

**Programmatic Environmental Assessment for Marketing
Orders for Four New Combusted Filtered Cigarettes
Manufactured by Philip Morris USA Inc.**

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

January 24, 2019

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1. Applicant and Manufacturer Information

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|--|--|
| Applicant Name: | Altria Client Services LLC |
| Applicant Address: | 2325 Bells Road Richmond, VA 23234 |
| Manufacturer Name: | Phillip Morris USA Manufacturing Center. |
| Products Manufacturing Address: | 3601 Commerce Road Richmond, VA 23234 |

2. Products Information

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

| New Products Names | STN | Predicate Product Names |
|-----------------------------|-----------|------------------------------|
| Merit Blue Pack 100's Box | SE0014912 | Merit Ultra Lights 100's Box |
| Marlboro Black Label Box | SE0014913 | Marlboro Blend No. 27 Box |
| L&M Turkish Blend Box | SE0014914 | Players Kings Box |
| L&M Turkish Blend 100's Box | SE0014915 | Players 100's Box |

Products Identification

| | |
|--------------------------------------|---|
| Product Category | Cigarette |
| Product Subcategory | Combusted, filtered |
| Product Numbers per Unit Sale | Twenty cigarettes per pack with ten packs per paperboard carton. |
| Products Package | The hard packs consist of a foil inner liner, inner frame paper, paperboard hard box, polypropylene outer wrap, polypropylene tear tape, and paperboard carton. |

3. The Need for the Proposed Actions

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

The new products differ from the corresponding predicate products in the changes in composition of tipping inks and tipping ink extenders and changes in composition of base tipping paper (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

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

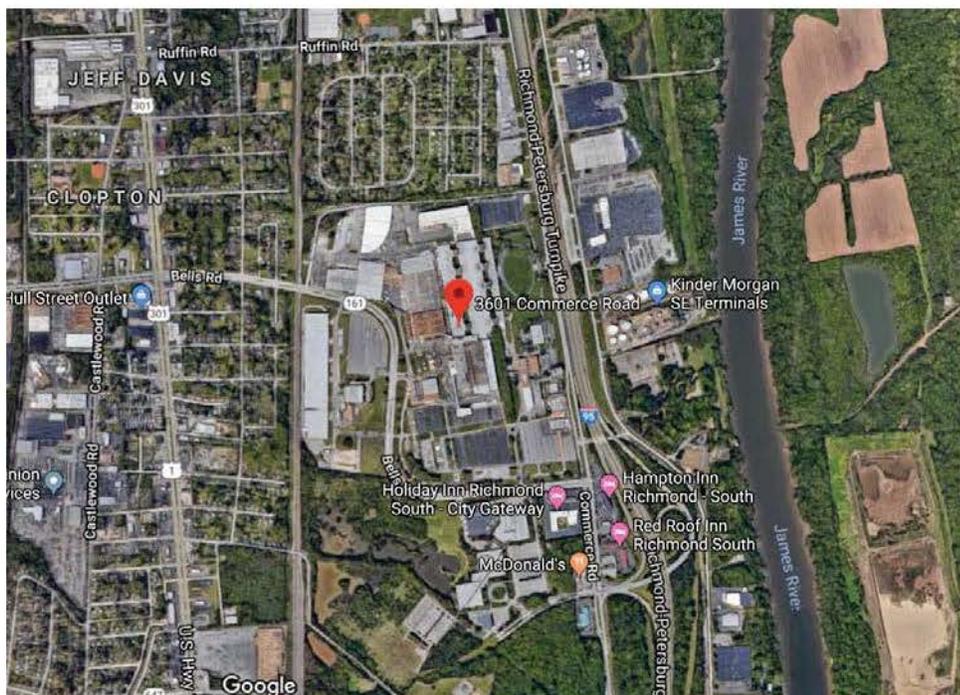
The Agency evaluates potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- None of the materials or ingredients that are added or increased are burned during use of the new products.
- The new products are intended to compete with or replace other tobacco 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 current permitted production capacity is expected due to manufacturing the new products.
- No additional environmental protection measures or alternative actions are necessary with respect to the proposed actions.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products are manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of 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 facility.¹ Station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing The facility is located in the James River watershed, which occupies the central portion of Virginia and covers approximately 10,265 square miles (24% of total land area of the state of Virginia).² ³ Land use within the watershed is predominantly forest (65%). Agriculture and farming account for approximately 19% of the remaining land use, and 12% is urbanized area.⁴

5.2 Air Quality

The Agency does not anticipate any new chemicals would be released into the environment because of 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 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; accordingly, the applicant concluded that manufacturing the new products would not require revised or new wastewater discharge permits.

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 facility expansion or new construction due to manufacturing the new products would not be expected. Therefore, no zone changes or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be expected.

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

¹ Google. 2018. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. June 5, 2018.

² A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See <https://water.usgs.gov/edu/watershed.html> and

³ Virginia Department of Environmental Quality. Available at: <http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf>. Accessed April 17, 2018

⁴ See Virginia Department of Conservation and Recreation at: <http://www.dcr.virginia.gov/soil-and-water/wsheds>. Accessed April 17, 2018.

such species identified under the Endangered Species Act (ESA). The applicant stated that there are no plans to expand the facility production beyond current permitted levels. The applicant consulted the U.S. Fish and Wildlife Services' (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two plants, and one northern long-eared bat), and one endangered freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties).^{5,6} However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations, including the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. The applicant provided detailed information for the following air emission and wastewater permits:

- (1) Air permits: Title V Air Permit number PRO50076 and a Stationary Source Permit, 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 C.F.R. §§ 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The applicant stated that the facility submits regular discharge monitoring reports to VA DEQ.

The Agency's search of 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.

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 manufacturing facility is operating below its permitted capacity and the future year projections of cigarette production at the facility, including the new products, is within the existing permitted manufacturing capacity and would not require expansion. Also, as discussed, the emissions and

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

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

⁷ EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 18, 2018.

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 the introduction of the new products would notably affect the current manufacturing waste generated from the facility's production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment, transferred to a POTW, and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the air from the facility due to tobacco manufacturing. A search in EPA's Toxic Release Inventory (TRI) database showed that in 2017, Philip Morris USA manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air, (a total of 29,396 pounds), but released no other hazardous air pollutants at reportable levels (Table 1).⁹ Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.¹⁰ The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and therefore, a revised or new air permit would not be required. The TRI database search did not show that the Philip Morris USA manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at the Philip Morris USA Facility in 2017

⁸ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 18, 2018.

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 March 7, 2018.

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's address and clicking on the facility's location on the map. Accessed May 24, 2018.

| Production-Related Waste Managed or Released | | Chemical Mass (Pounds) | |
|--|-----------------------------|-----------------------------|--------|
| Recycled | | 126,020 | |
| Energy Recovery | | 0 | |
| Treated | | 104,427 | |
| <i>Subtotal Waste Managed</i> | | <i>230,447</i> | |
| On-Site Release | Air | Ammonia | 18,713 |
| | | Nicotine and Nicotine Salts | 10,683 |
| | Water | Ammonia | 0 |
| | | Nicotine and Nicotine Salts | 0 |
| Land | Ammonia | 0 | |
| | Nicotine and Nicotine Salts | 0 | |
| Off-Site Release | | 60,822 | |
| <i>Subtotal Waste Released</i> | | <i>90,218</i> | |
| Total Production-Related Waste | | 320,665 | |

The applicant does not anticipate manufacturing the new products would require a revised or new waste water permit.

5.11 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing cigarettes, as many similar tobacco products would continue to be marketed.

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

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 the documented decline in cigarette use in the United States.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

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 cigarettes 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 cigarettes; (2) the new products are expected to compete with or replace other currently marketed cigarettes (Confidential Appendix 2); and (3) the ingredients in the new products are used in other currently marketed tobacco products.

Although there are changes in the new products compared to the corresponding predicate products (Confidential Appendix 1) none of the changes involve cigarette components that are burned, consequently the changes are not expected to affect air quality.

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 cigarettes. 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). The 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:

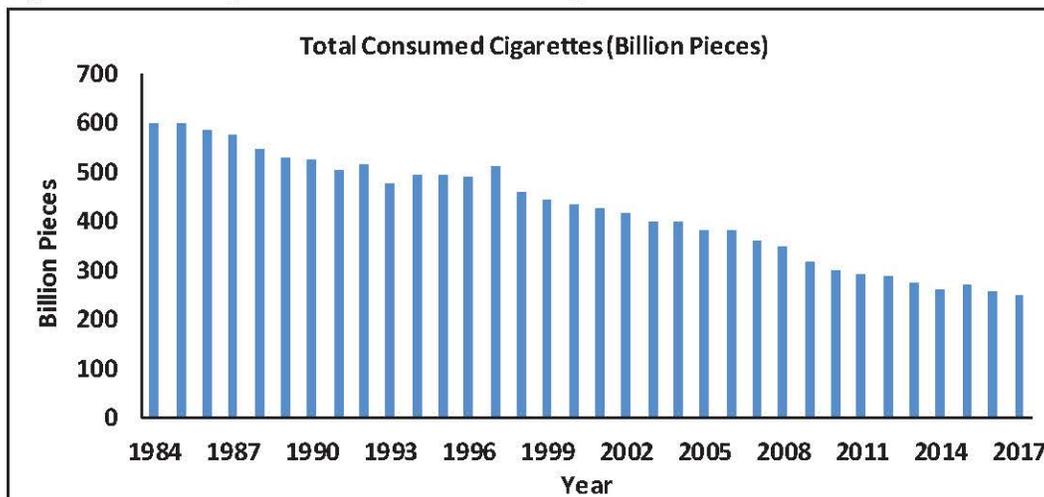
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent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

However, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).¹¹ 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

¹¹ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 7, 2018.

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 Cigarettes in the United States, 1984– 2017



As of December 2015, 26 states and the District of Columbia have 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 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes, 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 evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. Based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant’s submitted information, including the projected market volumes 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; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

7.2. Air Quality

The Agency does not anticipate disposal of the products or the packaging materials would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with or replace other currently marketed cigarettes, the butt 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 cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials of the new products would not 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 from the new products is a minuscule portion of the municipal solid waste based on FDA's experience in evaluating the packaging waste generated from cigarettes.

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 cigarettes has been implicated in many fire incidents,^{12,13} the disposal of the new products is not expected to change the fire frequency as it is similar to the disposal of cigarettes that are currently marketed in the United States.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts from the new products because the chemicals in the new products are the same as or similar to currently marketed cigarettes.

7.5. Solid Waste

The Agency does not foresee the introduction of the new products would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be in the same manner as any other waste generated from any other combusted, filtered cigarettes manufactured in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and that a portion of those are 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 cigarettes in the United

¹² 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.

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

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

A major existing environmental consequence of the use of the new products as well as other conventional cigarettes is littering of discarded cigarette filters or butts, which can persist in the environment for more than 10 years (Novotny and Zhao, 1999). Cigarette butts are some of the most common forms of litter found on beaches (Claereboudt, 2004; Smith, et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton, et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Seco Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from 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 cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹⁴

However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

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 cigarettes and cigarette packaging, as many other similar tobacco products would continue to be marketed.

¹⁴ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 24, 2018.

8. List of Preparers

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

Preparer:

Thomas Creaven, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology/Neuroscience

Experience: Three years in NEPA document review, ten years in chemistry/physics instruction

Expertise: NEPA document review, chemistry/physics education

Reviewer:

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

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

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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Confidential Appendix 1 Comparison of the New Products to the Corresponding Predicate Products

| Ingredients Decreased in the New Products Relative to the Corresponding Predicate Products | | |
|---|--------------------|--|
| STNs | Ingredients | Components |
| | (b) (4) | Filtration Material |
| | | Filtration Material |
| | | Paper Filler for Tipping and Filter Wrap Paper |
| SE0014912 | | Adhesive Secures Tipping and Filter Paper Seams |
| SE0014913 | | Adhesive Secures Filter Paper Seams |
| SE0014914 | | Adhesive Secures Plug Wrap to the Filter |
| SE0014915 | | Tipping Ink Extender |
| | | Monogram Ink |
| | | Monogram Ink |
| | | Monogram Ink |
| | | Dryer for ink |
| | | Paper Filler |

| Ingredients Increased in the New Products Relative to the Corresponding Predicate Products | | |
|---|------------|--|
| STN | Ingredient | Components |
| SE0014912 SE0014913 SE0014914 SE0014915 | (b) (4) | Adhesive for Plug Wraps and Tipping Paper |
| | | Adhesive for Side Seams |
| | | Adhesive for Filtration Materials and Filter Paper |
| | | Tipping Paper Inks |

Confidential Appendix 2

First- and Fifth-Year Market Volume Projections for the New Products and Percentages of Cigarette 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 cigarettes in the United States.¹⁵ Although the projected use of the new products would account for a total of (b) (4) of the forecasted cigarette use in the United States, in the first and fifth years of marketing, respectively, the applicant stated that the new products would compete with or replace other combusted cigarettes currently on the market.

| STN | Market Volume | | | |
|-----------|--------------------------------|--|--------------------------------|--|
| | First Year | | Fifth Year | |
| | New Products (# of Cigarettes) | New Products as a Percent of Total Cigarettes Used ¹⁶ | New Products (# of Cigarettes) | New Products as a Percent of Total Cigarettes Used |
| SE0014912 | (b) (4) | | | |
| SE0014913 | | | | |
| SE0014914 | | | | |
| SE0014915 | | | | |
| Total | | | | |

¹⁵ The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at (b) (4) billion cigarettes in the first year and (b) (4) billion cigarettes in the fifth year of marketing the new products.

¹⁶ Projected Market Occupation of the New Products in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$