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

December 06, 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 Number (STN): SE0002188**,** see Appendix A

Dear Dr. Ogden:

We completed our review of your SE Report[1] and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A. Under the provisions of sections 910 and 905(j) of the FD&C Act, you may continue to legally market the new tobacco product subject of this letter.

Our finding does not mean we "approved" the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product 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 publicly available our finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

All regulated tobacco products, including the tobacco product 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 product 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) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

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: 2019.12.06 11:50:51 -05'00'

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

Enclosures:

Appendix A – New and Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A
New and Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
Date of Submission:	March 22, 2011	
Date of Receipt:	March 22, 2011	
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product	**Predicate Tobacco Product**
	SE0002188: Old Gold Blue 100s[2]	**GF1200339: Old Gold Ultra Lights 100s[2]**
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	68%	68%

[2] Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B

Health Information Summary

Your SE Report did not provide a summary of any health information related to the new tobacco product, required by section 910(a)(4) of the FD&C Act; however, your SE Report 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 Report 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 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]."

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.