Programmatic Environmental Assessment for Marketing Orders for New Cigarettes Marketed by Westgate Distribution, LLC

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

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1. Applicant and Manufacturer Information

Applicant Name:	Westgate Distribution, LLC
Applicant Address:	831 Beacon Street, #303 Newton, MA 02459
Manufacturer Name:	Alturas Indian Rancheria
Product Manufacturing Location:	901 Country Road 56, Alturas, CA 96101

2. Product Information

New Product Name, Submission Tracking Number (STN), and Original Product Name

New Product Name	STN	Original Product Name
Barton Blue 100s Soft Pack	EX0000470	Barton Lights 100's Soft Pack
Barton Blue Kings Soft Pack	EX0000471	Barton Lights (king) Soft Pack
Barton Full Flavor Kings Soft Pack	EX0000472	Barton Full Flavor (king) Soft Pack
Barton Menthol Full Flavor 100s Soft Pack	EX0000473	Barton Menthol 100's Soft Pack
Barton Menthol Full Flavor Kings Soft Pack	EX0000474	Barton Menthol (king) Soft Pack
Bueno Full Flavor Kings Soft Pack	EX0000475	Barton Full Flavor (king) Soft Pack

Product Identification

Product Category	Cigarette
Product Sub-Category	Combusted, Filtered
Number of Products per Retail Unit	Twenty cigarettes per soft pack, ten packs per carton, sixty cartons per shipping box
Product Package	The packaging materials consist of a paperboard soft pack, an aluminum foil inner liner, polypropylene overwrap, polypropylene tear tape, cardboard carton and cardboard shipping box.

3. The Need for the Proposed Action

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 combusted, filtered 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 wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the product 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 product for which the applicant has obtained exemption from demonstrating substantial equivalence.

The new products are made by modifying the original products by changing the cigarette paper (Confidential Appendix 2).

4. Alternatives to the Proposed Action

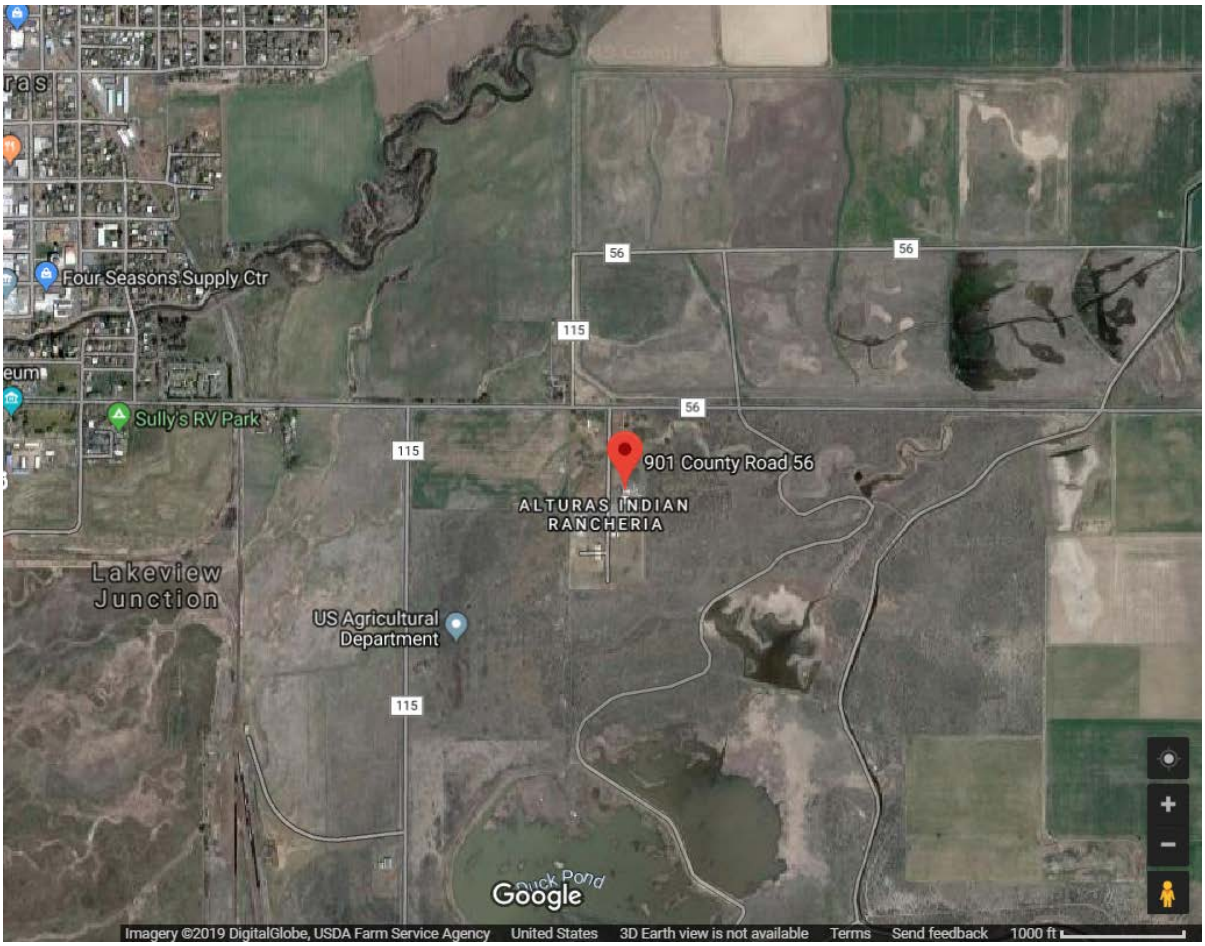
The no-action alternative is FDA does not issue the marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Action 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 applicant-submitted information:

- There are no significant increases in any ingredients in the new products compared to the original products.
- The modification to the original products has no effect on the amount or type of cigarette residue or the tobacco smoke generated.
- The changes to the original products have no significant impact on the amount of solid waste generated by disposal of the cigarettes or the packaging material.

5.1 Affected Environment



The manufacturing facility is within the Alturas Indian Rancheria area, in Modoc County, CA in the Upper Pit watershed, hydrologic unit code 18020002.[1,2] The facility is surrounded by farmland and undeveloped land. The city of Alturas and the Pit River are located approximately one mile northwest.

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 would not

[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.

produce any unique emissions that are not already addressed by emission requirements promulgated by Federal, triabal, and state laws and regulations.

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 the facility that will manufacture the new products does not generate industrial waste water.

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). The search of the U.S. Fish and Wildlife Service critical habitat and endangered species list shows two endangered fish and their critical habitat (the Lost River sucker and the Shortnose sucker), one endangered plant (Greene's tuctoria), two threatened birds, one threatened amphibian, and one threatened plant in Modoc County.[3,4] The applicant stated that the Westgate manufacturing facility is not within or in close proximity to a critical habitat.

5.6 Regulatory Compliance

The applicant stated that the manufacturing process produces no unique emission circumstances which are not addressed by emission requirements already promulgated by federal, tribal and state laws and regulations. The Agency searched for the manufacturing facility using the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO)[5] database, but only found the Alturas Desert Rose Casino at the address provided by the applicant. This facility has no violations in the listed history.

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[3] U.S. Fish and Wildlife Services, available at: https://www.fws.gov/klamathfallsfwo/es/species_list/Modoc%20County%20Species%20List%2020171214.pdf. Accessed June 11, 2019.

[4] Critical habitate map available at: https://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77. Accessed June 11, 2019.

[5] U.S. EPA ECHO Detailed Facility Report: Alturas Desert Rose Casino, Alturas, CA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110050922365. Accessed June 11, 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 on the Alturas Indian Rancheria, a federally recognized tribe of Achomawi Indians. Alturas, CA had a population of 2,827 based on the 2010 Census, of which, 19% lived below the poverty level.[6] However, no facility expansion is expected due to manufacturing the new products; therefore, no changes in impacts on environmental justice are anticipated.

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 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 air from the tobacco manufacturing facility.

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 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

[6] U.S. Census Bureau, Fact Finder, available at: https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk. Accessed June 11, 2019.

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 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 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 any 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.

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. 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).

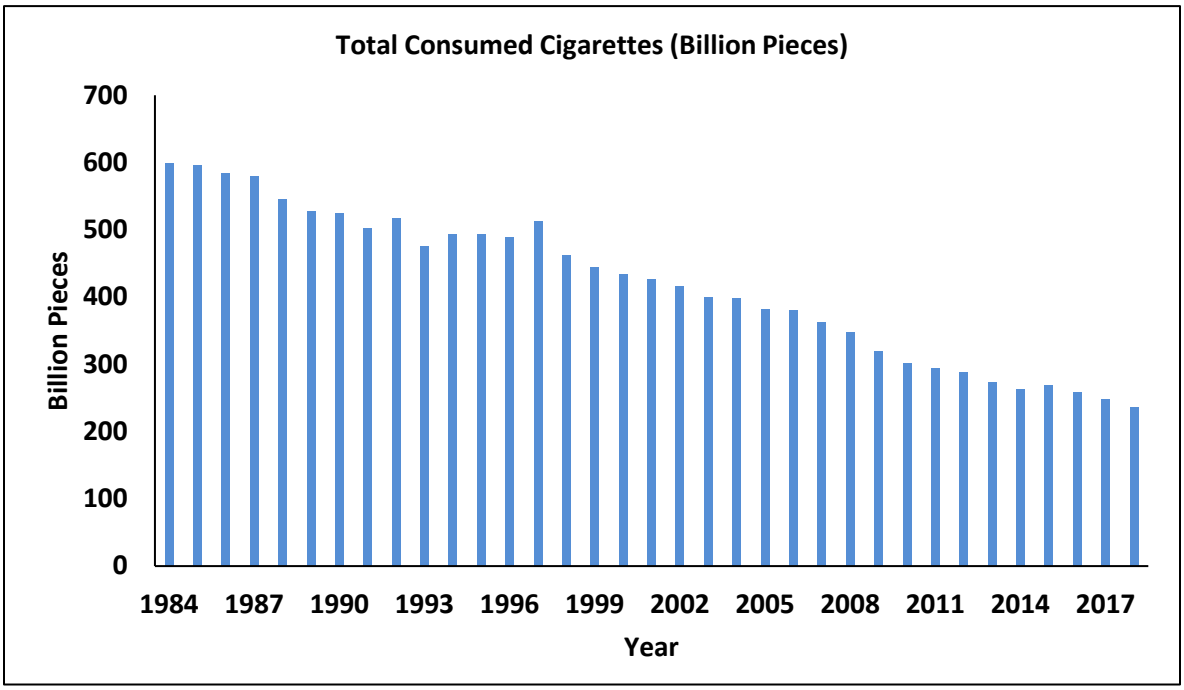
However, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[7] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children

[7] 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.

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).

As of March 2019, 28 states plus 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.

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



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. The Agency found no significant impacts 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.

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 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 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 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. 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.

7.4. Water Resources

No changes in any 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 like chemicals in currently marketed cigarettes and the new products would compete with or replace other cigarettes currently on the market.

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[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.

7.5. Solid Waste and Hazardous Materials

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

As for the glass matt component in the heat source assembly, it can persist in the environment, but is inert and would be a small fraction of waste as compared to the total waste disposed of in the United States.

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 cigarettes 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

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., 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.[10] 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.

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

8. List of Preparers

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

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. References

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Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. Environ Health Persp. 2011; 119(9): 1218-1226.

Novotny TE, Zhao F. Consumption and production waste: Another externality of tobacco use. Tob Control. 1999; 8(1): 75-80.

Patel V, Thomson GW, Wilson N. Cigarette butt littering in city streets: A new methodology for studying and results. Tob Control. 2013; 22(1): 59-62.

Seco Pon, JP, Becherucci ME. Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. Waste Manage. 2012; 32(2): 343-348.

Smith CJ, Livingston SD, Doolittle DJ. An international literature survey of "IARC Group I carcinogens" reported in mainstream cigarette smoke. Food Chem Toxicol. 1997; 35(10-11): 1107-1130.

U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA. 2014.

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U.S. Environmental Protection Agency. Advancing Sustainable Materials Management: Facts and Figures. 2018.

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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 Rep. 2016; 131: 357-366.

CONFIDENTIAL APPENDIX 1

Modifications: The New Products Compared to the Original Products

The applicant proposes to change the cigarette paper from non-FSC paper in the original products to FSC paper in the new products.

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projection for the New Products and Percentage of Cigarettes 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 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 a fraction of the forecasted cigarette use in the United States.

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]
EX[redacted]470	(b) (4)			
EX[redacted]471				
EX[redacted]472				
EX[redacted]473				
EX[redacted]474				
EX[redacted]475				
Total				

[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 R^2 value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.66 billion cigarettes in the first year and 205.02 billion cigarettes in the fifth year of marketing the new products.

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

[13] Ibid