DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

EXEMPT

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

FDA Submission Tracking Number (STN): EX0000207

Dear Dr. Figlar:

The Food and Drug Administration (FDA) 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]	Kent III Silver Soft Pack
Tobacco Product Category:	Cigarettes
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 Cigarettes
Length:	84 mm
Diameter:	7.9 mm
Ventilation:	52%
Characterizing Flavor:	None
Modification:	Addition/Deletion of tobacco additives: Deletion of a complex purchased flavor (b) (4) deletion of tipping paper ((b) (4) offline); and addition of tipping paper (b) (4) online) Increasing quantities of existing tobacco additives: glycerin and water

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The name of the tobacco product being modified is Kent III Ultra Lights Kings

Based on our review of your EX REQ, we find the new tobacco product specified above exempt from the requirements 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.**

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

Our finding does not mean FDA "approved" the modified 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 marketing 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 modified 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
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 FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers 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 the prior business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Jennifer Schmitz, Regulatory Health Project Manager, at (240) 402-5892.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.01.16 15:31:13 -05'00'

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