

**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**

**September 30, 2019**

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**1. Applicant and Manufacturer Information**

|  |   |
|--|---|
| <b>Applicant Name:</b>                 | Altria Client Services LLC                                  |
| <b>Applicant Address:</b>              | 2325 Bells Road<br>Richmond, VA 23234                       |
| <b>Manufacturer Name:</b>              | John Middleton Co.  |
| <b>Product Manufacturing Location:</b> | 2211 Bells Road<br>JMC Bay 8 Building<br>Richmond, VA 23234 |

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

**2. Product Information**

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

| <b>New Product Name</b>     | <b>STN</b> | <b>Predicate Product Name</b> |
|-----------------------------|------------|-------------------------------|
| Black & Mild® Jazz          | SE0015206  | Black & Mild Wine             |
| Black & Mild® Jazz Wood Tip | SE0015207  |                               |

**Product Identification**

|                                       |  |
|---------------------------------------|--|
| <b>Product Category</b>               | Cigar  |
| <b>Product Subcategory</b>            | Unfiltered, sheet wrapped  |
| <b>Tip Property</b>                   | SE0015206: plastic tip<br>SE0015207: wood tip  |
| <b>Product Number per Retail Unit</b> | Twenty-five individually wrapped cigars per pack, 30 packs per shipping case   |
| <b>Product Package</b>                | 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 a marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce two 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 marketing orders if the new products are found substantially equivalent to the single predicate product. The predicate product, GF1602168, is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new products differ from the single predicate product in the ingredients, cigar rod length and diameter, and the cigar wrapper (Confidential Appendix 2). In addition, the plastic tip in the predicate product is replaced by a wood tip in the new product in SE0015207.

#### 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 Products

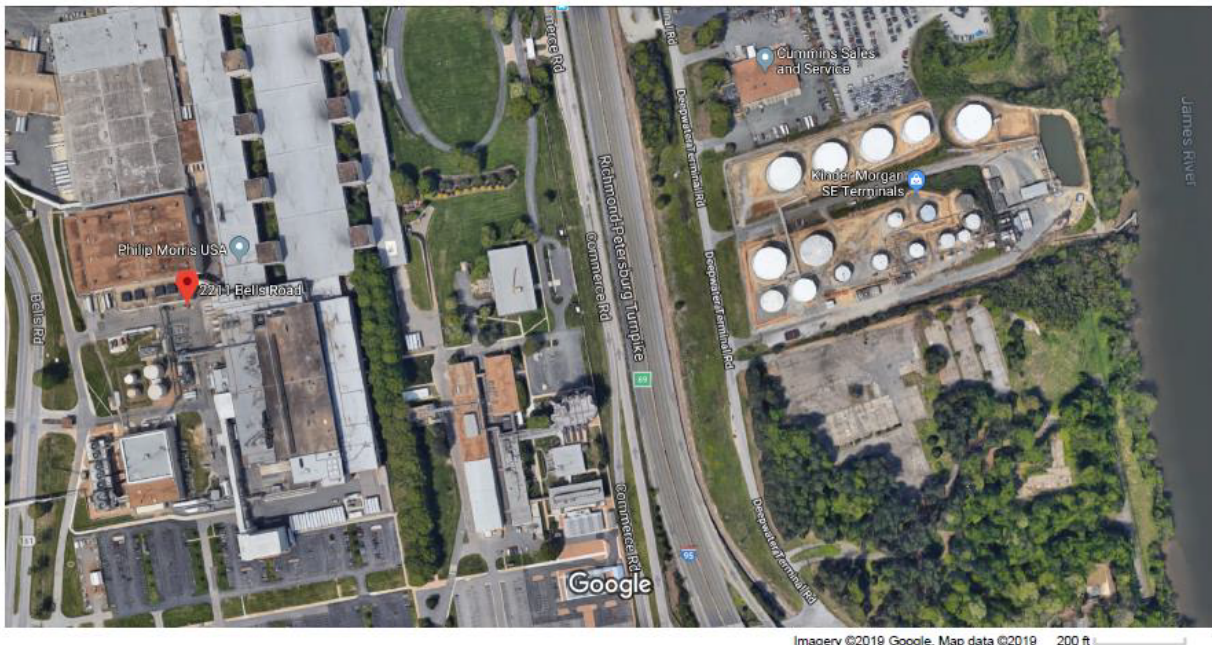
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The ingredients in the new products are used in other cigars manufactured at the facility.
- The production of the new products will replace production of similar products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.
- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new products.

##### 5.1 Affected Environment

The 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.<sup>1</sup>

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.<sup>2,3</sup> Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.<sup>4</sup>

## **5.2 Air Quality**

The Agency does not anticipate that 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 a revised 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 discharge and therefore, manufacturing the new products would not require a revised or a new wastewater 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. 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.

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<sup>1</sup> Google. 2019. Map of 2211 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: [www.google.com/maps](http://www.google.com/maps). Accessed April 25, 2019.

<sup>2</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> and <http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf>.

<sup>3</sup> Virginia Department of Environmental Quality. Available at: <http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf>. Accessed April 25, 2019.

<sup>4</sup> 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).<sup>5,6</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. 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) manufacturing facility:

- (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 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 the U.S. Environmental Protection Agency's (EPA) Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.<sup>7</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.

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

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<sup>5</sup> U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed April 25, 2019.

<sup>6</sup> Critical habitat maps available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>. Accessed April 25, 2019.

<sup>7</sup> EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 25, 2019.

## **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>8</sup> 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 Native American lands.

## **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 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.

## **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. John Middleton Co. (JMC) is a wholly owned subsidiary of Philip Morris USA Inc. (PMUSA) and the JMC Bay 8 facility is located in the PMUSA manufacturing center. Therefore, production-related releases from the JMC manufacturing facility are included in PMUSA's toxic release data reported in the EPA's Toxic Release Inventory (TRI) database. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, PMUSA manufacturing facility in Richmond, Virginia released 10,3133 pounds of nicotine and nicotine salts to air

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<sup>8</sup> Ibid.

(Table 1).<sup>9</sup> Nicotine and nicotine salts have known adverse developmental effects.<sup>10</sup> 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 2018**

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

The applicant stated that manufacturing the new products would not require any additional environmental controls for air emission, water discharges, or solid waste disposal.

#### 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 at the listed facility, as many similar tobacco products would continue to be manufactured.

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

The Agency considered 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 (Confidential Appendix 3) and the documented cigar use in the United States.

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<sup>9</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 April 25, 2019.

<sup>10</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 April 25, 2019.



## **6.1 Affected Environment**

The affected environment includes human and natural environments in the United States because 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 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 SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. Such exposure can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

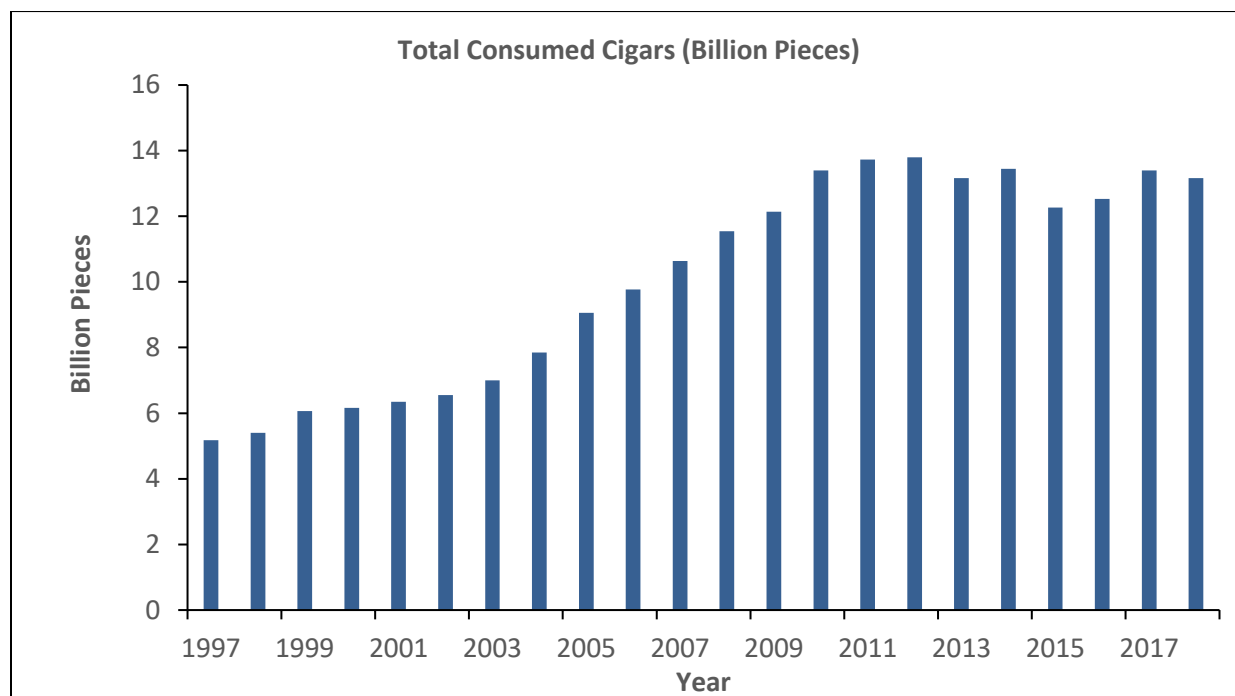
The consumption of cigars in the United States increased significantly from 1997 to 2011. From 2011 through 2018, the trend of cigar use has stabilized with minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).<sup>11</sup> In combination 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). Despite the considerable ethnic and racial disparities in

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<sup>11</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 25, 2019.

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 – 2018**



As of March 2019, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2019). 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 used in United States.

## 7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on TTB data which shows relatively stable rates of cigar use in the United States since 2010, and the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

## **7.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the applicant to distribute and sell the new tobacco products to consumers in the United States.

## **7.2 Air Quality**

The Agency does not anticipate that 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 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 (U.S. Environmental Protection Agency, 2018) 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 unburned cigars, cigar tips, or packaging material from the new products because (1) the wood tip in SE0015207 would be biodegradable; thus, it is a relatively shorter-lasting environmental issue compared to the plastic tips, specifically in waterbodies and run-offs from an urban environment; (2) the chemicals in the new products and in the plastic tip in SE0015206 are the same or similar to chemicals in currently marketed cigars; (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste (U.S. Environmental Protection Agency, 2018); and (3) the new products would compete with or replace similar cigars currently on the market.

## **7.4 Biological Resources**

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering tobacco products like cigars and cigarettes has been implicated in many fire incidents,<sup>12,13</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 similar to the disposal of cigars that

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<sup>12</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 May 22, 2018.

<sup>13</sup> UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

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 expected 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 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 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 generated waste from cigar consumption includes littered non-combusted cigar and cigar tips. The environmental impacts from plastic cigar tip litter are 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 SE0015207 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. However, factors influencing the airborne emissions after disposal of plastic cigar tips are likely to resemble those factors that influence airborne emissions after disposal of cigarette butts. Airborne emissions after disposal of cigarette butts depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette 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.<sup>14</sup>

However, the Agency does not anticipate that the proposed actions will incrementally increase or change the cumulative impacts from cigar tip litter as TTB data shows a relatively stable rate of cigar usage in the United States since 2011 and the proposed actions are unlikely to change that.

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<sup>14</sup> NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 23, 2019.

## 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 disposed of in the United States.

## 8. List of Preparers

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

### **Preparer:**

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

### **Reviewer:**

Gregory G. Gagliano, M.S., Center for Tobacco Products  
Education: M.S. in Environmental Science  
Experience: Thirty-seven years in environmental compliance and analysis  
Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

## 9. A Listing of Agencies and Persons Consulted

Not applicable.

## 10. References

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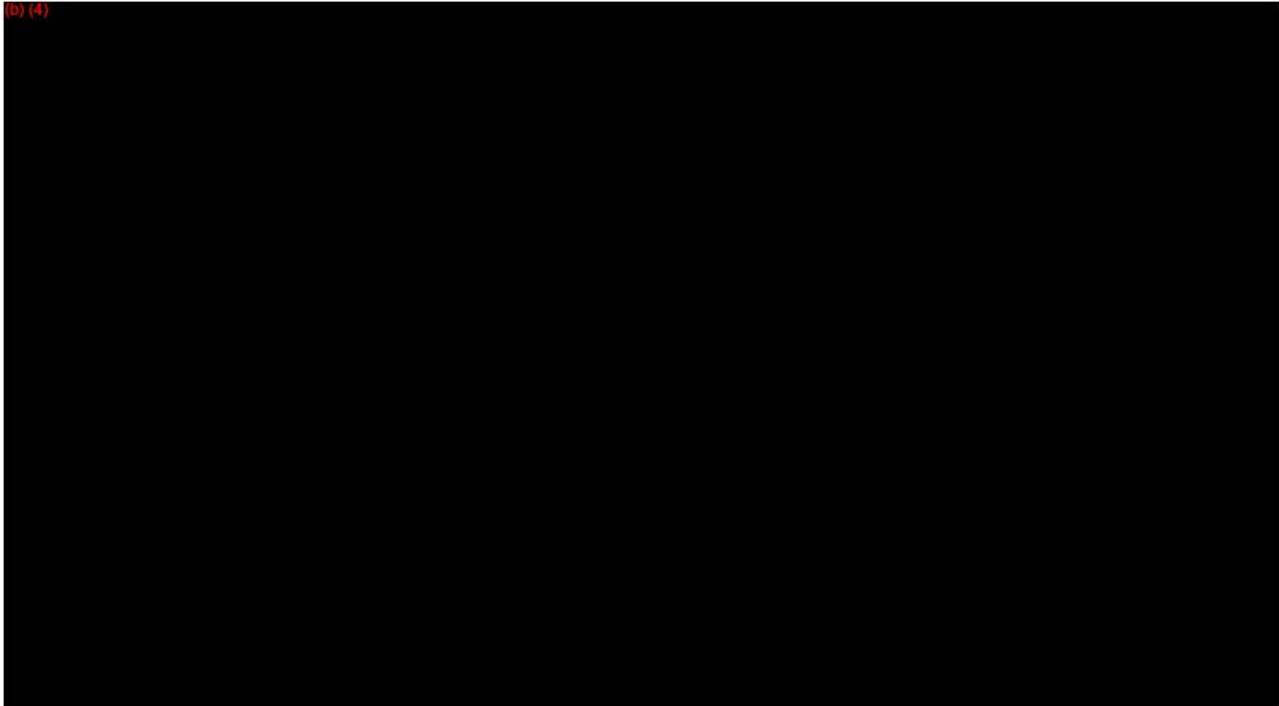
Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;131:357-366.

CONFIDENTIAL APPENDIX 1

Subcontracted Manufacturing Facility

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

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



CONFIDENTIAL APPENDIX 2

Changes in the New Products as Compared to the Predicate Product

| STN                    | Component            | Change   |
|------------------------|----------------------|--|
| SE0015206<br>SE0015207 | Cigar rod            | Decreased rod length, diameter, and weight.  |
|                        | Cigar tobacco filler | Decreased weight due to removal of 54 ingredients (although 2 ingredients were added) and reduction in all other ingredients, including tobacco, except for 4 increased ingredients. |
|                        | Cigar binder         | Decreased weight due to reduction in tobacco and (b) (4) replacement of (b) (4) and (b) (4) with a lesser amount of (b) (4) and (b) (4), and reduction in all other ingredients.     |
|                        | Cigar wrapper        | Decreased weight due to reduction in tobacco and (b) (4) replacement of (b) (4) with a lesser amount of (b) (4) and reduction in all other ingredients.                              |
|                        | Seam adhesive        | Decreased weight due to reduction in added ingredients.  |
| SE0015206              | Cigar tip            | Reduction in (b) (4) and addition of (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.<sup>15</sup> The new products account for a small percent of the forecasted cigar use in the United States. In addition, the applicant stated that the predicate product is not currently on the market. The applicant also stated that the new products would compete with, or replace, similar currently marketed cigars.

| STN          | Projected Market Volume   |   |                           |   |
|--------------|---------------------------|---|---------------------------|---|
|              | First Year                |   | Fifth Year                |   |
|              | New Product (# of Cigars) | New Product as a Percent of Total Cigars Used <sup>16</sup> | New Product (# of Cigars) | New Product as a Percent of Total Cigars Used <sup>17</sup> |
| SE0015206    | (b) (4)                   |   |                           |   |
| SE0015207    | (b) (4)                   |   |                           |   |
| <b>Total</b> | (b) (4)                   |   |                           |   |

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<sup>15</sup> The Agency used historical data regarding total use of cigars from 1997 to 2018 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R<sup>2</sup> value of 0.92, the forecasted number of cigars that would be used in the United States is estimated at 13.664 billion cigars in the first year and 13.429 billion cigars in the fifth year of marketing the new products.

<sup>16</sup> Projected Market Occupation of the New Product in the United States (%) =  $\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} \times 100$

<sup>17</sup> Ibid.