



July 21, 2021

EXEMPT

R.J. Reynolds Tobacco Company
Attention: Aaron P. Williams, Ph.D., Senior Vice President - Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston Salem, NC 27101

FDA Submission Tracking Numbers (STNs): EX0001387-PD1 through EX0001391-PD1

Dear Dr. Williams:

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 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: 2021.07.21 09:40:52 -04'00'

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 A⁷**New and Corresponding Original Tobacco Products Subject of This Letter**

Common Attributes		
Submission date	December 18, 2020	
Receipt date	December 18, 2020	
Applicant:	R.J. Reynolds Tobacco Company	
Product manufacturer	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001387-PD1	SE0000068
Product name	Tareyton Classic 100 Soft Pack	Tareyton 100's Soft Pack
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	August 20, 2019
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 millimeters (mm)	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	20%	20%
Product 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 cigarette paper (b) (4); target: (b) (4) mg/cigarette) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increasing the quantity of tipping paper adhesive (b) (4) Increasing the quantity of cork tipping paper (b) (4) 	

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

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001388-PD1	SE0000067
Product name	Tareyton Classic Soft Pack	Tareyton Soft Pack
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	August 20, 2019
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	16%	16%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); target (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4); (b) (4); target (b) (4) mg/cigarette) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive (b) (4) • Increasing the quantity of cork tipping paper (b) (4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001389-PD1	GF1702758
Product name	State Express 555 Gold Box	State Express 555 Gold Box
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	December 21, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	18%	18%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesiv (b) (4) • Deletion of filter sideseam adhesiv (b) (4) • Addition of filter sideseam adhesive (b) (4) • Deletion of cigarette sideseam adhesive (b) (4) • Addition of cigarette sideseam adhesive (b) (4) • Deletion of tipping paper adhesiv (b) (4) • Addition of tipping paper adhesiv (b) (4) • Deletion of cork tipping pape (b) (4); target (b) (4) mg/cigarette) • Addition of cork tipping pape (b) (4); target (b) (4) mg/cigarette) • Deletion of non-porous plug wrap (b) (4) target (b) (4) mg/cigarette) • Addition of non-porous plug wrap (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 gold monogram ink on the cigarette barrel • Deletion of blue monogram ink on the cigarette barrel 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001390-PD1	SE0000068
Product name	Tareyton Classic 100 Soft Pack	Tareyton 100's Soft Pack
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	August 20, 2019
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	20%	20%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette pape (b) (4) (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) (b) (4) mg/cigarette) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive (b) (4) • Increasing the quantity of cork tipping paper (b) (4) .) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001391-PD1	GF1702758
Product name	State Express 555 Gold Box	State Express 555 Gold Box
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	December 21, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	18%	18%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of filter sideseam adhesive (b) (4) • Addition of filter sideseam adhesive (b) (4) • Deletion of cigarette sideseam adhesive (b) (4) • Addition of cigarette sideseam adhesive (b) (4) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of cork tipping paper (b) (4) target (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) target (b) (4) mg/cigarette) • Deletion of non-porous plug wrap (b) (4) target (b) (4) mg/cigarette) • Addition of non-porous plug wrap (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 gold monogram ink on the cigarette barrel • Deletion of blue monogram ink on the cigarette barrel 	

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**