

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001377-PD1 – EX0001382-PD1 and EX0001387-PD1 – EX0001391-PD1
Common Attributes	
Submission date	December 7, 2020 ¹ and December 18, 2020 ²
Receipt date	December 7, 2020 ¹ and December 18, 2020 ²
Applicant	R.J. Reynolds Tobacco Company
Product manufacturer	R.J. Reynolds Tobacco Company
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
EX0001389-PD1 EX0001391-PD1	Social Science Evaluation of the Design of Cigarette Tipping Paper (May 16, 2017)
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S3
Date: 2021.04.06 14:19:26 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Division Director
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.04.06 14:24:39 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

¹ EX0001377-PD1 – EX0001382-PD1

² EX0001387-PD1 – EX0001391-PD1

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

The applicant submitted information for the new and original products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewers	Review Date
Regulatory	Sarah Amyot	12/21/2020 ¹
	Camille Hayslett	12/31/2020 ²
Chemistry	Therese Ku	3/10/2021
Environmental Science	Hermes Reyes Caballero	3/8/2021

2. COMPLIANCE REVIEW

For EX0001377-PD1 – EX0001382-PD1 and EX0001389-PD1 – EX0001391-PD1, the Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated March 10, 2021 and March 12, 2021, concludes that the evidence submitted by the applicant for EX0001377-PD1 - EX0001382-PD1, EX0001389-PD1 and EX0001391-PD1 respectively, is adequate to demonstrate original products are grandfathered products. For EX0001387-PD1, EX0001390-PD1 and EX0001388-PD1, the original products in SE0000068 and SE0000067, respectively, were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA. Therefore, the original products are eligible for modification under the Exemption Request pathway.³

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original products compared to the corresponding new products are the result of:

- deleting additives (tipping paper adhesive and filter tow) in EX0001377-PD1 – EX0001382-PD1, EX0001389-PD1, and EX0001391-PD1

³ Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

- adding additives (tipping paper adhesive and filter tow) in EX0001377-PD1 – EX0001382-PD1, EX0001389-PD1, and EX0001391-PD1
- deleting an additive (Fire Standards Compliant (FSC) cigarette paper) in EX0001387-PD1 – EX0001388-PD1, and EX0001390-PD1
- adding an additive (FSC cigarette paper) in EX0001387-PD1, EX0001388-PD1, and EX0001390-PD1
- increasing the quantities of existing additives (tipping paper adhesive and cork tipping paper) in EX0001387-PD1 – EX0001388-PD1, and EX0001390-PD1
- deleting additives (filter center line adhesive, filter sideseam adhesive, cigarette sideseam adhesive, cork tipping paper, non-porous plug wrap, gold monogram ink on the cigarette barrel, and blue monogram ink on the cigarette barrel) in EX0001389-PD1 and EX0001391-PD1
- adding additives (filter center line adhesive, filter sideseam adhesive, cigarette sideseam adhesive, cork tipping paper, and non-porous plug wrap) in EX0001389-PD1 and EX0001391-PD1

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the products. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

The final environmental review found that the applicant did not provide complete market volume information for the new or original products. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or a finding of no significant impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new products to be marketed would be appropriate for the protection of the public health. For EX0001387-PD1 – EX0001388-PD1, and EX0001390-PD1, the review identifies that the applicant intends to delete the original FSC cigarette paper and add an alternate FSC cigarette paper. There are minor differences in the levels of (b) (4)

(b) (4) in the FSC cigarette paper between the new and original products.

However, these differences are not expected to have a significant impact on the product performance or HPHC yields. For EX0001377-PD1 – EX0001382-PD1, EX0001389-PD1, and EX0001391-PD1, the applicant proposes to delete the filter tow and add an alternate filter tow which is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product.

Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. For EX0001377-PD1 – EX0001382-PD1, EX0001389-PD1, and EX0001391-PD1, the applicant intends to delete various adhesives (tipping paper adhesive, filter center line adhesive, filter sideseam adhesive, or cigarette sideseam adhesive) in the original products and the addition of an alternate adhesives (tipping paper adhesive, filter center line adhesive, filter sideseam adhesive, or cigarette sideseam adhesive) in the new products is a minor modification. These adhesives are not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between these adhesives of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new products relative to the original products. For EX0001387-PD1 – EX0001388-PD1, and EX0001390-PD1, there are also an increase in the tipping paper adhesive, however, as stated above, the ingredient differences and relatively small increase in content between in the tipping paper adhesive of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new products relative to the original products. EX0001389-PD1 and EX0001391-PD1, the applicant proposed the deletion of white tipping paper and the addition of white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception as outlined in the May 16, 2017 social science memo. The applicant also intends to increase the tipping paper resulting in a slight increase in length of EX0001387-PD1 – EX0001388-PD1, and EX0001390-PD1 which is not intended, nor is it expected, to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. For EX0001389-PD1 and EX0001391-PD1, the applicant proposes the deletion of plug wrap and the addition of an alternate plug wrap. The plug wraps between the new and original products contain minimal differences in the additives that compose the plug wraps. In addition, there is no change in the perforation during manufacturing, meaning the plug wraps are non-porous in the original and new products. These minor differences are not expected to have a significant impact on product performance or HPHCs (e.g., tipping paper and filter tow), and is considered a minor modification. Finally, for EX0001389-PD1 and EX0001391-PD1, the applicant intends to delete the monogram ink (gold and blue) on the cigarette barrel which is a minor modification and this removal of the monogram ink is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products and may potentially decrease HPHC yields. Lastly, I find that an exemption for these modifications is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are grandfathered products; i.e., were commercially marketed in the United States as of February 15, 2007, or previously found SE and in compliance with the FD&C Act by FDA.

FDA has examined the environmental effects of finding these new products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA may be precluded or delayed from issuing an EX order.

An Environmental Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack sufficient market volume information for the original and new products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products as compared to the original products. Provide the current market volume for the original products and the first- and fifth-year projected market volume for the original products in the Table below.

Market Volume for the New and Corresponding Original Products

STN	Current Year	Projected Market Volume	
EX0001377 - PD1	(b) (4)		
Original Product to EX0001377 - PD1 (GF1501171)			
EX0001378 - PD1			
Original Product to EX0001378 - PD1 (GF1501171)			
EX0001379 - PD1			
Original Product to EX0001379 - PD1 (GF1501095)			
EX0001380 - PD1			
Original Product to EX0001380 - PD1 (GF1501173)			
EX0001381 - PD1			
Original Product to EX0001381 - PD1 (GF1501172)			
EX0001382 - PD1			
Original Product to EX0001382 - PD1 (GF1501170)			
EX0001387 - PD1			
Original Product to EX0001387 - PD1 (SE0000068) ⁴			
EX0001388 - PD1			(b) (4)
Original Product to EX0001388 - PD1 (SE0000067) ⁴			
EX0001389 - PD1		(b) (4)	
Original Product to EX0001389 - PD1 (GF1702758)			

(b) (4)

EX0001390 - PD1		(b) (4)	
Original Product to EX0001390 - PD1 (SE0000068) ⁴			
EX0001391 - PD1		(b) (4)	
Original Product to EX0001391 - PD1 (GF1702758) ⁵			
Total			

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new products in EX0001377-PD1 – EX0001382-PD1 and EX0001387-PD1 – EX0001391-PD1, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original products

Common Attributes of EX REQs		
Submission date	December 7, 2020 ¹ and December 18, 2020 ²	
Receipt date	December 7, 2020 ¹ and December 18, 2020 ²	
Applicant	R.J. Reynolds Tobacco Company	
Product manufacturer	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Product	Original Product
STN	EX0001377-PD1	GF1501171
Product name	Capri Menthol Jade Super Slim 100 Box	Capri Ultra Light Menthol 100s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	97 mm	97 mm
Diameter	5.4 mm	5.4 mm
Ventilation	64%	64%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	

Attributes	New Product	Original Product
STN	EX0001378 - PD1	GF1501174
Product name	Capri Violet Super Slim 100 Box	Capri Ultra Light 100s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	97 mm	97 mm
Diameter	5.4 mm	5.4 mm
Ventilation	67%	67%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	
STN	EX0001379-PD1	GF1501095
Product name	Capri Menthol Indigo Super Slim 120 Box	Capri Menthol 120s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	120 mm	120 mm
Diameter	5.4 mm	5.4 mm
Ventilation	40%	40%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	

Attributes	New Product	Original Product
STN	EX0001380-PD1	GF1501173
Product name	Capri Menthol Indigo Super Slim 100 Box	Capri Menthol 100s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	97 mm	97 mm
Diameter	5.4 mm	5.4 mm
Ventilation	49%	49%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	
STN	EX0001381-PD1	GF1801172
Product name	Capri Magenta Super Slim 120 Box	Capri 120s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	120 mm	120 mm
Diameter	5.4 mm	5.4 mm
Ventilation	42%	42%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	

Attributes	New Product	Original Product
STN	EX0001382-PD1	GF1501170
Product name	Capri Magenta Super Slim 100 Box	Capri Light 100s Box
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	97 mm	97 mm
Diameter	5.4 mm	5.4 mm
Ventilation	55%	55%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of filter tow (b) (4); target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4); target: (b) (4) mg/cigarette) 	
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 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) 	

Attributes	New Product	Original 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	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) (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) (b) (4) • Increasing the quantity of cork tipping paper (b) (4) 	

Attributes	New Product	Original 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	Addition/Deletion of tobacco additives: <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) • (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 Product	Original 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	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4); (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) 	

Attributes	New Product	Original 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	Addition/Deletion of tobacco additives: <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. Amendment Received for These Applications

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
March 5, 2021	March 5, 2021	EX0001389, EX0001391	Yes	Response to March 3, 2021, FDA Information Request