

**Programmatic Environmental Assessment for Marketing
Orders for Two New Non-Combusted, Filtered Cigarettes by
R.J. Reynolds Tobacco Company**

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

July 17, 2018

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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 N Main St. Winston Salem, NC 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Address:	Shorefair, a manufacturing facility within R.J. Reynolds Tobacco Company's Whitaker Park Complex, 2901 Shorefair Drive, Winston-Salem, NC 27105

2. Product Information

New Product Names, Submission Tracking Number (STN), and Predicate Product Name

New Product Name	STN	Predicate Product Name
Eclipse	SE0014246	Eclipse Menthol
Eclipse Menthol	SE0014221	Eclipse Menthol

Product Identification

Product Type	Cigarette
Product Subtype	Non-Combusted Filtered
Product Package	Twenty cigarettes per pack with ten packs per bleached sulphate board carton. The pack consists of a solid bleached sulphate board box, foil inner liner, C2S 100# paper pack insert, bleached sulphate board Inner frame, and an oriented polypropylene film overwrap.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders finding the new tobacco products substantially equivalent to the single predicate product under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports submitted by the applicant, the new products are found substantially equivalent to the predicate product. The predicate product was on the market as of February 15, 2007.

In the SE Reports, the new and predicate products are heat-not-burned tobacco products. SE0014246 differs from the predicate product in tobacco mass, tobacco blend, additives, structural materials, and aspects of the heating source; the predicate product contains the characterizing flavor of menthol while the new product does not (Confidential Appendix 1). SE0014221 differs from the predicate product in tobacco mass, tobacco blend, additives, structural materials, aspects of the heating source, and levels of menthol (Confidential Appendix 1).

4. Alternative to the Proposed Actions

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

5. Potential Environmental Impacts of the Proposed Actions and Alternative—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 information submitted by the applicant:

- There will be no changes between how the new and predicate products are manufactured.
- The new products are intended to compete with combusted cigarette products currently marketed.
- No facility expansion or new construction is due to the manufacturing of the new products.
- Manufacturing the new products will not require additional resources (e.g., landfills, recycling centers) for disposal of manufacturing waste.

5.1 Affected Environment

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

Figure 1. Location of the Manufacturer



The facility is located in the Yadkin River Headwaters, which occupies the north-western portion of North Carolina in Forsyth County and land use varies from generally undisturbed in the western highlands to decidedly urban in the eastern portion of the watershed around the Winston-Salem metro

area. Land use within the watershed is predominantly forest (57%). Agriculture and developed areas account for approximately 24% and 13% of the watershed, respectively.¹

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

5.2 Air Quality

The Agency does not anticipate any new substances or new type of emissions to be released into the environment because of manufacturing the new products. The applicant stated that the facility does not anticipate a change to the facilities' air permit from the manufacture of the new products. In turn, the same or similar substances and types of emissions associated with tobacco products currently manufactured at the facility would be released into the environment as a result of manufacturing the new products.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water. The applicant stated that the facility does not anticipate a change to the facilities' storm water permit from the manufacture of the new products. In turn, the same or similar substances and types of water discharge associated with tobacco products currently manufactured at the facility would be released into the environment as a result of manufacturing the new products.

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 facility expansion or new construction due to manufacturing the new products would not be expected. Therefore, no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be expected.

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 applicant consulted the U.S. Fish and Wildlife Services' (U.S. FWS) critical habitat and endangered species maps. The applicant stated that none of the materials to be used in the new products are manufactured using any of the endangered or threatened species listed by the U.S. Fish and Wildlife Service.^{2,3}

¹ https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf. Accessed June 8, 2018.

² U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>.

³ Critical habitat map available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations, including the U.S. Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI) requirements; however, the volume of materials processed is lower than the minimum threshold required for reporting on the TRI. The applicant provided detailed information for the following air emission and storm water permits:

- (1) Air permits: Permit number 00779R16, issued in accordance with applicable EPA and North Carolina Department of Environment and Natural Resources regulations is currently expired, but the applicant submitted for a renewal on May 11, 2017 and is waiting on a response.
- (2) Storm water permit: Permit number NCG060000 issued by North Carolina Department of Environmental Quality for Whitaker Park. The applicant stated that they comply with the numerous requirements of this permit, which include maintaining storm water pollution prevention plans, quantitative and qualitative discharge monitoring, and site inspections.

The applicant stated that the facility does not anticipate any future expansion and a revised new air and storm water permit is pending. The Agency's search of the EPA Enforcement and Compliance History Online (ECHO) database did not list the specific manufacturing address provided in the SE Reports.⁴

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

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.

No changes in impacts on environmental justice are anticipated. The applicant stated that the new products would not require expansion of the current facility. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new products. Thus, though 2010 U.S. Census and American Community Survey data show that 62% of the population within a three-mile radius of the manufacturing facility is minority,⁵ no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products. In addition, the facility is not located within an Indian reservation.

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's production of all non-combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment, transferred to a publicly owned treatment works (POTW), and disposed of in

⁴ U.S. EPA ECHO Detailed Facility Report: R. J. Reynolds Tobacco Co. Whitaker Park, Winston Salem, NC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000345332>. Accessed June 7, 2018.

⁵ U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding R. J. Reynolds Tobacco Co. Whitaker Park, Winston Salem, NC area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000345332>. Accessed June 7, 2018.

landfills in the same manner as any other waste generated from any other products manufactured in the same facility and in a similar manner to combusted, filtered cigarettes manufactured in the United States.

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 facility's tobacco manufacturing because as specified in section 5.6, the applicant stated that they comply with EPA TRI requirements; however, the volume of materials processed at the manufacturing location is lower than the minimum threshold required for reporting on the TRI.

5.11 No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing all cigarettes, as many combusted tobacco products would continue to be manufactured and marketed.

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 may 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 is the entire United States because the marketing orders will allow for the new tobacco products to be sold to consumers nationwide.

6.2. Air Quality

The Agency does not anticipate new substances would be released into the environment as a result of use of the new products, relative to combusted, filtered cigarettes currently on the market, because (1) the substances from the new products would be released in the same manner as the substances from marketed combusted, filtered cigarettes; (2) the applicant stated that analytical testing showed a decrease in tar, nicotine and CO yields from the new products as compared to the predicate product; (3) the new products are expected to compete with or replace currently marketed combusted cigarettes so the Agency does not expect that new or increased air emissions would be associated with use of the new products (Confidential Appendix 2); (4) the majority of ingredients in the new products

are used in currently marketed combusted, filtered cigarette products; and (5) the new products will not be marketed simultaneously with the predicate product in the United States.

6.3. Environmental Justice

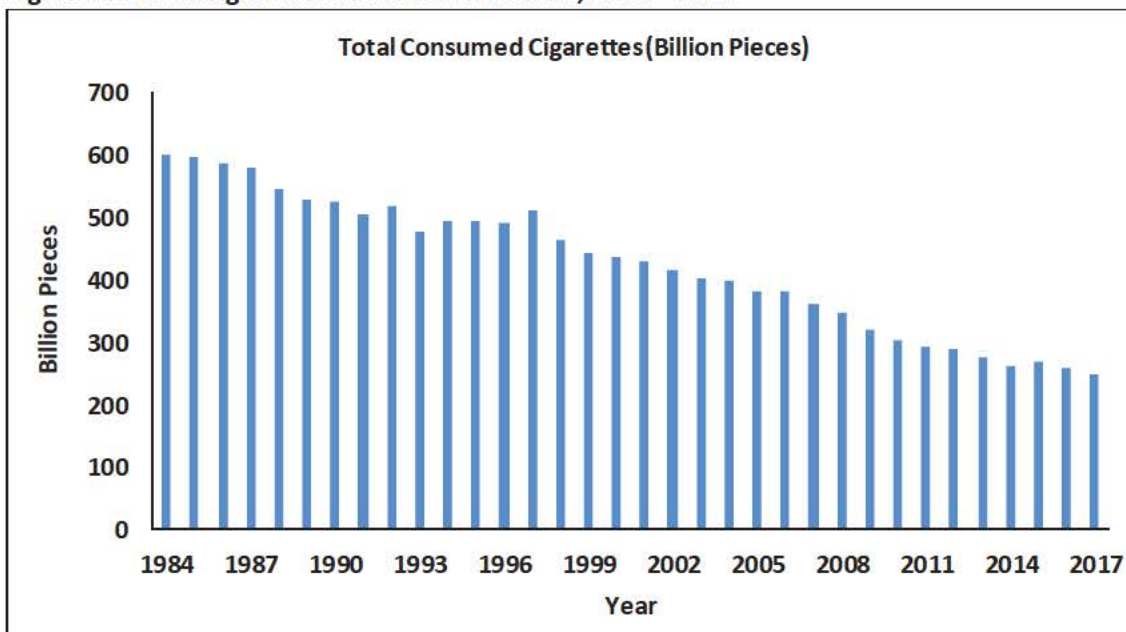
No new emissions are expected due to use of the new products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.4. Cumulative Impacts

The heating components in the new and predicate products differ from conventional cigarettes. The new and predicate products contain a heat source that is comprised of a carbon fuel element and fiberglass. The carbon fuel element oxidizes to carbon dioxide during use. Carbon dioxide is also released when conventional cigarettes are used. The use of the carbon heat source in the new products will not add to environmental emissions because the new products would not be marketed simultaneously with the predicate product. A heated combusted, filtered cigarette produces environmental tobacco smoke or secondhand smoke (SHS). 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. While a non-combusted cigarette may not produce the same SHS, some of the same harmful chemicals have been measured in the aerosol from heat-not-burn cigarettes. (Auer, R., Concha-Lozano, N., & Jacot-Sadowski, I., 2017)

It is relevant to note, however, that 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).⁶

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



⁶ 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.

6.5 No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of use of all cigarettes, as many combusted tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternative – Disposal of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on publicly available information such as the documented continuous decline in use of combusted 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 will allow for the new tobacco products to be sold to consumers nationwide.

7.2. Air Quality

The Agency does not anticipate disposal of the 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 used new products because the new products are composed of ingredients commonly used in combusted cigarettes currently on the market. In addition, the new product is not anticipated to be sold simultaneously with the predicate product and will compete with currently marketed combusted cigarettes. (Confidential Appendix 3).

As stated in section 6.4, the heating components in the new products differ from combusted cigarettes. The carbon fuel element is biodegradable; oxidization during use produces carbon dioxide; carbon dioxide emissions occur with use of conventional cigarettes. The fiberglass component 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.

No changes in air quality from disposal of the packaging materials of the new products is anticipated 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 is a minuscule portion of the municipal solid waste based on FDA's experience in evaluating the packaging waste generated from cigarettes.

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.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the used cigarette from the new products because the chemicals in the new products are similar to those in currently marketed combusted, filtered cigarettes.

7.5. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. No new emissions are expected due to disposal of the new products; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.6. Cumulative Impacts

A major existing environmental consequence of the use of the new products 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 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 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 combusted tobacco products would continue to be marketed.

8. List of Preparers

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

Preparers:

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Education: M.S. in Biology

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

Experience: 10 years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Comparison Between the New Products and the Predicate Product Relevant to the Environmental Assessment

STN	Component	Change
SE0014221	Tobacco	Decreased total mass
	Tobacco Blend	Decreased (b) (4) Increased (b) (4) Added (b) (4)
	Heat Source	Removed (b) (4) in the heat source mix
	Tobacco Roll Rod	Added (b) (4) in the tobacco roll rod (TBR) and substrate (SUB) sections
	SUB section	Added (b) (4) into tobacco beads in the SUB section
	Ingredients	Added two complex flavor ingredients (b) (4) (Removed three complex flavor ingredients (b) (4))
	Characterizing flavor	Increased menthol
SE0014246	Tobacco	Decreased total mass
	Tobacco Blend	Increased (b) (4) Added (b) (4)
	Heat Source	Shortened tobacco rods Increased substrate rod density Removed (b) (4) in the heat source mix
	Tobacco Roll Rod	Added (b) (4) tobacco
	SUB section	Longer combined filter and shorter tobacco SUB and TBR
	Ingredients	Increased (b) (4) (Removed menthol
	Characterizing flavor	Removed menthol

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigarettes in the United States.⁷ The projected use of the new products would account for (b) (4) of the forecasted cigarette use in the United States, the applicant stated that they will not commercially market the predicate product simultaneously with the new products within the United States.

STN	Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ⁸	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarette Used ⁹
SE0014221	(b) (4)			
SE0014246				
Total				

⁷ 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 R² value of 0.9786, the forecasted number of cigarettes that will be used in the United States is estimated at 236.26 billion cigarettes in the first year and 210.92 billion cigarettes in the fifth year of marketing the new products.

⁸ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

⁹ See footnote # 10 and #11

CONFIDENTIAL APPENDIX 3

Projected Calculated Waste of Used Cigarettes in the First and Fifth-Year of Marketing the New Products

$\sum_{i=1}^z A_i = \sum_{i=1}^z (B_i * C_i) D_i$	<i>A_i</i> : Projected total waste generation of the product (metric tons) <i>B_i</i> : Market Volume (pieces) <i>C_i</i> : Cigarette Weight (grams) <i>D_i</i> : 1.0 x 10 ⁻⁶ metric tons/gram
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Projected Year	STN	Market Volume (pieces) <i>B_i</i>	Cigarette Weight (grams) <i>C_i</i>	Spent Cigarette Waste (metric tons) <i>A_i</i>
First-Year	SE0014221	(b) (4)	1.3216	(b) (4)
	SE0014246		1.3174	
	Total			
Fifth-Year	SE0014221		1.3216	
	SE0014246		1.3174	
	Total			

The used cigarette is discarded after use, however unlike a combusted cigarette, the new products do not burn down. If all of the used cigarette waste generated from use of the new products is disposed of in landfills, the projected waste of (b) (4) metric tons and (b) (4) metric tons in the first and fifth years of marketing the new products would be negligible fractions of the 234.47 million metric tons of total waste reported in the United States in 2014 (U.S. EPA, 2016).