



October 6, 2022

EXEMPT

R.J. Reynolds Tobacco Company
Attention: Patrick Murphy, RAC (U.S.), 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 Patrick Murphy:

We completed review of your EX REQ¹s 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 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 Sequoia Bacon, M.H.A., Regulatory Health Project Manager, at (301) 796-0736 or Sequoia.Bacon@fda.hhs.gov.

Sincerely,

Todd L. Cecil -S

Digitally signed by Todd L.
Cecil -S
Date: 2022.10.06 15:54:12
-04'00'

Todd L. Cecil, Ph.D.
Acting 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^{7,8,9}

New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs		
Date of Submission	September 29, 2021	
Date of Receipt	September 29, 2021	
Product Manufacturer	R.J. Reynolds Tobacco Company	
Product Category	Cigarette	
Product Sub-Category	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000896
Static Product ID	PD41	Not Applicable (N/A)
Product Name	GPC Classic Menthol Gold 100 Soft Pack	Monarch Classic Menthol Gold 100 Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 millimeters (mm)	7.89 mm
Length	99 mm	99 mm
Ventilation	28%	28%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	June 9, 2020
Abbreviated Report	N/A	July 15, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] mg/cigarette) 	

⁷ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification.

<https://www.congress.gov/bill/117th-congress/house-bill/2471>

⁸ Brand/sub-brand or other commercial name used in commercial distribution.

⁹ The applicant submitted the circumference which allowed for a calculation for diameter.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000910
Static Product ID	PD43	N/A
Product Name	GPC Classic Gold Box	GPC Classic Gold Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	29%	29%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 14, 2020
Abbreviated report	N/A	May 12, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] mg/cigarette) 	
STN	EX0002447	EX0000894
Static Product ID	PD45	N/A
Product Name	GPC Classic Menthol Gold Soft Pack	Monarch Classic Menthol Gold Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	26%	26%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	June 9, 2020
Abbreviated Report	N/A	July 15, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000912
Static Product ID	PD47	N/A
Product Name	GPC Classic Red Box	Monarch Classic Red Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	19%	19%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 14, 2020
Abbreviated Report	N/A	May 12, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	
STN	EX0002447	EX0000893
Static Product ID	PD49	N/A
Product Name	Monarch Classic Menthol Soft Pack	Monarch Classic Menthol Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	17%	17%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	June 9, 2020
Abbreviated Report	N/A	July 15, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000883
Static Product ID	PD51	N/A
Product Name	Monarch Classic Gold 100 Soft Pack	Monarch Classic Gold 100 Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	98 mm	98 mm
Ventilation	34%	34%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	April 14, 2020
Abbreviated Report	N/A	June 3, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	
STN	EX0002447	EX0000896
Static Product ID	PD53	N/A
Product Name	Monarch Classic Menthol Gold 100 Soft Pack	Monarch Classic Menthol Gold 100 Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Length	99 mm	99 mm
Ventilation	28%	28%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	June 9, 2020
Abbreviated Report	N/A	July 15, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000911
Static Product ID	PD55	N/A
Product Name	Monarch Classic Gold Box	Monarch Classic Gold Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.89 mm	7.89 mm
Length	83 mm	83 mm
Ventilation	29%	29%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 14, 2020
Abbreviated report	N/A	May 12, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████ /cigarette) • Addition of alternate filter tow ((b) (4) ██████████ mg/cigarette) 	
STN	EX0002447	EX0000894
Static Product ID	PD57	N/A
Product Name	Monarch Classic Menthol Gold Soft Pack	Monarch Classic Menthol Gold Soft Pack
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	26%	26%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	June 9, 2020
Abbreviated Report	N/A	July 15, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████ /cigarette) • Addition of alternate filter tow ((b) (4) ██████████ mg/cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000912
Static Product ID	PD59	N/A
Product Name	Monarch Classic Red Box	Monarch Classic Red Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	19%	19%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 14, 2020
Abbreviated Report	N/A	May 12, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████ /cigarette) • Addition of alternate filter tow ((b) (4) ██████████ /cigarette) 	
STN	EX0002447	EX0000303
Static Product ID	PD61	N/A
Product Name	Camel Classic Menthol Box	Camel Classic Menthol
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	10%	10%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Rate	N/A	March 28, 2019
Abbreviated Report	N/A	July 3, 2019
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████ /cigarette) • Addition of alternate filter tow ((b) (4) ██████████ /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000290
Static Product ID	PD63	N/A
Product Name	Camel Classic Menthol Silver Box	Camel Classic Menthol Silver Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	38%	38%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	May 22, 2019
Abbreviated Report	N/A	July 3, 2019
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow (b) (4) [REDACTED] /cigarette) 	
STN	EX0002447	EX0000665
Static Product ID	PD65	N/A
Product Name	Camel Royal Box	Camel Royal
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	24%	24%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 13, 2020
Abbreviated Report	N/A	March 31, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow (b) (4) [REDACTED] /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000665
Static Product ID	PD71	N/A
Product Name	Camel Royal Box	Camel Royal
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	24%	24%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 13, 2020
Abbreviated Report	N/A	March 31, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	
STN	EX0002447	EX0000760
Static Product ID	PD73	N/A
Product Name	Doral Classic Menthol 100 Box	Doral Classic Menthol 100 Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	98 mm	98 mm
Ventilation	17%	17%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	November 8, 2019
Abbreviated Report	N/A	February 7, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002447	EX0000906
Static Product ID	PD79	N/A
Product Name	GPC Classic Red 100 Box	GPC Classic Red 100 Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Tobacco	Tobacco
Diameter	7.79 mm	7.79 mm
Length	98 mm	98 mm
Ventilation	17%	17%
Nicotine Source	Tobacco	Tobacco
Eligibility Status	N/A	Previously Found Exempt
Marketing Authorization Date	N/A	February 14, 2020
Abbreviated Report	N/A	May 12, 2020
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) [REDACTED] /cigarette) • Addition of alternate filter tow ((b) (4) [REDACTED] /cigarette) 	

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