Programmatic Environmental Assessment for Thirty Marketing Orders for Joseph Anderson D/B/A Smokin Joes Tobacco

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

February 13, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Joseph Anderson D/B/A Smokin Joes Tobacco
Applicant Address:	4900 Indian Hill Road Lewiston, NY 14092
Manufacturer Name:	Joseph Anderson D/B/A Smokin Joes Tobacco
Product Manufacturing Location:	4900 Indian Hill Road Lewiston, NY 14092

2. Product Information

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

New Product Name	STN New Product	Original Product Name
Smokin Joes Red 100 Box FSC	EX0000374	Smokin Joes Full Flavor 100 Box
Smokin Joes Red King Box FSC	EX0000375	Smokin Joes Full Flavor King Box
Smokin Joes Gold 100 Box FSC	EX0000376	Smokin Joes Light 100 Box
Smokin Joes Gold King Box FSC	EX0000377	Smokin Joes Light King Box
Smokin Joes Blue 100 Box FSC	EX0000378	Smokin Joes Ultra Light 100 Box
Smokin Joes Blue King Soft Pack FSC	EX0000379	Smokin Joes Ultra Light King Soft Pack
Smokin Joes Menthol 100 Soft Pack FSC	EX0000380	Smokin Joes Menthol 100 Soft Pack
Smokin Joes Menthol King Soft Pack FSC	EX0000381	Smokin Joes Menthol King Soft Pack
Smokin Joes Menthol Gold 100 Soft Pack FSC	EX0000382	Smokin Joes Menthol Light 100 Soft Pack
Smokin Joes Menthol Gold King Soft Pack FSC	EX0000383	Smokin Joes Menthol Light King Soft Pack
Smokin Joes Non Filter King Soft Pack FSC	EX0000384	Smokin Joes Non Filter King Soft Pack
SJ Natural Purple 100 Soft Pack FSC	EX0000385	Smokin Joes Natural Full Flavor 100 Soft Pack
SJ Natural Purple King Box FSC	EX0000386	Smokin Joes Natural Full Flavor King Box
SJ Natural Red 100 Soft Pack FSC	EX0000387	Smokin Joes Natural Medium 100 Soft Pack
SJ Natural Red King Soft Pack FSC	EX0000388	Smokin Joes Natural Medium King Soft Pack
SJ Natural Silver 100 Soft Pack FSC	EX0000389	Smokin Joes Natural Light 100 Soft Pack
SJ Natural Silver King Soft Pack FSC	EX0000390	Smokin Joes Natural Light King Soft Pack
SJ Natural White 100 Soft Pack FSC	EX0000391	Smokin Joes Natural Ultra Light 100 Soft Pack
SJ Natural White King Soft Pack FSC	EX0000392	Smokin Joes Natural Ultra Light King Soft Pack
SJ Natural Menthol 100 Soft Pack FSC	EX0000393	Smokin Joes Natural Menthol 100 Soft Pack
SJ Natural Menthol King Box FSC	EX0000394	Smokin Joes Natural Menthol King Box
SJ Natural Menthol Gold 100 Soft Pack FSC	EX0000395	Smokin Joes Natural Menthol Light 100 Soft Pack
SJ Natural Menthol Gold King Box FSC	EX0000396	Smokin Joes Natural Menthol Light King Box
SJ Natural Non Filter King Soft Pack FSC	EX0000397	Smokin Joes Natural Non Filter King Soft Pack
Smokin Joes Red 100 Soft Pack FSC	EX0000398	Smokin Joes Full Flavor 100 Soft Pack
Smokin Joes Red King Soft Pack FSC	EX0000399	Smokin Joes Full Flavor King Soft Pack
Smokin Joes Gold 100 Soft Pack FSC	EX0000400	Smokin Joes Light 100 Soft Pack
Smokin Joes Gold King Soft Pack FSC	EX0000401	Smokin Joes Light King Soft pack
Smokin Joes Blue 100 Soft Pack FSC	EX0000402	Smokin Joes Ultra Light 100 Soft Pack
SJ Natural Purple King Soft Pack FSC	EX0000403	Smokin Joes Natural Full Flavor King Soft Pack

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered and non-filtered[1]
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton
Product Package	The hard pack consists of a foil inner liner, inner frame paper, paperboard box, polypropylene outer wrap, polypropylene tear tape, and paperboard carton. The soft pack consists of a foil inner liner, paper label and closure, plastic film overlap, plastic tear tape, and cardboard carton.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. 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 twenty-eight combusted, filtered and two combusted, non-filtered cigarettes. 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 products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The differences between the new products and the corresponding original products are deletion of non-fire standards compliant (FSC) cigarette paper and addition of FSC cigarette paper.

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue exemptions from demonstrating substantial equivalence for marketing orders for the new tobacco products.

[1] The new products in EX0000384 and EX0000397 are combusted, non-filtered cigarettes.

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

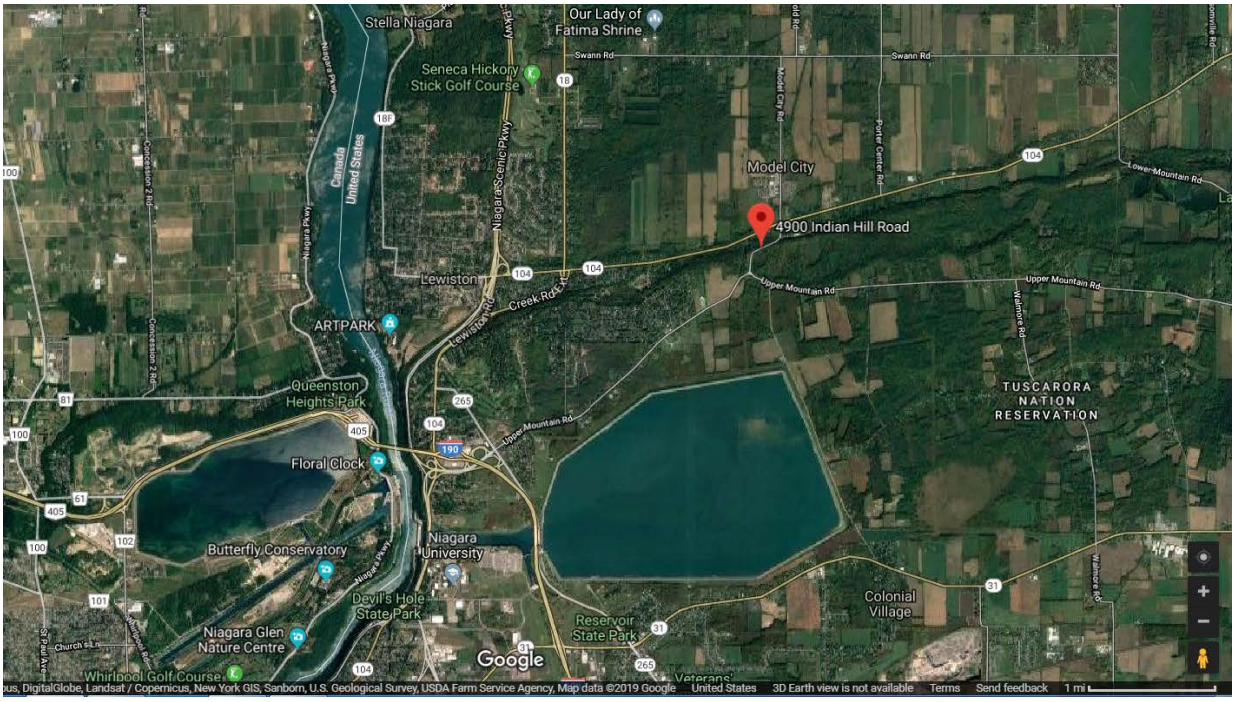
The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the cigarette paper are commonly used in other products manufactured at the facility.
- The new products are intended to replace the legally marketed original products that were manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility



The manufacturing facility is in Niagara County in the Niagara River/Lake Erie watershed.[2,3,4] The facility is surrounded by woodlands and is located on the Tuscarora Indian reservation within a commercial area with a restaurant, retail shop, and two gas stations.

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 into the environment. 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 any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The new products are intended to replace similar tobacco products currently manufactured at the facility. 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 the new products are intended to replace the legally marketed original products. Therefore, there would be no expected facility expansion, 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 applicant stated that manufacturing the new products is not expected to threaten any endangered species or critical habitat because there would be no anticipated changes in air emission or waste generation.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and tribal environmental regulations and with the ESA.

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

[3] New York State, Department of Environmental Conservation. Niagara River/Lake Erie watershed. Available at: https://www.dec.ny.gov/lands/48024.html. Accessed January 8, 2019.

[4] USGS. National Water Information System: Mapper. Available at: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed January 8, 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 the legally marketed original products that were manufactured at the facility.

Although the manufacturing facility is on an Indian reservation, no changes in impacts on minority populations would be expected due to manufacturing the new products because no new chemical releases to the environment from manufacturing the new products were identified.

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 production of all combusted cigarettes. 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.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no anticipated 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 that the proposed actions will incrementally increase or change the chemicals released to the environment from the facility tobacco manufacturing. The applicant stated that manufacturing the new products would not require additional environmental controls for air emission, water discharge or solid waste disposal. Therefore, no cumulative impacts were identified.

5.11 Impacts of 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 in the listed 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 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 from the original products and any other marketed cigarettes; (2) the new products are expected to compete with, or replace, other currently marketed cigarettes, so the Agency does not expect that new or increased air emissions would be associated with use of the new products; 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 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 mixtures 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:

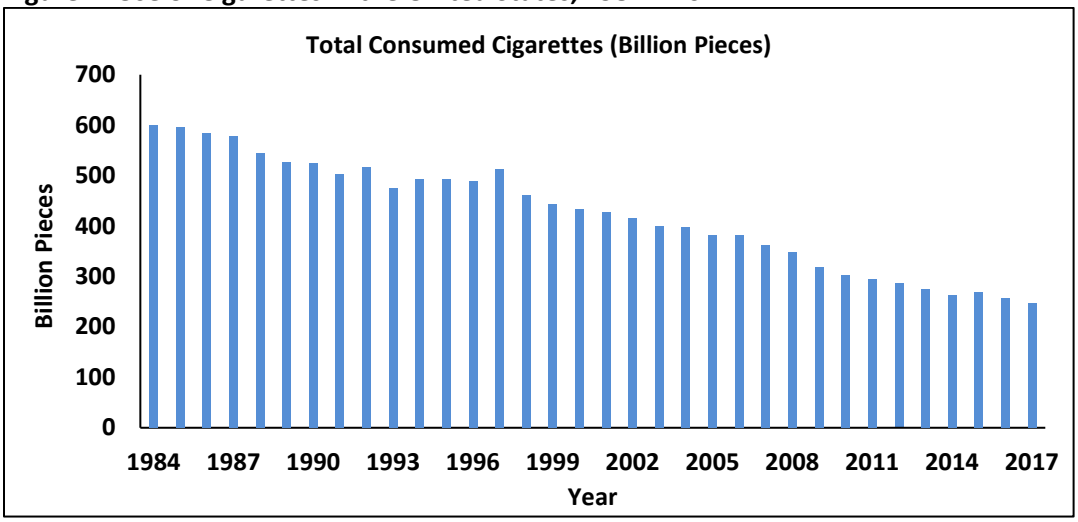
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent 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).[5] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and

[5] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed December 27, 2018.

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).

Figure 2. Use of Cigarettes in the United States, 1984 – 2017



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

6.5. Impacts of 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 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.

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 replace the legally marketed original 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 be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from 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,[6,7] the new products are not expected to change the fire frequency as (1) the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of because the new products are anticipated to replace the legally marketed original cigarettes.

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 would be the same to chemicals in currently marketed cigarettes. The new products would replace the legally marketed original products currently on the market.

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 released to the environment and disposed of in landfills in the same manner as any other waste generated from any other combusted, filtered cigarettes in the United

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[6] National Fire Protection Association. The smoking-material fire problem. Available at: https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials. Accessed January 8, 2019.

[7] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed January 8, 2019.

States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 1) 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 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 the original products and 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 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 et al., 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, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[8]

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

7.8. Impacts of 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.

8. List of Preparers

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

[8] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed January 8, 2019.

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Twenty-five years in various scientific activities including seven years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

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

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

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Novotny, T. E., and F., Zhao. (1999). Consumption and production waste: Another externality of tobacco use. *Tobacco Control*. 8(1): 75-80.

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

Seco Pon, J. P., and M. E., Becherucci. (2012). Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 32(2): 343-348.

Smith, C. J., S. D., Livingston, and D. J., Doolittle. (1997). An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology*. 35(10-11): 1107-1130.

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Wilson, N., J., Oliver, and G., Thomson. (2014). Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ* 2.

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

CONFIDENTIAL APPENDIX 1

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.[9] The projected use of the new products account for a (b) (4) of the forecasted cigarette use in the United States. In addition, the applicant stated that the new products would replace the legally marketed original products.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[10]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[11]
EX0000374	(b) (4)			
EX0000375				
EX0000376				
EX0000377				
EX0000378				
EX0000379				
EX0000380				
EX0000381				
EX0000382				
EX0000383				
EX0000384				
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EX0000390				
EX0000391				
EX0000392				
EX0000393				
EX0000394				
EX0000395				
EX0000396				
EX0000397				
EX0000398				
EX0000399				

[9] 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 R^2 value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.258 billion cigarettes in the first year and 210.922 billion cigarettes in the fifth year of marketing the new products.

[10] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} x\ 100$$

[11] Ibid

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[10]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[11]
EX0000400	(b) (4)			
EX0000401				
EX0000402				
EX0000403				
Total				