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

May 16, 2019

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 Numbers (STNs): EX0000368-EX0000371

Dear Dr. Ogden:

The Food and Drug Administration (FDA) has completed review of your 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) for the tobacco products specified in Appendix A.

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

To market each of the new tobacco products that are the subject of these EX REQs, 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 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 products specified in Appendix A; therefore, you may not promote or in any way represent the modified tobacco products specified in Appendix A, or their labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. These orders are 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 products specified in Appendix A, 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 products specified in Appendix A comply 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)[1] 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

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/abouctp/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, M.P.H., Regulatory Health Project Manager, at (240) 402-65892 or Jennifer.Schmitz@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.05.16 10:24:24 -04'00'

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

Enclosures – Appendix A: List of New Tobacco Products Subject of This Letter
Appendix B: FDA's Recommended Format of the Submission of an Abbreviated Report

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

Appendix A

List of new tobacco products that FDA has found exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent

Common Attributes of EX REQs	
Date of Submission:	December 18, 2018
Date of Receipt:	December 20, 2018
Product Manufacturer:	R.J. Reynolds Tobacco Company
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000368
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Modifications:	Addition/Deletion of tobacco additives: • Deletion of FSC[3] cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cig) • Addition of FSC cigarette paper (b) (4) [redacted] Target: (b) (4) mg/cig)
Original Tobacco Product Specific Attributes	
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Eligibility Status:	Previously Found SE Under SE0014484

[2] Brand/sub-brand or other commercial name used in commercial distribution.
[3] FSC: Fire Standards Compliant.

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000369
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Modifications:	Addition/Deletion of tobacco additives: • Deletion of FSC cigarette paper ((b) (4) [redacted]; Target: (b) (4) [redacted] mg/cig) • Addition of FSC cigarette paper ((b) (4) [redacted]; Target: (b) (4) [redacted] mg/cig) • Deletion of filter tow ((b) (4) [redacted]) • Addition of filter tow ((b) (4) [redacted])
Original Tobacco Product Specific Attributes	
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Eligibility Status:	Previously Found SE Under SE0014484

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000370
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Modifications:	Addition/Deletion of tobacco additives: • Deletion of FSC cigarette paper ([redacted]; Target: [redacted] mg/cig) • Addition of FSC cigarette paper [redacted] Target: [redacted] mg/cig) • Deletion of filter tow [redacted]) • Addition of filter tow [redacted])
Original Tobacco Product Specific Attributes	
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Eligibility Status:	Previously Found SE Under SE0014484

Submission Tracking Number	EX0000371
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Modifications:	Addition/Deletion of tobacco additive: • Deletion of FSC cigarette paper ([redacted]; Target: [redacted] mg/cig) • Addition of FSC cigarette paper ([redacted]; Target: [redacted] mg/cig)
Original Tobacco Product Specific Attributes	
Product Name:[2]	Old Gold Box
Package Type:	Box
Package Quantity:	20 Cigarettes
Length:	80 mm
Diameter:	7.9 mm
Ventilation:	18%
Characterizing Flavor:	None
Eligibility Status:	Previously Found SE Under SE0014484

Appendix B
FDA's Recommended Format of the Submission of 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
Vice President
Mock-Up Tobacco Company