

**Programmatic Environmental Assessment for Marketing
Orders by Skookum Creek Tobacco
Company, Inc.**

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

June 10, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Skookum Creek Tobacco Company, Inc.
Applicant Address:	1041 W State Route 108 Shelton, WA 98584
Manufacturer Name:	Skookum Creek Tobacco Company, Inc.
Product Manufacturing Location:	1041 W State Route 108 Shelton, WA 98584

2. Product Information

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

New Product Name	STN	Original Product Name
Complete Full Flavor Deluxe 100s Box	EX0000538	Complete Full Flavor Deluxe 100s
Complete Full Flavor Deluxe Kings Box	EX0000539	Complete Full Flavor Deluxe Kings Box
Complete High Air Filter Deluxe 100s Box	EX0000540	Complete Lights Filter Deluxe 100s
Complete High Air Filter Deluxe Kings Box	EX0000541	Complete Lights Filter Deluxe Kings Box
Complete Menthol Deluxe 100s Box	EX0000542	Complete Menthol Deluxe 100s
Complete Menthol Deluxe Kings Box	EX0000543	Complete Menthol Deluxe Kings Box
Complete Menthol High Air Filter Deluxe 100s Box	EX0000544	Complete Menthol High Air Filter Deluxe 100s
Complete Menthol High Air Filter Deluxe Kings Box	EX0000545	Complete Menthol Lights Filter Deluxe Kings Box
Complete Non-Filter Deluxe Kings Box	EX0000546	Complete Non-Filter Deluxe Kings Box
Complete Ultra High Air Filter Deluxe 100s Box	EX0000547	Complete Ultra Lights Filter Deluxe 100s
Complete Ultra High Air Filter Deluxe Kings Box	EX0000548	Complete Ultra Lights Filter Deluxe Kings Box

Product Identification

Product Type	Cigarette
Product Subtype	Combusted, filtered (EX0000538-EX0000545 and EX0000547-EX0000548) and combusted, non-filtered (EX0000546)
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per carton.
Product Package	The packaging materials consist of an aluminum foil inner liner, cellophane film, plastic tear tape, inner frame cardboard, cardboard flip top box, cardboard carton and cardboard case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of eleven combusted, filtered (EX0000538-EX0000545 and EX0000547-EX0000548) and combusted, non-filtered

(EX0000546) cigarettes 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 must obtain written notification that FDA has granted the products an exemption 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 an exemption from demonstrating substantial equivalence.

The new products, as compared to the corresponding original products, are modified by minor changes in the cigarette 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

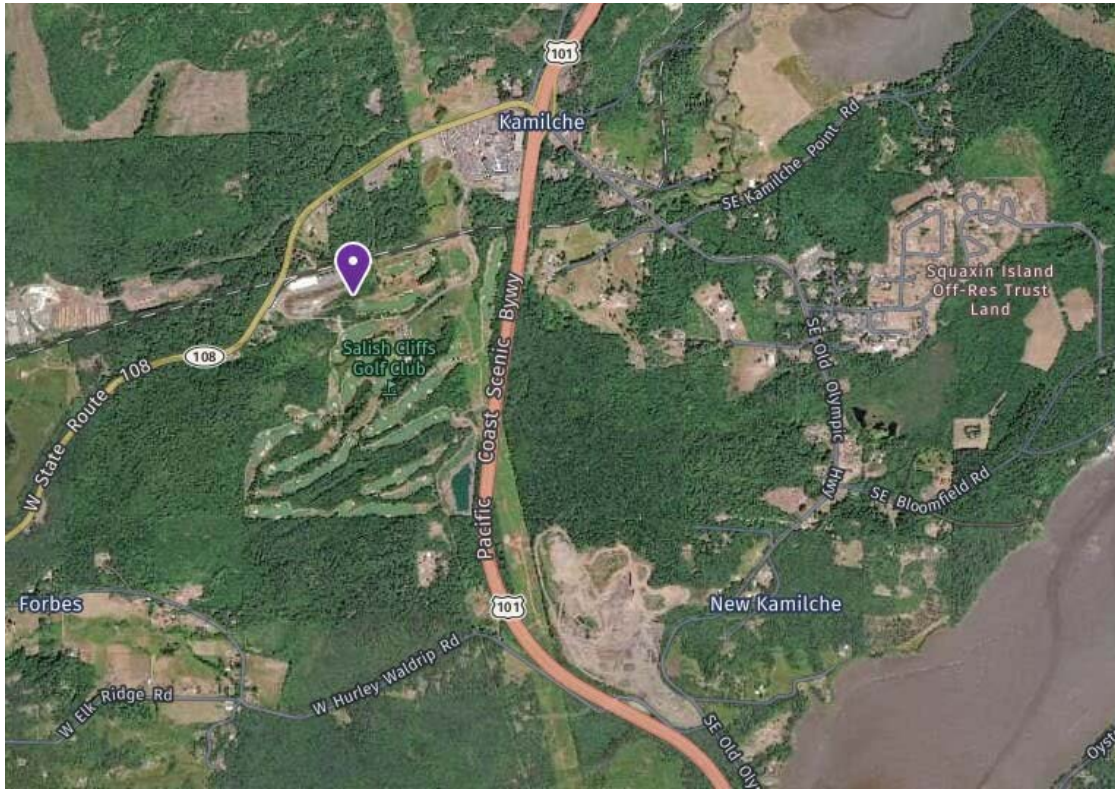
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products would not be commercially marketed simultaneously with the original products if marketing orders are granted for the new products.
- Sales of the new products are not expected to increase appreciably compared to the original products.
- No facility expansion or new construction is expected due to manufacturing the new products.
- There would be no changes to waste water or air discharged due to manufacturing the new products.

5.1 Affected Environment

The new products would be manufactured at 1041 W State Route 108, Shelton, WA 98584 (Figure 1).

Figure 1. Location of the Manufacturer



The manufacturing facility is within the Squaxin Island Tribal area, in Mason County, WA in Skookum Creek watershed, hydrologic unit code 171100190603, that drains into the Puget Sound.^{1,2} The facility is surrounded by woodlands to the north and west; US 101 (a four-lane, divided highway) to the east; and mixed use residential, commercial, and agricultural land to the east.

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

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals or new type of emissions into the environment. The applicant stated that no changes to

¹ 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>.

² USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed Jan 09, 2019.

air discharges are expected from manufacturing the new products; accordingly, the applicant concluded that no new control practices of air emissions are needed for manufacturing the new products.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water. The new products are intended to replace the corresponding original products. The applicant also stated that manufacturing the new products would not require any additional environmental controls 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 there would be no expected facility expansion or new construction due to manufacturing the new products. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

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). As per Washington state's Department of Natural Resources provided Washington Natural Heritage Program Element data, no federally listed species are found in Mason County.^{3,4} The applicant also reviewed the U.S. Fish and Wildlife Service maps and stated that the manufacturing facility is not within or near a critical habitat, or endangered animal and plant species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided statement from the Squaxin Island Tribe's Department of Natural Resources declaring that they comply with all tribal and federal environmental laws.

There is no entry for the facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database.

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

³ WA DNR, available at: http://geo.wa.gov/datasets/34fb23d474d14a55bfb670d065209c3_2 Accessed Jan 09, 2019.

⁴ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed Jan 09, 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.

The manufacturing facility is located in the Squaxin Island Tribe reservation. Over 22% of the population in the reservation live at or below the poverty level.⁵ However, manufacturing the new products would not disproportionately impact minority populations because no new adverse environmental impacts are expected. As discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new products. Additionally, the applicant stated that no revised or new environmental permits will be required due to manufacturing the new products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the facility production of all combusted, filtered or non-filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment, transferred to a publicly owned treatment works (POTW), 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 environment from the facility's tobacco manufacturing. The manufacturing facility was not listed in EPA's Toxic Release Inventory (TRI), indicative of a minor facility.⁶

The applicant stated that manufacturing the new products would not require revised or new air, waste water, or storm water permits.

⁵ U.S. Census Bureau, 2013-2017 American Community Survey 5-Year Estimates. Available at <https://www.census.gov/tribal/?aianihh=3955>. Accessed June 10, 2019

⁶ 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 Jan 09, 2019.

5.11 Impacts of No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing cigarettes, as many similar tobacco products would continue to be manufactured at the 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 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 applicant intends to introduce the new tobacco products into interstate commerce.

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 the original products and any other marketed cigarettes; (2) the new products are expected to replace the original products, so the Agency does not expect that new or increased air emissions would be associated with use of the new products (Confidential Appendix 2); and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.4. Cumulative Impacts

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned 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). 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

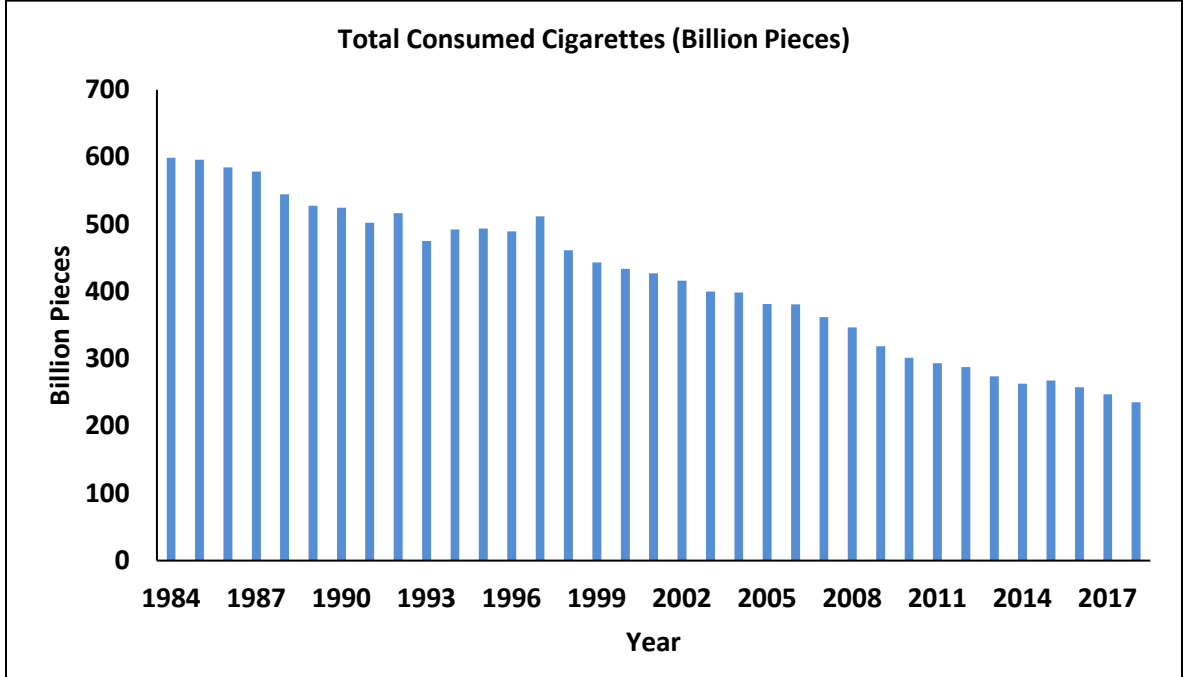
- Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
 - SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, (Figure 2).⁷ 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. SHS exposure 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).

As of December 2018, 28 states plus the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2018). Such laws are expected to reduce the levels of exposure of non-users to SHS and THS.

⁷ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed May 23, 2019.

Figure 2. Use of Cigarettes in the United States, 1984 – 2018



6.5. Impacts of the No-Action Alternative

The environmental impact 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 considered 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 of cigarette use in the United States 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 is the entire United States because 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 new products or the packaging materials would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the new products’ cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated replace the original products, 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 new products' package materials 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 new products' packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. 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 or similar to chemicals in the currently marketed cigarettes. The new products would replace similar products currently on the market.

7.4. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,^{8,9} the new products are not expected to change the fire frequency as the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States.

7.5. 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 disposal of other cigarettes 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.

7.6. 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 18 months (Novotny and Zhao, 1999). Cigarette butts are among 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.,

⁸ 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.

⁹ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

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 affected 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.¹⁰ However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

7.7. Impacts of the No-Action Alternative

The environmental impact 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.

8. List of Preparers

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

Preparer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Reviewer:

Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-six years in environmental toxicology

Expertise: NEPA analysis, ecotoxicology, environmental risk assessment

9. A Listing of Agencies and Persons Consulted

Not applicable.

¹⁰ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 24, 2018.

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CONFIDENTIAL APPENDIX 1

Modifications: New Products as Compared with the Corresponding Original Products

STN	Component	Modification
EX0000538 EX0000539 EX0000540 EX0000541 EX0000542 EX0000543 EX0000544 EX0000545 EX0000546 EX0000547 EX0000548	Cigarette paper	Replacement of non-fire standards compliant (non-FSC) cigarette paper with FSC cigarette paper

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New Products and Percentage 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.¹¹ The new products would account for a minor percentage (b)(4) and (b)(4) of the total forecasted cigarette use in the United States in the first and fifth years, respectively. In addition, the applicant stated that the new products would replace the currently marketed original products.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹²	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹³
EX0000538	(b)(4)			
EX0000539	(b)(4)			
EX0000540	(b)(4)			
EX0000541	(b)(4)			
EX0000542	(b)(4)			
EX0000543	(b)(4)			
EX0000544	(b)(4)			
EX0000545	(b)(4)			
EX0000546	(b)(4)			
EX0000547	(b)(4)			
EX0000548	(b)(4)			
Total	(b)(4)			

¹¹ The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

¹² Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹³ *IBID*