

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

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

**November 12, 2019**

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### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	RAI Services Company on behalf of R.J. Reynolds Tobacco Company
<b>Applicant Address:</b>	401 North Main Street Winston-Salem, NC 27101
<b>Manufacturer Name:</b>	R.J. Reynolds Tobacco Company
<b>Product Manufacturing Location:</b>	7855 King-Tobacoville Road Tobacoville, NC 27050

### 2. Product Information

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

New Product STN	New Product Name	Original Product Name	Original Product STN
EX0000812	Carlton Menthol Green Soft Pack	Carlton Menthol King Soft Pack	GF1501207
EX0000813	Carlton Menthol Green 100	Carlton Menthol 100s Box	GF1501234
EX0000814	Carlton Red 100	Carlton 100s Box	GF1501233
EX0000815	Carlton Red	Carlton 100s Box	GF1501235

### Product Identification

<b>Product Category</b>	Cigarette
<b>Product Subcategory</b>	Combusted filtered
<b>Product Number per Retail Unit</b>	Twenty cigarettes per pack with ten packs per carton
<b>Product Package</b>	The packaging materials consist of a solid bleached sulphate inner frame, box, and carton; foil inner liner; and polypropylene film overwrap.

### 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 four 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. 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 new products are made by modifying the corresponding original products. These modifications are to the filter tow, tipping paper, filter centerline adhesive, and filter sideseam adhesive. (Confidential Appendix 1).

#### 4. Alternatives 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 Alternatives – Manufacturing the New Products

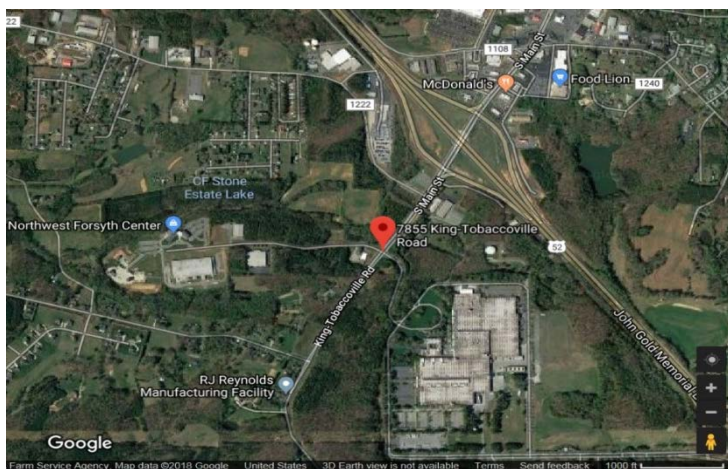
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The alternate tipping paper, filter tow, and seam adhesives are commonly used in other products manufactured at the facility.
- The new products would be manufactured in the same manner as the predicate products.
- Endangered species and critical habitats are not expected to be affected by production of the new products.
- No facility expansion or new construction would be required due to manufacturing the new products.
- The new products would compete with or replace similar tobacco products currently manufactured at the facility.

##### 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**







## 5.8. Solid Waste and Hazardous Materials

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

## 5.9. Floodplains, Wetlands, and Coastal Zones

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

## 5.10. Cumulative Impacts

The Agency does not anticipate the proposed actions 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. No TRI-reportable chemicals were released to water or land (Table 1).<sup>8</sup> No other hazardous air pollutants were reported. Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.<sup>9</sup> 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.

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<sup>8</sup> U.S. Environmental Protection Agency (EPA). *TRI Data* <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A>. Searched on August 15, 2019.

<sup>9</sup> 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 August 15, 2019.

**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
<b>Subtotal Waste Managed</b>		<b>5,815</b>
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>
<b>Total Production-Related Waste</b>		<b>39,622</b>
* Ammonia plus nicotine and nicotine salts		

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.<sup>10</sup>

The applicant stated that manufacturing the new products 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 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 (Confidential Appendix 2) 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.

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<sup>10</sup> 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](https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf). Accessed August 15, 2019.











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**9. A Listing of Agencies and Persons Consulted**

Not applicable.

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**CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products**

STN	Component	Modification
EX0000813 EX0000814 EX0000815	Filter centerline adhesive	Deletion of filter center line adhesive
		Addition of alternate filter centerline adhesive
EX0000812 EX0000813 EX0000814 EX0000815	Tipping paper	Deletion of white tipping paper
		Addition of alternate white tipping paper
EX0000812 EX0000813 EX0000814 EX0000815	Filter tow	Deletion of filter tow
		Deletion of alternate filter tow
EX0000813 EX0000814 EX0000815	Filter sideseam adhesive	Increase quantity of filter sideseam adhesive



**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 of the new products were compared to the total forecasted use of cigarettes in the United States.<sup>15</sup> The new products would account for about (b) (4) and (b) (4) of the forecasted cigarette use in the United States in the first and fifth years of marketing the new products, respectively.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used
EX0000812	(b) (4)			
EX0000813	(b) (4)			
EX0000814	(b) (4)			
EX0000815	(b) (4)			
<b>Total</b>	(b) (4)			

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<sup>15</sup> 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<sup>2</sup> value of 0.9786, the forecasted number of cigarettes that would 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.