

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000550 – EX0000568**

EX0000550: 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)
EX0000551: 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)
EX0000552: 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)
EX0000553: 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)
EX0000554: 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)

EX0000555: 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)
EX0000556: 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)
EX0000557: 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)
EX0000558: 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)
EX0000559: 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)

EX0000560: 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)
EX0000561: 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)
EX0000562: 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)
EX0000563: 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)
EX0000564: 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)

EX0000565: 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)
EX0000566: 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)
EX0000567: 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)
EX0000568: 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)
Common Attributes of Exemption Requests	
Applicant	Commonwealth Brands, LLC
Product Category	Cigarette
Product Sub-Category	Combusted Filtered: EX0000550 – EX0000558 and EX0000560 – EX0000568 Combusted Non-Filtered: EX0000559
Package Quantity	20 cigarettes
Package Type	Box: EX0000550, EX0000553, EX0000555, EX0000556, EX0000560, EX0000562, EX0000564, and EX0000567 Soft Pack: EX0000551, EX0000552, EX0000554, EX0000557, EX0000558, EX0000559, EX0000561, EX0000563, EX0000565, EX0000566, and EX0000568
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2019.07.08 18:35:07 -04'00'

For 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: 2019.07.09 06:13:53 -04'00'

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

EX0000550: 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
EX0000551: 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
EX0000552: 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
EX0000553: 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

EX0000554: 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
EX0000555: USA Gold Menthol Dark Green 100s Box	
Product Name	USA Gold Full Flavor Menthol 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.75 mm
Ventilation	6%
Characterizing Flavor	Menthol
EX0000556: 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
EX0000557: 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
EX0000558: 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

EX0000559: 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
EX0000560: 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
EX0000561: 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
EX0000562: 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
EX0000563: 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

EX0000564: 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
EX0000565: 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
EX0000566: 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
EX0000567: 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
EX0000568: 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

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 23, 2019, FDA received Exemption Requests (EX0000550 – EX0000568) from Commonwealth Brands, LLC. On May 30, 2019, FDA issued Acknowledgement letters to the applicant. On June 2, 2019, the Office of Compliance and Enforcement (OCE) sent a request for information to the applicant to clarify the commercially marketed date of the original products. In response, the applicant submitted an amendment EX0000607, received by FDA on June 7, 2019. On June 25, 2019, FDA received unsolicited amendments (EX0000641 – EX0000659) from the applicant that corrected spelling errors for original product names on the cover letters for EX0000552, EX0000555, EX0000558, and EX0000562.

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 Nicholas Hasbrouck and Megan Nguyen on May 30, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

OCE completed reviews 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 June 25, 2019, and June 26, 2019, conclude that the original tobacco products are grandfathered products.

4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Coraggio on July 8, 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 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 and of identical amounts (b) (4) mg per cigarette) compared to the corresponding original products and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on June 20, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 26, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 26, 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 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 tobacco products are of similar composition and of identical amounts (b) (4) mg per cigarette) compared to the corresponding original products, and are not expected to materially affect any other characteristic (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.

Exempt order letters should be issued for the new tobacco products in EX0000550 – EX0000568 as identified on the cover page of this review.