



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 14, 2019

SUBSTANTIALLY EQUIVALENT

R.J. Reynolds Tobacco Company
Attention: Michael W. Ogden, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Dr. Ogden:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A.² Under the provisions of sections 910 and 905(j) of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

² In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco products in these SE Reports to the grandfathered tobacco products in SE0006177 and SE0006178. Although the new products have different characteristics than the grandfathered tobacco products in SE0006177 and SE0006178, FDA found that those differences do not cause the new tobacco products to raise different questions of public health, and thus the new tobacco products are also substantially equivalent to the grandfathered products in SE0006177 and SE0006178.

If you have any questions, please contact Jennifer Schmitz, M.P.H., Regulatory Health Project Manager, at (240) 402-5892 or Jennifer.Schmitz@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2019.11.14 08:35:23 -05'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Attributes of SE Report		
Date of Submission:	January 4, 2019	
Date of Receipt:	January 4, 2019	
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Non-combusted, non-filtered ³	
	New Tobacco Product	Predicate Tobacco Product
	SE0015044: Eclipse Menthol ⁴	SE0006178: Eclipse Menthol ⁴
Package Type:	Box	Box
Package Quantity:	20 cigarettes	20 cigarettes
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	24%	24%
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	N/A	Previously Found SE
Source of Energy:	Carbon Heat Source	Carbon Heat Source
Attributes of SE Report		
Date of Submission:	January 31, 2019	
Date of Receipt:	January 31, 2019	
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Non-combusted, non-filtered ³	
	New Tobacco Product	Predicate Tobacco Product
	SE0015074: Eclipse ⁴	SE0006177: Eclipse ⁴
Package Type:	Box	Box
Package Quantity:	20 cigarettes	20 cigarettes
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	24%	24%
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Source of Energy:	Carbon Heat Source	Carbon Heat Source

³ The applicant stated that the new and corresponding predicate tobacco products are non-combusted, filtered cigarettes. However, the applicant also stated that the filter tips do not function as mainstream smoke filters per se but are hollow tubes composed of cellulose acetate and serve as a mouthpiece for the user and lessen the chance of any tobacco entering the mouth. Based on this information, and in the absence of pressure drop, FDA has determined that the new and predicate tobacco products are non-combusted, non-filtered cigarettes.

⁴ Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

Description of the new tobacco products

Description of the predicate tobacco products

List of all differences in characteristics between the new and predicate tobacco products

Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health

Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.