Programmatic Environmental Assessment for Marketing Orders for New Combusted Filtered Cigarettes Manufactured by R.J. Reynolds Tobacco Company

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

April 5, 2021

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1. Applicant and Manufacturer Information

Applicant Name:	RAI Services Company
Applicant Address:	401 N. Main Street Winston-Salem, NC 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Location:	7855 King Tobaccoville Road Tobaccoville, NC 27050

2. Product Information

New Product (STNs), New Product Names, and Original Product Names

New Product STN	New Product Name	Original Product Name
EX0001393-PD1	Camel Royal Box	Camel Royal
EX0001394-PD1	Camel Crush Smooth Menthol Box	Camel Crush Smooth Menthol
EX0001396-PD1	Camel Crush Smooth Menthol Silver Box	Camel Crush Smooth Menthol Silver

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered
Product Number per Retail Unit	20 cigarettes per pack, 10 packs per carton, and 60 cartons per shipping box.
Product Package	The packing materials consist of an aluminum foil liner, cardboard pack, polypropylene pack overwrap, polypropylene tear tape, cardboard carton, and cardboard shipping box.

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 three combusted, 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.

The new products are made by modifying the corresponding original tobacco products. The modifications are to the filter, tipping paper, filter tow, and tobacco flavoring (Confidential Apprendix 1).

4. Alternatives to the Proposed Actions

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

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

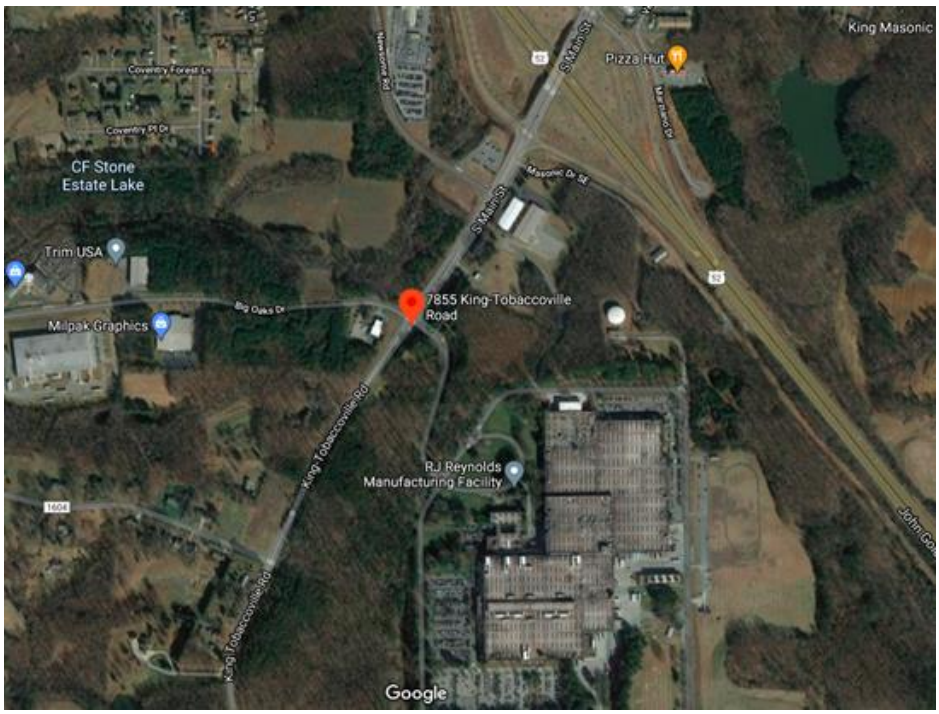
The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products are expected to replace the market share of similar products currently manufactured at the facility.
- Components of the new products are commonly used in other commercially marketed cigarettes currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. 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[1]



[1] Google Maps. 2021. Map of 7855 King Tobaccoville Road, Tobaccoville NC 27050. Retrieved from Google Maps. April 5, 2021

The manufacturing facility is located in Forsyth County, NC in Headwaters Muddy Creek watershed, hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries.[2,3] The facility is surrounded by woodlands; bounded by the city of King, NC to the north; US 52 (a four-lane, divided highway) to the east; and mixed use residential, commercial, and agricultural land to the south and west.

5.2 Air Quality

A search in the U.S. Environmental Protection Agency (EPA)'s Toxic Release Inventory (TRI) database showed that in 2019, R.J. Reynolds Tobacco Company manufacturing facility in Tobaccoville, North Carolina released 7,832 pounds of ammonia and 18,279 pounds of nicotine and nicotine salts to air and transferred 871 pounds of ammonia and 5,399 pounds of nicotine and nicotine salts offsite (Table 1). The TRI database search did not show that the R.J. Reynolds manufacturing facility released into the environment any other reportable toxicants associated with manufacturing tobacco products. No other hazardous air pollutants were reported. In addition, EPA's Enforcement and Compliance History Online (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.[4]

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Product at R.J. Reynolds Facility in 2019

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated*		6,681
Subtotal Waste Managed		*6,681*
On-site Release	Ammonia	7,832
	Nicotine and Nicotine Salts	18,279
Off-site Release	Ammonia	871
	Nicotine and Nicotine Salts	5,399
Subtotal Waste Released		*32,381*
Total Production-Related Waste		**39,062**
* Ammonia plus nicotine and nicotine salts		

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

[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. Accessed April 5, 2021.

[3] USGS. National Water Information System: Mapper. Available at: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed April 5, 2021.

[4] U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Tobaccoville, NC. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000345225. Accessed April 5, 2021.

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

No TRI-reportable chemicals were released to water from the manufacturing facility. According to the North Carolina Department of Environmental Quality, water quality in Headwaters Muddy Creek watershed where the facility is located is relatively good compared to other sub basins in the greater Yadkin-Pee Dee River basin.[5] The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

5.4 Soil, Land Use, and Zoning

No TRI-reportable chemicals were released to land from the manufacturing facility. The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated there would be no expected facility expansion. 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 that manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The search of the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps shows two threatened species (one bog turtle and one northern long-eared bat), one endangered plant, and one at-risk fresh water mussel are listed in Forsyth County.[6,7] The applicant also reviewed the U.S. FWS 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 manufacturing facility has the following permits:

(1) Air permit number 00745-TV-40 issued by the Forsyth County Office of Environmental Assistance Protection.[8]

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[5] North Carolina Department of Environmental Quality. *Yadkin River Headwaters*. Available at: https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf Accessed April 5, 2021.

[6] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/raleigh/species/cntylist/forsyth.html. Accessed April 5, 2021.

[7] Critical habitat map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed April 5, 2021.

[8] Air permit available at: https://www.co.forsyth.nc.us/EAP/assets/doc/00745_TV_permit.pdf. Accessed April 5, 2021.

(2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality.[9]

Additionally, the facility submits release data to the EPA under the provisions of the TRI program (permit # 27050RJRYN7855A).

The Agency's search of the EPA's ECHO database did not reveal any violations of the federal environmental laws and regulations.[10] The applicant also stated that they did not identify any adverse effects on species or critical habitats of species identified under ESA.

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 compete with, or replace, other cigarettes manufactured at the facility.

Manufacturing the new products would not disproportionately impact minority populations, because no new chemical releases to the environment from manufacturing the new products were identified. In addition, the facility is not located in or near a Native American land.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would noticeably 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 tobacco 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 Impacts of the No-Action Alternative

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

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[9] U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Tobaccoville, NC. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000345225. Accessed April 5, 2021.

[10] Ibid.

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 (Confidential Appendix 2) 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 products to be sold to consumers in the United States.

6.2. Air Quality

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:

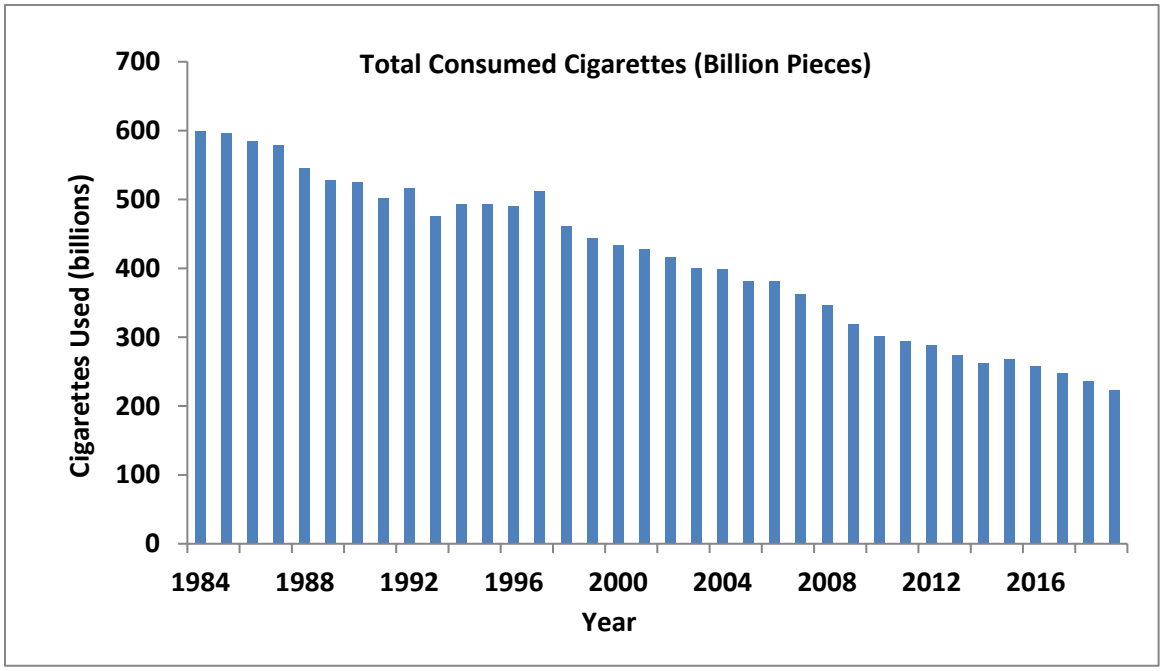
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent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

[11] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at https://www.ttb.gov/tobacco/tobacco-stats.shtml. April 5, 2021.

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 – 2019



As of January 2021, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

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, 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. 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 because the marketing orders would allow for the new 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 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 be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste (U.S. Environmental Protection Agency, 2020) 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,[12] 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 compete with, or replace, other currently marketed cigarettes.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals in the new products would be used in in

[12] 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. April 5, 2021.

currently marketed cigarettes. Furthermore, the new products would compete with or replace other cigarettes currently on the market.

7.5. Solid Waste

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 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 (Pon and Becherucci, 2012).

Compounds in littered 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, tobacco filler, ingredients in the cigarette, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[13]

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 States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) 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. 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 disposed of in the United States

[13] NIST Technical Report 8147 available at: https://nvlpubs.nist.gov/nistpubs/ir/2016/NIST.IR.8147.pdf. Accessed April 5. 2021.

8. A Listing of Agencies and Persons Consulted

Not applicable.

9. List of Preparers

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

Preparer:

Thomas E. Creaven, Ph.D., Center for Tobacco Products
Education: B.S. in Chemistry/Biology, Ph.D. in Biology/Neuroscience
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Education: Ph.D. in Plant Molecular Biology and Virology
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Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

10. References

American Lung Association. 2021. Smokefree Air Laws (last updated January 27, 2021). www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html. Accessed March 12, 2021.

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*. 2011;*119*(2):A70-A74.

Becherucci ME, Pon JPS. What is left behind when the lights go off? Comparing the abundance and composition of litter in urban areas with different intensity of nightlife use in Mar del Plata, Argentina. *Waste Management*. 2014;34(8):1351-1355.

Claereboudt MR. Shore litter along sandy beaches of the Gulf of Oman. *Marine Pollution Bulletin*. 2004;49(9-10): 770-777.

Healton CG, Cummings KM, O'Connor RJO, Novotny TE. Butt really? The environmental impact of cigarettes. *Tobacco Control*. 2011;20: I1-I1.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*. 2015;*64*(4):103-108.

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang, Y, Hang, B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*. 2011;*119*(9):1218-1226.

Novotny TE, Zhao F. Consumption and production waste: Another externality of tobacco use. *Tobacco 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. *Tobacco Control*. 2013;22(1):59-62.

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

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

U.S. Department of Health and Human Services. 2014. 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.

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Environmental Protection Agency. 2020. Advancing Sustainable Materials Management: 2018 Fact Sheet. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. November 2020.

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

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

Confidential Aappendix 1: Modifications in the New Products as Compared with the Corresponding Original Products

New Product STN	Component	Modification
EX0001394-PD1 EX0001396-PD1	Filter	• Deletion of filter capsule and addition of an alternate filter capsule
EX0001394-PD1 EX0001396-PD1	Filter tow	• Increase in quantity of (b) (4) applied to the filter tow
EX0001393-PD1	Tipping adhesive	• Deletion of tipping adhesive • Addition of alternate tipping adhesive
EX0001393-PD1	Flavor ingredient	• Deletion of flavor ingredient (b) (4) and addition of an alternate flavor ingredient (b) (4) • Increase in quantity of flavor ingredient (b) (4) (b) (4) • Increase in the quantity of (b) (4)

Confidential Appendix 2: Market Volumes for the New and Corresponding Original 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 of the new products were compared to the total forecasted use of cigarettes in the United States.[14] The projected use of the new products in the first and fifth year of marketing after marketing orders are issued account for about (b) (4) and (b) (4) respectively, of the forecasted cigarette use in the United States. The applicant stated that they will market the original products and the new products simultaneously after the marketing orders for the new products are issued. The applicant also stated that the introduction of the new products is not expected to impact overall future projected marketed volume. Based on information provided by the applicant, the new products are expected to replace portions of the original products.

STN	Market Volume				
	Current Year Market Volume (# of Cigarettes)	Projected Market Volume			
		First Year		Fifth Year	
		New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[15]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[16]
EX0001393-PD1 (b)(4)	[redacted]	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0001394-PD1	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
EX0001396-PD1	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Total	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

[14] The Agency used historical data regarding total use of cigarettes from 2002 to 2019 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 192.24 billion cigarettes in the first year and 145.78 billion cigarettes in the fifth year of marketing the new products.

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

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

[14] Ibid.