

**Environmental Assessment for a Marketing Order for
Eclipse Menthol
Manufactured by
R.J. Reynolds Tobacco Company**

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

November 5, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	RAI Services Company on behalf of R.J. Reynolds Tobacco Company
Applicant Address:	401 North 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 Submission Tracking Number (STN), Name, and Predicate Product Name

STN	New Product Name	Predicate Product Name
SE0015044	Eclipse Menthol	Eclipse Menthol

Product Identification

Product Category	Cigarette
Product Subcategory	Non-combusted non-filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per carton.
Product Package	The package consists of a solid bleached sulphate board box and inner frame with a foil inner liner, oriented polypropylene film overwrap, and solid bleached sulphate board carton.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States and submitted to the Agency a substantial equivalence (SE) report to obtain a marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product.

In the SE Report, the new and predicate products are heated tobacco products. The new product is made by modifying the predicate product. This modification is to remove one tobacco additive and replace it with a similar alternative (Confidential Appendix 1).

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

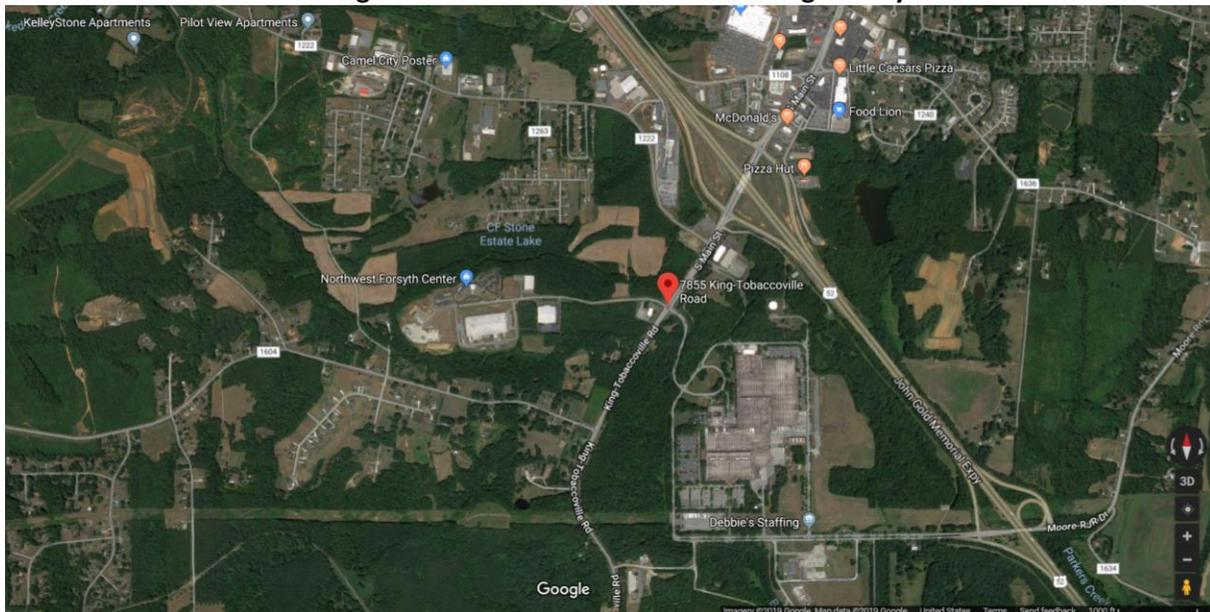
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- There would be no changes between how the new and predicate products are manufactured.
- The proposed modification is not expected to affect any other characteristic of the new product and the alternate tobacco additive is of the same type used in the predicate product.
- No new compounds would be emitted, and no additional environmental controls would be needed relative to the manufacturing of the new product.
- No facility expansion or new construction is expected due to manufacturing the new product.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new product would be manufactured at 7855 King-Tobaccoville Road, Tobaccoville, NC (Figure 1).

Figure 1. Location of the Manufacturing Facility¹



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

¹ Land use surrounding manufacturing facility via Google Map. Accessed October 1, 2019.

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 USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed October 1, 2019.

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.⁴

5.2 Air Quality

The Agency does not anticipate that any new chemicals would be released into the environment due to manufacturing the new product. The applicant stated that manufacturing the new product is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing the new product would not require any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new product would cause the discharge of any new chemicals into the water. The applicant stated that manufacturing the new product is not expected to result in changes in water discharge; accordingly, the applicant concluded that manufacturing the new product would not require any additional environmental controls for water discharge.

5.4 Soil, Land Use, and Zoning

The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no changes in soil, land use or zoning would occur as a direct impact from the proposed action.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new product 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.^{5,6} 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 agency verified the applicant's statement using information available on the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO)

⁴ Google Maps. 2019. Map of 7855 King-Tobaccoville Road Tobaccoville, North Carolina 27050. Retrieved from Google Maps. October 1, 2019

⁵ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/forsyth.html>. Accessed October 1, 2019.

⁶ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed October 1, 2019.

database that the facility is in compliance with air emission, storm water, and wastewater requirements under the following permits:

- (1) Air permit number 00745-TV-39 issued by the Forsyth County Office of Environmental Assistance Protection.⁷
- (2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality.⁸
- (3) Waste water permit number IUP 3001 issued by the North Carolina Department of Environmental Quality.

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

The Agency's search of EPA's ECHO did not reveal any violations of the federal environmental laws and regulations.⁹

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.

5.7 Socioeconomics and Environmental Justice

No changes in socioeconomic measures are anticipated due to manufacturing the new product. No facility expansion is anticipated; therefore, no impacts are expected on employment; state or municipal revenue and taxes; demand on community services; and state and municipal resources, such as police force and fire department resources.

Manufacturing the new product would not disproportionately impact minority populations because only nine percent of the population within a three-mile radius of the manufacturing facility is minority per 2010 U.S. Census and American Community Survey data.¹⁰ In addition, the facility is not located within Native American lands.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new product would notably affect the current manufacturing waste generated from the facility production of all cigarettes. The Agency anticipates the waste generated due to manufacturing the new product 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. The applicant stated that manufacturing the new product would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of a new waste management facility is expected.

⁷ Air permit available at: https://www.co.forsyth.nc.us/EAP/assets/doc/00745_TV_permit.pdf Accessed October 1, 2019. Accessed October 1, 2019.

⁸ U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Tobaccolville, NC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000345225>. Accessed October 1, 2019.

⁹ Ibid.

¹⁰ Ibid.

5.9 Floodplains, Wetlands, and Coastal Zones

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

5.10 Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. A search in EPA's TRI database showed that in 2018, R.J. Reynold's manufacturing facility in Tobaccoville, North Carolina released 8,399 pounds of ammonia and 19,639 pounds of nicotine and nicotine salts to air (a total of 28,038 pounds), and 885 pounds of ammonia and 4,884 pounds of nicotine and nicotine salts (a total of 5,769 pounds) offsite (Table 1).¹¹ Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.¹² The TRI database search did not show that the R.J. Reynolds manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at R.J. Reynolds Facility in 2018

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated*		5,815
<i>Subtotal Waste Managed</i>		<i>5,815</i>
On-Site Release	Ammonia	8,399
	Nicotine and Nicotine Salts	19,639
Off-Site Release	Ammonia	885
	Nicotine and Nicotine Salts	4,884
<i>Subtotal Waste Released</i>		<i>33,807</i>
Total Production-Related Waste		39,622
* Ammonia plus nicotine and nicotine salts		

¹¹ U.S. Environmental Protection Agency (EPA). *TRI Data* <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A>. Searched on October 1, 2019.

¹² U.S. EPA. myRight-to-Know, available at: <https://myrtk.epa.gov/info>. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed October 1, 2019.

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.¹³

The applicant stated that manufacturing the new product would not release new substances into the environment.

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 facility.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Product

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 order would allow for the new tobacco product 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 product, relative to chemicals released into the environment due to use of any other heated tobacco products already on the market, because (1) the combustion products from the new product would be released in the same manner as the combustion products of other marketed heated tobacco products; (2) the new product is expected to compete with or replace the predicate product or other marketed combusted or heated tobacco products; (3) the majority of ingredients in the new product are used in other currently marketed cigarettes and heated tobacco products; and (4) the new product differs from the predicate product in a modification to remove one tobacco additive and replace it with a similar alternative.

6.3. Environmental Justice

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

¹³ 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 October 1, 2019.

6.4. Cumulative Impacts

The impacts from use of non-combusted tobacco products include exposure to secondhand smoke (SHS), which includes CO and HPHCs similar to combusted cigarettes, but with less respirable suspended particles (IARC, 2004). These 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).

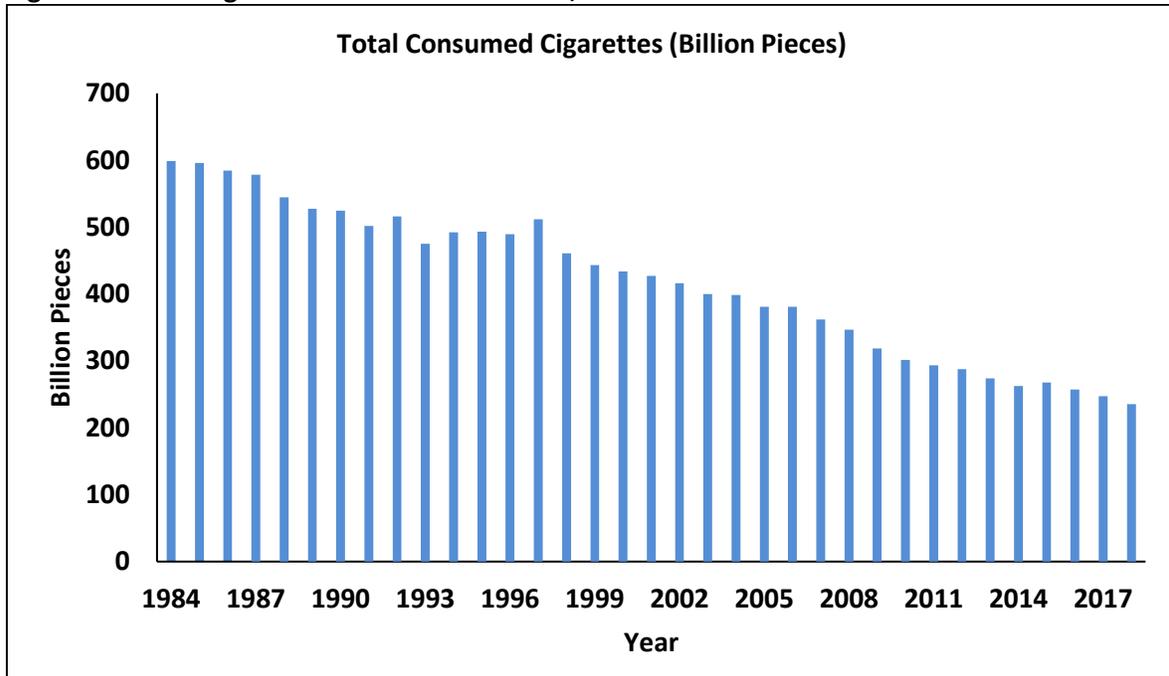
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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).¹⁴ This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics 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).

¹⁴ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed October 1, 2019.

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



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

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 Action and Alternative – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product. 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 includes human and natural environments in the United States because the marketing order would allow for the new tobacco product to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the product 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 spent cigarette waste of the new product. The chemicals in the spent cigarette waste are commonly used in other currently marketed cigarettes.

Unlike combusted cigarettes, Eclipse disposal would also include the spent carbon fuel element, which is biodegradable and the glass component, which can persist in the environment, but is inert. Because the new product is anticipated to compete with or replace the predicate product or other marketed combusted or heated tobacco products, the spent waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product is anticipated to be the same as any materials from other cigarettes and heated tobacco products disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new product 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. The applicant stated the new and predicate product packaging are similar.

7.3. Biological Resources

The proposed action is 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. Disposal of smoldering cigarettes has been implicated in many fire incidents.^{15, 16} However, similar to the disposal of combusted cigarette butts, the disposal of the new product, which would still have an internal carbon element that burns and is not extinguished, is not expected to change the fire frequency. This is because (1) the disposal of the new product would be the same as the disposal of the currently marketed predicate product, (2) there would be no anticipated increase in number of heated cigarettes being disposed of as the new product is anticipated to compete with the predicate product, and (3) the internal heating element core is surrounded by unburned tobacco potentially shielding it from igniting surrounding flammables.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the spent cigarette waste from the new product because (1) the new product differs from the predicate product in a modification to remove one tobacco additive and replace it with a similar alternative, (2) the chemicals in the new product are the same or similar to chemicals in currently marketed combusted cigarettes, and (3) exceptions to the new product compared to a combusted cigarette include the spent carbon fuel element, which is biodegradable and the glass component, which can persist in the environment, but is inert. The new product would compete with or replace the predicate product or combusted or heated tobacco products currently on the market.

7.5. Solid Waste

The Agency does not foresee the introduction of the new product would notably affect the current spent cigarette waste generated from all combusted or heated tobacco products. The waste generated due to disposal of the new product and packaging materials would be in the same manner as any other

¹⁵ 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 October 1, 2019.

¹⁶ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed October 1, 2019.

waste generated from any other non-filtered cigarettes in the United States. The number of spent cigarettes generated is equivalent to the market projection (Confidential Appendix 2) a portion of those would be littered.

As for the spent carbon fuel element, it is biodegradable and for the glass component, 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 product. The waste generated due to disposal of the new product is expected to be handled in the same manner as the waste generated from other cigarettes in the United States. No new emissions are expected due to disposal of the new product; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.7. Cumulative Impacts

A major existing environmental consequence of the use of the new product is littering of discarded used cigarettes. However, the cumulative impact from discarded cigarettes is declining because the use of cigarettes in the United States is declining.

As for the spent carbon fuel element, it is biodegradable and 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.

7.8 Impacts of the No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of disposal of all cigarettes and cigarette packaging, as many cigarettes would continue to be marketed.

8. List of Preparers

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

Preparer:

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-four years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

Gregory Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Matt GE, Quintana PJE, Destailats 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.

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CONFIDENTIAL APPENDIX 1. Modifications: New Product as Compared to the Predicate Product

STN	Component	Modification
SE0015044	(b) (4)	Deletion of tobacco additive (b) (4) and addition of a tobacco additive (b) (4).

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New Product and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Product

First- and fifth-year market volume projections of the new product was compared to the total forecasted use of cigarettes in the United States.¹⁷ The projected use of the new product in the first and fifth year of marketing after a marketing order is issued accounts for about (b) (4) respectively, of the forecasted cigarette use in the United States. The applicant stated they intend to market the predicate product and the new product simultaneously after the marketing order for the new product is issued. The applicant expects that the new product would replace a portion of the predicate product’s volume. The new product would account for a fraction of the forecasted cigarette use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁸	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁹
SE0015044	(b) (4)	(b) (4)	(b) (4)	(b) (4)

¹⁷ 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 bestfit 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 228.66 billion cigarettes in the first year and 205.02 billion cigarettes in the fifth year of marketing the new product.

¹⁸ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹⁹ Ibid.