's Cherry Blend
Black & Mild® Wine	EX0000344	Black & Mild Wine
Black & Mild® Wine	EX0000345	Black & Mild Wine
Middleton's Cherry Blend	EX0000346	Middleton's Cherry Blend
Prince Albert Soft Cherry Vanilla	EX0000347	Prince Albert Soft Cherry Vanilla
Prince Albert Soft Cherry Vanilla	EX0000348	Prince Albert Soft Cherry Vanilla

Product Identification

Product Category	Cigar
Product Sub-Category	Unfiltered, sheet-wrapped
Number of Products per Retail Unit	EX0000343, EX0000344 and EX0000347: Five individually wrapped plastic mouth tipped cigars per pack and ten packs per display tray with 30 trays per shipping case. EX0000345, EX0000346 and EX0000348: Twenty-five individually wrapped plastic mouth tipped cigars per pack (which serves as a display tray) with 30 packs per shipping case.
Product Package	The packaging materials consist of a polypropylene single stick 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 exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act for the introduction of six new unfiltered, tipped, sheet-wrapped cigars into interstate commerce for commercial distribution in the United States. 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 six 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 (EX0000343, EX0000346, EX0000347, and EX0000348) are made by modifying the original products by removing two ingredients and replacing them with equal quantities of alternate ingredients. The new products (EX0000344 and EX0000345) are made by modifying the original products by three ingredients and replacing them with three alternate ingredients (Confidential Appendix 2).

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:

- The level of the alternative ingredients in the new products that are replacing the ingredients in the original products are each a small percentage of the total products. These ingredient changes are the only differences between the new and corresponding original products.
- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new products.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The new products 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 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

The affected environment includes human and natural environments surrounding the facility.

5.2 Air Quality

The Agency does not anticipate 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. January 16, 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 January 16, 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 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 one mammal - northern long-eared bat), and one endangered freshwater mussel species - James spiny mussel 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 – 699) to control the discharge of pollutants in the wastewater, ensuring the wastewater is of a

⁵ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed January 16, 2019.

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

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 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.

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.

⁷ EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed January 16, 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 January 16, 2019.

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 tobacco manufacturing facility. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, the manufacturing facility in Richmond, VA 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 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>			230,447	
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>			90,218	
Total Production-Related Waste			320,665	

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.^{11,12} 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

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 January 16, 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 January 16, 2019.

¹¹ See footnote 7.

¹² See footnote 10.

threshold levels to air. The applicant does not anticipate manufacturing the new products would require revised or new storm or waste water permits.

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 listed 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 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 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 3); 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

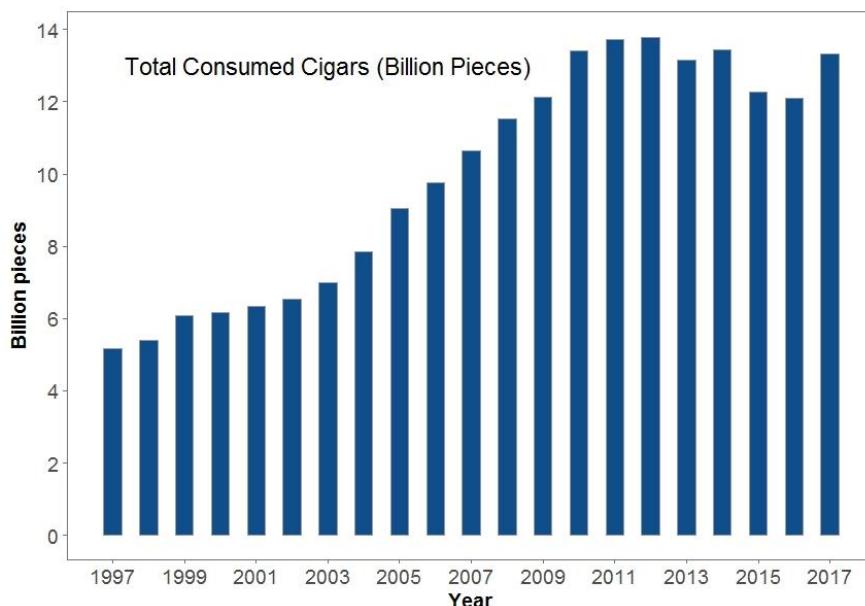
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos, and pipes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment 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. Since 2011 through 2017, the trend of cigar use has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).¹³ In combination with declines in use of other tobacco products, this likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

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



¹³ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed January 16, 2019.

As of December 2018, 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 be sold 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 and plastic 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 and plastic 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. 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 the number of cigars being disposed of as the new products are anticipated to replace similar marketed cigars.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the cigar butts and plastic tips 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.

7.5. 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.

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 plastic 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 10 years (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,

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 May 22, 2018.

¹⁵ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

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 a 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.

8. List of Preparers

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

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

Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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

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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Matt, G.E., Quintana, P.J.E., Destaillats, H., Gundel, L.A., Sleiman, M., Singer, B.C., Jacob, P., Benowitz, N., Winickoff, J.P., Rehan, V., Talbot, P., Schick, S.F., Samet, J., Wang, Y., Hang, B., Martins-Green, M., Pankow, J.F., & Hovell, M.E. (2011). Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*, 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. 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.

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Yao, T., Sun, H.Y., Wang, Y., Lightwood, J., & Max, W. (2016). Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*, 131, 357-366.

CONFIDENTIAL APPENDIX 1

Subcontracted Manufacturing Facility

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

The facility is located in the (b) (4)(b) (4)(b) (4) industrial park and is bounded by residential and agricultural land.¹⁷ The applicant stated that 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

Modifications: The New Products Compared to the Original Products

STN	Component	Modification
EX0000343 EX0000346 EX0000347 EX0000348	Cigar tobacco filler	(b) (4)
	Cigar wrapper	(b) (4)
EX0000344 EX0000345	Cigar tobacco filler	(b) (4)
	Cigar wrapper	(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.¹⁸ The original products are not currently marketed, and the applicant does not intend to simultaneously manufacture the new and original products if the new products receive marketing orders. The new products account for **(b) (4)** of the forecasted cigar use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used ¹⁹	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used ²⁰
EX0000343	(b) (4)			
EX0000344				
EX0000345				
EX0000346				
EX0000347				
EX0000348				
Total				

¹⁸ 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 R² value of 0.91, the forecasted number of cigars that would be used in the United States is estimated at 13.67 billion cigars in the first year and 13.66 billion cigars in the fifth year of marketing the new products.

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 Ibid