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

June 18, 2018

EXEMPT

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

FDA Submission Tracking Number (STN): EX0000219

Dear Dr. Ogden:

The Food and Drug Administration (FDA) has completed review of your Request for Exemption from Substantial Equivalence (EX REQ), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco product:

Tobacco Product Manufacturer:	R.J. Reynolds Tobacco Company
Tobacco Product Name:[1,2]	Vantage Classic Menthol 100 Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:	7.9 mm
Ventilation:	45%
Characterizing Flavor:	Menthol
Modifications:	Addition/Deletion of tobacco additives: • Deletion of non-Fire Standards Compliant (FSC) cigarette paper ((b) (4) [redacted]) • Addition of FSC cigarette paper ((b) (4) [redacted]) • Deletion of cork-on-white tipping paper ((b) (4) [redacted]) • Addition of alternate cork-on-white tipping paper ((b) (4) [redacted]) • Deletion of filter tow ((b) (4) [redacted]) • Addition of alternate filter tow ((b) (4) [redacted])

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Vantage Menthol 100s Soft Pack

Based on our review of your EX REQ, we find the new tobacco product specified above exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco product that is the subject of this EX REQ, the following must be met:

1. **Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
2. **Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix A for FDA's recommended format for the submission of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA "approved" the new tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. This order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

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

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.06.18 14:45:14 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products