

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19
Common Attributes	
Submission date	September 25, 2020
Receipt date	September 25, 2020
Applicant	Commonwealth Brands, Inc.
Product manufacturer	ITG Brands
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All EX Requests	(b)(4)
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 Jeannie H. Jeong-im -S
Date: 2021.01.25 10:41:33 -05'00'

Jeannie Jeong-Im, Ph.D.
Branch Chief, Chemistry Branch III
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.01.25 10:43:49 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND.....	3
1.1. NEW AND ORIGINAL TOBACCO PRODUCTS	3
1.2. REGULATORY ACTIVITY.....	3
1.3. SCOPE OF REVIEW.....	3
2. COMPLIANCE REVIEW.....	3
3. TOBACCO ADDITIVE MODIFICATION.....	4
4. SCIENTIFIC REVIEW.....	4
5. ENVIRONMENTAL DECISION.....	4
6. CONCLUSION AND RECOMMENDATION.....	4
7. APPENDIX	6

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 appendix for tobacco products.

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: Reviewer(s)	Review Date
regulatory	Maliha Choudhury	11/19/2020
chemistry	Jason Hsieh	12/18/2020
environmental science	Hermes Reyes Caballero	12/11/2020

2. COMPLIANCE REVIEW

The original tobacco products in EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19 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. A report under section 905(j)(1)(A)(ii) (Abbreviated Report) was submitted for each, and at least 90 days have elapsed since receipt of the Abbreviated Reports by FDA.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.¹

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.

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 (fire-standards compliant [FSC] cigarette paper (b)(4) in all EX Requests
- adding an additive (FSC cigarette paper (b)(4) in all EX Requests
- deleting an additive (tipping paper, (b)(4) in EX0001301-PD1 and EX0001301-PD3
- adding an additive (tipping paper, (b)(4) in EX0001301-PD1 and EX0001301-PD3
- deleting an additive (tipping paper, (b)(4) in EX0001301-PD5 and EX0001301-PD7
- adding an additive (tipping paper, (b)(4) in EX0001301-PD5 and EX0001301-PD7
- deleting an additive (tipping paper, (b)(4) in EX0001301-PD9 and EX0001301-PD11
- adding an additive (tipping paper, (b)(4) in EX0001301-PD9 and EX0001301-PD11
- deleting an additive (tipping paper, (b)(4) in EX0001301-PD13 and EX0001301-PD15
- adding an additive (tipping paper, (b)(4) in EX0001301-PD13 and EX0001301-PD15
- deleting an additive (tipping paper, (b)(4) in EX0001301-PD17 and EX0001301-PD19
- adding an additive (tipping paper, (b)(4) in EX0001301-PD17 and EX0001301-PD19

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 December 11, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 11, 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 intends to delete the original FSC cigarette paper and add an alternate FSC cigarette paper. There are minor differences (b)(4) /cigarette) in the levels of (b)(4) (b)(4) and other ingredients less than (b)(4) (b)(4) cigarette in the FSC cigarette paper between the new and original tobacco products. These differences are not expected to have a significant impact on the product performance or measurable effect on tobacco smoke. The applicant also proposed to delete the original tipping paper and add an alternate tipping paper. There are minor differences in the tipping paper that are less than (b)(4)/cigarette. Since the tipping papers, including printing ink, are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients are not expected to significantly alter the smoke chemistry nor affect consumer exposure to chemical constituents from the tipping paper. The applicant provided tar, nicotine, and carbon monoxide (TNCO) under both International Organization of Standardization (ISO) and Canadian Intense (CI) smoking regimens. Although HPHCs and TNCO are not needed to evaluate the modifications in these Exemptions Requests, FDA evaluated the submitted information and found that the TNCO data did not raise concerns. 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 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, an Abbreviated Report was submitted for each, and 90 days have elapsed since FDA receipt of the Abbreviated Reports.

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 EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19, as identified on the cover page of this review.

EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19

7. APPENDIX

Appendix A. New and original tobacco products

Common Attributes		
Submission date	September 25, 2020	
Receipt date	September 25, 2020	
Applicant	Commonwealth Brands, Inc.	
Product manufacturer	ITG Brands	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001301-PD1	EX0000550
Product name	USA Gold Blue 100s Box	USA Gold Blue 100s Box
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	47%	47%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of Fire Standards Compliant (FSC) cigarette paper (b)(4) Addition of FSC cigarette paper (b)(4) Deletion of tipping paper (b)(4) Addition of tipping paper (b)(4) 	
STN	EX0001301-PD3	EX0000551
Product name	USA Gold Blue 100s Soft Pack	USA Gold Blue 100s Soft Pack
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	47%	47%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of FSC cigarette paper (b)(4) Addition of FSC cigarette paper (b)(4) Deletion of tipping paper (b)(4) Addition of tipping paper (b)(4) 	
STN	EX0001301-PD5	EX0000555

EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19

Product name	USA Gold Menthol Dark Green 100s Box	USA Gold Menthol Dark Green 100s Box
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	6%	6%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD7	EX0000563
Product name	USA Gold Menthol Dark Green 100s Soft Pack	USA Gold Menthol Dark Green 100s Soft Pack
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	6%	6%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD9	EX0000556
Product name	USA Gold Menthol Green 100s Box	USA Gold Menthol Green 100s Box
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm

EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19

Ventilation	18%	18%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD11	EX0000557
Product name	USA Gold Menthol Green 100s Soft Pack	USA Gold Menthol Green 100s Soft Pack
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	18%	18%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD13	EX0000560
Product name	USA Gold Gold 100s Box	USA Gold Gold 100s Box
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	18%	18%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD15	EX0000561
Product name	USA Gold Gold 100s Soft Pack	USA Gold Gold 100s Soft Pack
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019

EX0001301-PD1, EX0001301-PD3, EX0001301-PD5, EX0001301-PD7, EX0001301-PD9, EX0001301-PD11, EX0001301-PD13, EX0001301-PD15, EX0001301-PD17, and EX0001301-PD19

Abbreviated report date	Not applicable	July 17, 2019
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	18%	18%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD17	EX0000567
Product name	USA Gold Red 100s Box	USA Gold Red 100s Box
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	6%	6%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	
STN	EX0001301-PD19	EX0000568
Product name	USA Gold Red 100s Soft Pack	USA Gold Red 100s Soft Pack
Eligibility status	Not applicable	Previously found Exempt
Marketing authorization date	Not applicable	July 9, 2019
Abbreviated report date	Not applicable	July 17, 2019
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.75 mm	7.75 mm
Ventilation	6%	6%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of tipping paper (b)(4) • Addition of tipping paper (b)(4) 	