

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000831 and EX0000833 – EX0000850**

EX0000831: USA Gold Blue 100s Box	
Length	99 mm
Diameter	7.75 mm
Ventilation	47%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000833: USA Gold Blue 100s Soft Pack	
Length	99 mm
Diameter	7.75 mm
Ventilation	47%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000834: USA Gold Red 100s Box	
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000835: USA Gold Red 100s Soft Pack	
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000836: USA Gold Red Kings Box	
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)

EX0000837: USA Gold Red Kings Soft Pack	
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000838: USA Gold Menthol Green 100s Soft Pack	
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000839: USA Gold Non-Filter Kings Soft Pack	
Length	83 mm
Diameter	7.86 mm
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000840: USA Gold Menthol Green Kings Soft Pack	
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000841: USA Gold Gold Kings Box	
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)

EX0000842: USA Gold Gold Kings Soft Pack	
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000843: USA Gold Menthol Dark Green 100s Box	
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000844: USA Gold Blue Kings Soft Pack	
Length	83 mm
Diameter	7.85 mm
Ventilation	47%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000845: USA Gold Gold 100s Box	
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000846: USA Gold Gold 100s Soft Pack	
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)

EX0000847: USA Gold Menthol Dark Green 100s Soft Pack	
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000848: USA Gold Menthol Dark Green Kings Box	
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000849: USA Gold Menthol Dark Green Kings Soft Pack	
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
EX0000850: USA Gold Menthol Green 100s Box	
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of side seam adhesive (b) (4) • Addition of side seam adhesive (b) (4)
Common Attributes of Exemption Requests	
Applicant	Commonwealth Brands, LLC
Product Category	Cigarette
Product Sub-Category	Combusted Filtered: EX0000831 – EX0000838 and EX0000840 – EX0000850 Combusted Non-Filtered: EX0000839
Package Quantity	20 cigarettes
Package Type	Box: EX0000831, EX0000834, EX0000836, EX0000841, EX0000843, EX0000845, EX0000848, and EX0000850 Soft Pack: EX0000833, EX0000835, EX0000837 – EX0000840, EX0000842, EX0000844, EX0000846, EX0000847, and EX0000849
Recommendation	
Issue Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.12.13 11:08:07 -05'00'

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

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.12.13 12:02:33 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000831: USA Gold Blue 100s Box	
Product Name	USA Gold Ultra Lights 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	47%
Characterizing Flavor	None
EX0000833: USA Gold Blue 100s Soft Pack	
Product Name	USA Gold Ultra Lights 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.75 mm
Ventilation	47%
Characterizing Flavor	None
EX0000834: USA Gold Red 100s Box	
Product Name	USA Gold Full Flavor 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	None
EX0000835: USA Gold Red 100s Soft Pack	
Product Name	USA Gold Full Flavor 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	None

EX0000836: USA Gold Red Kings Box	
Product Name	USA Gold Full Flavor Kings Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	None
EX0000837: USA Gold Red Kings Soft Pack	
Product Name	USA Gold Full Flavor Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	None
EX0000838: USA Gold Menthol Green 100s Soft Pack	
Product Name	USA Gold Menthol Lights 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	Menthol
EX0000839: USA Gold Non-Filter Kings Soft Pack	
Product Name	USA Gold Non-Filter Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.86 mm
Characterizing Flavor	None
EX0000840: USA Gold Menthol Green Kings Soft Pack	
Product Name	USA Gold Menthol Lights Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	Menthol

EX0000841: USA Gold Gold Kings Box	
Product Name	USA Gold Lights Kings Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	None
EX0000842: USA Gold Gold Kings Soft Pack	
Product Name	USA Gold Lights Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	None
EX0000843: USA Gold Menthol Dark Green 100s Box	
Product Name	USA Gold Menthol Full Flavor 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	Menthol
EX0000844: USA Gold Blue Kings Soft Pack	
Product Name	USA Gold Ultra Lights Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.85 mm
Ventilation	47%
Characterizing Flavor	None
EX0000845: USA Gold Gold 100s Box	
Product Name	USA Gold Lights 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	None

EX0000846: USA Gold Gold 100s Soft Pack	
Product Name	USA Gold Lights 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	None
EX0000847: USA Gold Menthol Dark Green 100s Soft Pack	
Product Name	USA Gold Full Flavor Menthol 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	Menthol
EX0000848: USA Gold Menthol Dark Green Kings Box	
Product Name	USA Gold Full Flavor Menthol Kings Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	Menthol
EX0000849: USA Gold Menthol Dark Green Kings Soft Pack	
Product Name	USA Gold Full Flavor Menthol Kings Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.85 mm
Ventilation	6%
Characterizing Flavor	Menthol
EX0000850: USA Gold Menthol Green 100s Box	
Product Name	USA Gold Menthol Light 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	18%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 5, 2019, FDA received Exemption Requests (EX0000831, EX0000833 – EX0000850) from Commonwealth Brands, Inc. FDA issued an Acceptance letter for these Exemption Requests on November 7, 2019. On November 14, 2019, FDA received a response to a request for information for EX0000833-EX0000835, EX0000837, EX0000838, EX0000841-EX0000844, EX0000846, EX0000847, EX0000849, and EX0000850 (EX0000855). On November 20, 2019, FDA received a response to a request for information for EX0000834, EX0000841, EX0000843, EX0000844, and EX0000850 (EX0000887).

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- Deletion of side seam adhesive (b) (4)
- Addition of side seam adhesive (b) (4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Megan Nguyen on November 7, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE reviews dated December 3, 2019, December 4, 2019 and December 6, 2019, conclude that the original tobacco products are grandfathered products. Therefore, the original 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.

4. SCIENTIFIC REVIEW

A scientific review was completed by Tianrong Cheng on December 13, 2019.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Side seam adhesive is used in the manufacturing of the original tobacco products and is an additive because the 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 modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The review determines that the deletion of side seam adhesive (b) (4) and the addition of an alternative side seam adhesive (b) (4) is a minor modification and the side seam adhesive in the new products are of similar composition compared to the corresponding original products, and are not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Bria Martin on November 26, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 2, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 2, 2019.

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- Deletion of side seam adhesive (b) (4)
- Addition of side seam adhesive (b) (4)

I concur with the conclusion of the scientific review that the modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines 'additive' as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I concur with the scientific review that that the deletion of side seam adhesive (b) (4) and addition of an alternative side seam adhesive (b) (4) is an addition/deletion of a tobacco additive. 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 protection of the public health. The review determines that the deletion of the side seam adhesive (b) (4) and the addition of an alternative side seam adhesive (b) (4) is a minor modification, and the side seam adhesive in the new products are of similar composition compared to the corresponding original products and are not expected to materially affect any other characteristics (materials, ingredients,

design, composition, heating source, or other features) of the tobacco products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications are 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 products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007).

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

An Exempt order letter should be issued for the new tobacco products in EX0000831 and EX0000833 – EX0000850 as identified on the cover page of this review.