

November 04, 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 Numbers (STNs): Multiple STNs, see Appendix A

Dear Dr. Ogden:

We completed review of your EX REQs¹ and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.²

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products 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 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 submitting of an Abbreviated Report.

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

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

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

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 date⁶; 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 Banchemo, Regulatory Health Project Manager, at (301)- 796 -1937 or Barbara.Banchemo@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2020.11.04 09:55:12 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Original Tobacco Products 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 Products Subject of This Letter

Common Attributes of EX REQs		
Product Manufacturer:	R.J. Reynolds Tobacco Company	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product	Original Tobacco Product
	EX0001062: Camel Classic Filters Soft Pack⁷	SE0000014: Kamel Red Originals Box⁷
Date of Submission:	April 23, 2020	N/A
Date of Receipt:	April 23, 2020	N/A
Product Name:⁷	Camel Classic Filters Soft Pack	Kamel Red Originals Box
Package Type:	Soft Pack	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date	N/A	12/05/2019
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	23%	23%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Deletion of red printed monogram ink on the cigarette barrel (b) (4) target: (b) (4) mg/cigarette) • Addition of blue printed monogram ink on the cigarette barrel (b) (4) target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of tipping adhesive ((b) (4) ; target: (b) (4) mg/cigarette) 		

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

	New Tobacco Product	Original Tobacco Product
	EX0001063: Camel Classic Filters Box⁷	SE0000014: Kamel Red Originals Box⁷
Date of Submission:	April 23, 2020	N/A
Date of Receipt:	April 23, 2020	N/A
Product Name:⁷	Camel Classic Filters Box	Kamel Red Originals Box
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date:	N/A	12/05/2019
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	23%	23%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Deletion of red printed monogram ink on cigarette barrel (b) (4) .; target: (b) (4) mg/cigarette) • Addition of blue printed monogram ink on barrel (b) (4) .; target: (b) (4) mg/cigarette) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of tipping adhesive (b) (4) ; target: (b) (4) mg/cigarette) 		
	New Tobacco Product	Original Tobacco Product
	EX0001064: Camel Classic Blue Soft Pack⁷	SE0006211: Kamel Red Smooth Taste Box⁷
Date of Submission:	April 23, 2020	N/A
Date of Receipt:	April 23, 2020	N/A
Product Name:⁷	Camel Classic Blue Soft Pack	Kamel Red Smooth Taste Box
Package Type:	Soft Pack	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date:	N/A	05/03/2018
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	25%	25%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of tipping adhesive (b) (4) ; target: (b) (4) mg/cigarette) 		

	New Tobacco Product	Original Tobacco Product
	EX0001065: Camel Classic Blue Box ⁷	SE0006211: Kamel Red Smooth Taste Box ⁷
Date of Submission:	April 23, 2020	N/A
Date of Receipt:	April 23, 2020	N/A
Product Name:⁷	Camel Classic Blue Box	Kamel Red Smooth Taste Box
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date:	N/A	05/03/2018
Length:	83 mm	83 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	25%	25%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of white tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) Addition of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of tipping adhesive (b) (4) target: (b) (4) mg/cigarette) 		
	New Tobacco Product	Original Tobacco Product
	EX0001067: True Blue 100 Box ⁷	EX0000975: True Blue 100 Box ⁷
Date of Submission:	April 28, 2020	N/A
Date of Receipt:	April 28, 2020	N/A
Product Name:⁷	True Blue 100 Box	True Blue 100 Box
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found Exempt
Market Authorization Date:	N/A	03/17/2020
Abbreviated Report Date:	N/A	04/26/2020
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	54%	54%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of filter tow (b) (4)]; Target: (b) (4) mg/cigarette) Addition of alternate filter tow (b) (4)]; Target: (b) (4) mg/cigarette) 		

	New Tobacco Product	Original Tobacco Product
	EX0001069: Old Gold Filter 100 Box ⁷	GF1200348: Old Gold [Filter] 100s Box ⁷
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Filter 100 Box	Old Gold [Filter] 100s Box
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Market Authorization Date:	N/A	N/A
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	0%	0%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion non-Fire Standards Compliant (FSC) cigarette paper (b) (4)]; target:^{(b) (4)} mg/cigarette) Addition of FSC paper (b) (4)]; target:^{(b) (4)} mg/cigarette) Deletion of cork tipping paper (b) (4) MM]; target:^{(b) (4)} mg/cigarette) Addition of cork tipping paper (b) (4) MM]; target:^{(b) (4)} mg/cigarette) Deletion of filter tow (b) (4) target:^{(b) (4)} mg/cigarette) Addition of filter tow (b) (4) target:^{(b) (4)} mg/cigarette) 		
	New Tobacco Product	Original Tobacco Product
	EX0001070: Old Gold Filter 100 Box ⁷	GF1200348: Old Gold [Filter] 100s Box ⁷
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Filter 100 Box	Old Gold [Filter] 100s Box
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Market Authorization Date:	N/A	N/A
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	0%	0%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of non-Fire Standards Compliant (FSC) cigarette paper (b) (4) target:^{(b) (4)} mg/cigarette) Addition of FSC paper (b) (4)]; target (b) mg/cigarette) Deletion of cork tipping paper (b) (4) MM]; target:^{(b) (4)} mg/cigarette) Addition of cork tipping paper (b) (4) MM]; target:^{(b) (4)} mg/cigarette) Deletion of filter tow (b) (4) target:^{(b) (4)} mg/cigarette) Addition of filter tow (b) (4) target:^{(b) (4)} mg/cigarette) 		

	New Tobacco Product	Original Tobacco Product
	EX0001071: Old Gold Blue Filter 100 Soft Pack ⁷	SE0002188: Old Gold Blue 100s ⁷
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Blue Filter 100 Soft Pack	Old Gold Blue 100s
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date:	N/A	12/06/2019
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	68%	68%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4)]; target: (b) (4) mg/cigarette) • Addition of FSC paper (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of complex flavor ingredient, (b) (4) " (target: (b) (4) mg/cigarette) • Deletion of complex flavor ingredient, (b) (4) (target: (b) (4) mg/cigarette) • Deletion of blue printed monogram ink on barrel 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) in the tobacco casing • Increase in the quantity of (b) (4) in the tobacco casing 		

	New Tobacco Product	Original Tobacco Product
	EX0001072: Old Gold Blue Filter 100 Soft Pack⁷	SE0002188: Old Gold Blue 100s⁷
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Blue Filter 100 Soft Pack	Old Gold Blue 100s
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Market Authorization Date:	N/A	12/06/2019
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	68%	68%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4)]; target (b) (4) mg/cigarette) • Addition of FSC paper (b) (4)]; target (b) (4) mg/cigarette) • Deletion of complex flavor ingredient, (b) (4) " from the tobacco casing (target: (b) (4) mg/cigarette) • Deletion of complex flavor ingredient, (b) (4) " from the tobacco casing (target: (b) (4) mg/cigarette) • Deletion of blue printed monogram ink on barrel 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) in the tobacco casing • Increase in the quantity of (b) (4) in the tobacco casing 		
	EX0001073: Old Gold Filter 100 Box⁷	
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Blue Filter 100 Soft Pack	Old Gold Blue 100s
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Market Authorization Date:	N/A	N/A
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	0%	0%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of non-Fire Standards Compliant (FSC) cigarette paper (b) (4)]; target (b) mg/cigarette) • Addition of FSC paper (b) (4) target (b) (4) mg/cigarette) • Deletion of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette) 		

	New Tobacco Product	Original Tobacco Product
	EX0001074: Old Gold Filter 100 Box ⁷	GF1200348: Old Gold [Filter] 100s Box ⁷
Date of Submission:	April 29, 2020	N/A
Date of Receipt:	April 29, 2020	N/A
Product Name:⁷	Old Gold Filter 100 Box	Old Gold Blue 100s
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Market Authorization Date:	N/A	N/A
Length:	99 mm	99 mm
Diameter:	7.9 mm	7.9 mm
Ventilation:	0%	0%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of non-Fire Standards Compliant (FSC) cigarette paper (b) (4)]; target^{(b) (4)} mg/cigarette) Addition of FSC paper (b) (4)]; target^{(b) (4)} mg/cigarette) Deletion of cork tipping paper (b) (4) MM]; target: ^{(b) (4)} mg/cigarette) Addition of cork tipping paper (b) (4) MM]; target: ^{(b) (4)} mg/cigarette) 		
	New Tobacco Product	Original Tobacco Product
	EX0001258: Pall Mall Blue Filter 100 Box ⁷	EX0001006: Pall Mall Blue Filter 100 Box ⁷
Date of Submission:	August 24, 2020	N/A
Date of Receipt:	August 24, 2020	N/A
Product Name:⁷	Pall Mall Blue Filter 100 Box	Pall Mall Blue Filter 100 Box
Static Product ID:	PD1	N/A
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found Exempt
Market Authorization Date:	N/A	04/22/2020
Abbreviated Report Date:	N/A	06/24/2020
Length:	98 mm	98 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	44%	44%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of white tipping paper (b) (4) mm]; target: ^{(b) (4)} mg/cig) Addition of alternate white tipping paper (b) (4) mm]; target: ^{(b) (4)} mg/cig) 		

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