

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001213 – EX0001217
Common Attributes	
Submission date	July 10, 2020
Receipt date	July 10, 2020
Applicant	R.J. Reynolds Tobacco Company
Product manufacturer	R.J. Reynolds Tobacco Company
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
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: 2020.11.13 14:50:30 -05'00'

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: 2020.11.13 15:32:00 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

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

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewers	Review Date
regulatory	Crystal Caesar	7/15/2020
chemistry	Sandra Salido	10/30/2020
environmental science	Thomas Creaven	10/30/2020

2. COMPLIANCE REVIEW

The original tobacco products in EX0001213, EX0001215, and EX0001217 were determined to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence by FDA. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and at least 90 days have elapsed since receipt of the Abbreviated Reports by FDA. The original tobacco products in EX0001214 and EX0001216 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 tobacco products are eligible for modification under the Exemption Request pathway.¹

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (cork or white tipping paper) in EX0001213, EX0001214, and EX0001216
- adding an additive (cork tipping paper) in EX0001213, EX0001214, and EX0001216
- deleting an additive (filter tow) in EX0001213, EX0001215, and EX0001217
- adding an additive (filter tow) in EX0001213, EX0001215, and EX0001217
- deleting an additive (box container closure system) in EX0001215 and EX0001217
- adding an additive (soft pack container closure system) in EX0001215 and EX0001217

¹ 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.

- increasing the quantity of an existing additive (tipping paper adhesive) in EX0001216

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 tobacco products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on November 6, 2020. The FONSI was supported by an environmental assessment prepared by FDA on November 6, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are a minor modification of a tobacco 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 tobacco products to be marketed would be appropriate for the protection of the public health. The applicant proposes for EX0001213, EX0001214, and EX0001216 the deletion of white or cork tipping paper and the addition of a cork or alternate cork tipping paper is not expected to have any significant effects on product chemistry or consumer perception. For EX0001213, EX0001215, and EX0001217, 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 tobacco product. The filter tow in the new products for EX0001213 and EX0001217 includes a 20 - 23% decrease in (b) (4) whereas the new tobacco product ins EX0001215 includes a 20% increase in (b) (4) compared to the original product and possess the same amounts of (b) (4) or minimal changes (b) (4) mg/cig). 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. Additionally, for EX0001216, the deletion of the tipping paper adhesive in the original product in the new product is a minor modification. Because the tipping paper adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between 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 product relative to the original product. As TPL, I also find that the change in container closure system for EX0001215 and EX0001217 is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. Lastly, I find that an exemption for this modification 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 tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports or are previously found SE and in compliance with the FD&C Act by FDA.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco products in EX0001213 – EX0001217, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes of EX REQs		
Submission date	July 10, 2020	
Receipt date	July 10, 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	EX0001213	EX0000203
Product name	Newport Boost Gold Box	Camel Crush Rich
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	12/22/2017
Abbreviated report date	Not applicable	01/30/2018
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • 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 filter tow (b) (4)]; target: (b) (4) mg/cigarette) • Addition of filter tow (b) (4)]; target: (b) (4) mg/cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001214	SE0014763
Product name	Newport Boost Box	Camel Crush Smooth Menthol
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	12/21/2018
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) ; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4)]; target: (b) (4) mg/cigarette) 	
STN	EX0001215	EX0000521
Product name	Newport Menthol Gold 100s	Newport Menthol Gold Box 100s
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	06/28/2019
Abbreviated report date	Not applicable	09/06/2019
Package type	Soft Pack	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	22%	22%
Product 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 filter tow (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001216	SE0006134
Product name	Newport Boost Gold Box	Camel Crush
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	08/07/2019
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4)]; target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4)]; target: (b) (4) mg/cigarette) Increase/Decrease in the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of tipping paper adhesive (Henkel Corporation) 	
STN	EX0001217	EX0000278
Product name	Newport Menthol Gold 100s	Newport Menthol Gold Box 100s
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	12/03/2018
Abbreviated report date	Not applicable	05/17/2019
Package type	Soft Pack	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	22%	22%
Product 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 filter tow (b) (4)]; target: (b) (4) mg/cigarette) • Deletion of box container closure system • Addition of soft pack container closure system 	