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

March 03, 2020

EXEMPT

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): EX0000964**,** see Appendix A

Dear Dr. Ogden:

We completed review of your EX REQ[1] and determined that the new tobacco product listed in Appendix A is exempt from the requirements of Substantial Equivalence effective on April 9, 2020.[2]

An Exemption Request may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product. A legally marketed product appropriate for modification can be a tobacco product FDA has previously found exempt from substantial equivalence and for which an Abbreviated Report was submitted at least 90 days prior to making such introduction or delivery for introduction into interstate commerce for commercial distribution. Although the tobacco product in Appendix A that you propose to modify is a tobacco product FDA has previously found exempt from SE, FDA received your Abbreviated Report for this product on January 10, 2020. This tobacco product cannot be legally marketed as a tobacco product until 90 days after submission of the Abbreviated Report, i.e., April 9, 2020. Therefore, the new tobacco product listed in Appendix A is exempt from the requirements of Substantial Equivalence effective on April 9, 2020.

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).

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 B for FDA's recommended format for submitting of an Abbreviated Report.

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

[1] Requests for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] See section 910(a)(3)(a) of the FD&C Act

All regulated tobacco products, including the tobacco product specified in Appendix A, is 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 comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] 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

The CTP Portal and FDA's 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[6]; 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, please contact Barbara Banchero, Regulatory Health Project Manager, at (301) 796-1937 or Barbara.Banchero@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2020.03.03 11:07:25 -05'00'

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

Enclosures:

Appendix A – New and Corresponding Original Tobacco Product Subject of This Letter
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal
[5] For more information about eSubmitter, see http://www.fda.gov/ForIndustry/FDAeSubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A

New and Corresponding Original Tobacco Product Subject of This Letter

Common Attributes of EX REQs		
Date of Submission:	January 23, 2020	
Date of Receipt:	January 23, 2020	
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product	**Original Tobacco Product**
	EX0000964: True Menthol Green 100 Soft Pack[7]	**EX0000633: True Menthol Green 100 Soft Pack[7]**
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	N/A	Previously Found Exempt
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	54%	54%

Modifications:

Addition/Deletion of tobacco additives:

- Deletion of filter tow [redacted] target: [redacted] mg/cigarette)
- Addition of filter tow [redacted] target: [redacted] mg/cigarette)

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

Appendix B

FDA's Recommended Format for Submitting an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe **[ink or digital signature]**
Vice President
Mock-Up Tobacco Company