

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000905 – EX0000913**

EX0000905: Vantage Classic Silver Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	51%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b)(4) ; [(b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of white tipping paper (b)(4) ; [(b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow (b)(4) ; [(b)(4)]; target: (b)(4) mg/cigarette) • Addition of filter tow (b)(4) ; [(b)(4)]; target: (b)(4) mg/cigarette) • Deletion of filter center line adhesive (RJRT <i>In-House</i>) • Addition of filter center line adhesive (b)(4)
EX0000906: GPC Classic Red 100 Box	
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b)(4) ; [(b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of cork tipping paper ((b)(4) [(b)(4) MM]; target: (b)(4) mg/cigarette)
EX0000907: Camel Crush Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable Menthol Capsule in Filter
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper ((b)(4) [(b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of white tipping paper ((b)(4) [(b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow (b)(4) ; [(b)(4)]; target: (b)(4) mg/cigarette) • Addition of filter tow (b)(4) ; [(b)(4)]; target: (b)(4) mg/cigarette)

EX0000908: Vantage Classic Silver 100 Box	
Length	98 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b)(4) ; (b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of white tipping paper (b)(4) ; (b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow (b)(4) ; (b)(4)]; target: (b)(4) mg/cigarette) • Addition of filter tow (b)(4) ; (b)(4)]; target: (b)(4) mg/cigarette)
EX0000909: GPC Classic Gold 100 Box	
Length	98 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork tipping paper ((b)(4) ; (b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of cork tipping paper ((b)(4) (b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow ((b)(4) ; (b)(4)]; target: (b)(4) mg/cigarette) • Addition of filter tow ((b)(4) ; (b)(4)]; target: (b)(4) mg/cigarette) • Deletion of non-porous plug wrap (b)(4) ; (b)(4) MM (b)(4)]; target: (b)(4) mg/cigarette) • Addition of non-porous plug wrap ((b)(4) (b)(4) MM (b)(4)]; target: (b)(4) mg/cigarette)

EX0000910: GPC Classic Gold Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	29%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of cork tipping paper (b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow ((b)(4) ; (b)(4)); target; (b)(4) mg/cigarette) • Addition of filter tow (b)(4) ; (b)(4)]; target (b)(4) mg/cigarette) • Deletion of non-porous plug wrap (b)(4) MM(b)(4) target: (b)(4) mg/cigarette) • Addition of non-porous plug wrap ((b)(4) MM(b)(4)]; target: (b)(4) mg/cigarette)
EX0000911: Monarch Classic Gold Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	29%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper ((b)(4) MM]; target (b)(4) mg/cigarette) • Addition of white tipping paper (b)(4) MM]; target: (b)(4) mg/cigarette) • Deletion of filter tow (b)(4) ; (b)(4)]; target; (b)(4) mg/cigarette) • Addition of filter tow (b)(4) ; (b)(4)]; target: (b)(4) mg/cigarette) • Deletion of non-porous plug wrap (b)(4) MM(b)(4)]; target: (b)(4) mg/cigarette) • Addition of non-porous plug wrap (b)(4) MM(b)(4)]; target: (b)(4) mg/cigarette)
EX0000912: Monarch Classic Red Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	19%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b)(4) MM]; target: (b)(4) mg/cigarette) • Addition of cork tipping paper (b)(4) MM]; target: (b)(4) mg/cigarette)

EX0000913: Now Menthol Green 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	73%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping adhesive (b)(4) • Addition of tipping adhesive (b)(4)
Attributes of Exemption Requests	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 Cigarettes
Package Type	Box: EX0000905-EX0000912 Soft Pack: EX0000913
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.02.12 14:49:12 -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: 2020.02.12 15:58:46 -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

EX0000905: Vantage Classic Silver Box	
Product Name	Vantage Classic Silver
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	51%
Characterizing Flavor	None
EX0000906: GPC Classic Red 100 Box	
Product Name	Doral Classic Red 100
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	None
EX0000907: Camel Crush Box	
Product Name	Camel Crush
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable Menthol Capsule in Filter
EX0000908: Vantage Classic Silver 100 Box	
Product Name	Vantage Ultra Light 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None

EX0000909: GPC Classic Gold 100 Box	
Product Name	Doral Light 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	None
EX0000910: GPC Classic Gold Box	
Product Name	Doral Lights Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	29%
Characterizing Flavor	None
EX0000911: Monarch Classic Gold Box	
Product Name	Doral Lights Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	29%
Characterizing Flavor	None
EX0000912: Monarch Classic Red Box	
Product Name	Doral Classic Red
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	19%
Characterizing Flavor	None
EX0000913: Now Menthol Green 100 Soft Pack	
Product Name	Now Menthol Green 100 Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	73%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are previously found exempt¹ or grandfathered²

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 17, 2019, FDA received Exemption Requests (EX0000905-EX0000913) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter to the applicant on December 23, 2019.

1.3. SCOPE OF REVIEW

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

1.4. TOBACCO ADDITIVE MODIFICATIONS

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

- Deletion of white, cork, or cork-on-white tipping paper (b)(4) . or (b)(4) for EX0000905 – EX0000912
- Addition of white or cork tipping paper (b)(4) for EX0000905 – EX0000912
- Deletion of filter tow (b)(4) for EX0000905, and EX0000907 – EX0000911
- Addition of filter tow (b)(4) for EX0000905, and EX0000907 – EX0000911
- Deletion of non-porous plug wrap (b)(4) for EX0000909 – EX0000911
- Addition of non-porous plug wrap (b)(4) for EX0000909 – EX0000911
- Deletion of filter center line adhesive (RJRT *In-House*) for EX0000905
- Addition of filter center line adhesive (b)(4) for EX0000905
- Deletion of tipping paper adhesive (b)(4)) for EX0000913
- Addition of tipping paper adhesive (b)(4)) for EX0000913

2. REGULATORY REVIEW

Regulatory reviews were completed by Pin Zhang on December 23, 2019. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products in EX0000908-EX0000911 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 January 14, 2020, conclude that the original tobacco products are grandfathered products.

¹ For EX0000905- EX0000907 and EX0000912- EX0000913

² For EX0000908-EX0000911

The original tobacco products in EX0000905 and EX0000907 were determined by FDA under EX0000174 and EX0000204, respectively, 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; 90 days have elapsed since FDA receipt of Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports).

The original tobacco products in EX0000906, EX0000912, and EX0000913 were determined by FDA under EX0000765, EX0000764, and EX0000708, respectively, to be exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration of substantial equivalence; and Abbreviated Reports were received on December 10, 2019.

Therefore, the original products subject of EX0000905, EX0000907 and EX0000908 – EX0000911 are eligible for modification under the Exemption Request pathway³ while the original products subject of EX0000906, EX0000912, and EX0000913 are eligible for modification under the Exemption Request pathway once found exempt and 90 days after FDA receipt of the Abbreviated Reports, i.e., March 9, 2020.

4. SCIENTIFIC REVIEW

A scientific review was completed by Samantha Reilly on February 12, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Tipping paper (white, cork or cork-on-white),⁴ plug wrap,⁵ filter tow,⁶ filter center line adhesive,⁷ and tipping paper adhesive⁸ are used in the manufacturing of the original tobacco products, and 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. The review concludes, for EX0000905 – EX0000912, that the deletion of white, cork or cork-on-white tipping paper and the addition of an alternate white or cork tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. For EX0000909 – EX0000911, the review concludes that the deletion of plug wrap and the addition of an alternate plug wrap is a minor modification. The plug wraps between the new and original products contain minimal differences in the additives that compose the plug wraps. In addition, there was no change in the perforation during manufacturing, meaning the plug wraps are non-porous in the original and new tobacco products. Along with limited other additional additive changes that could impact product performance and HPHCs (e.g., tipping paper and filter tow), in this case, the review concludes that the change in plug wrap is a minor modification of a tobacco product. Furthermore, for EX0000905 and EX0000907 – EX0000911, the review concludes that the deletion of filter tow and the addition of an alternate filter tow is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design,

⁴ EX0000905 – EX0000912 only

⁵ EX0000909 – EX0000911 only

⁶ EX0000905 and EX0000907 – EX0000911 only

⁷ EX0000905 only

⁸ EX0000913 only

composition, heating source, or other features) of the tobacco products. The filter tow of the new products include a 17% decrease in (b)(4) compared to the original product and possess the same amounts of (b)(4). 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. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products. In addition, for EX0000905, the review concludes, the deletion of filter center line adhesive in the original product and the addition of an alternate filter center line adhesive in the new product is a minor modification. Because the filter centerline adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. For EX0000913, the review also concludes that the deletion of tipping paper adhesive in the original product and the addition of an alternate tipping paper adhesive 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.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on January 9, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 3, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 3, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of white, cork, or cork-on-white tipping paper (b)(4) . or (b)(4) .) for EX0000905 – EX0000912
- Addition of white or cork tipping paper (b)(4) for EX0000905 – EX0000912
- Deletion of filter tow (b)(4) for EX0000905, and EX0000907 – EX0000911
- Addition of filter tow (b)(4)) for EX0000905, and EX0000907 – EX0000911
- Deletion of non-porous plug wrap (b)(4) p.) for EX0000909 – EX0000911
- Addition of non-porous plug wrap (b)(4) for EX0000909 – EX0000911
- Deletion of filter center line adhesive (RJRT *In-House*) for EX0000905
- Addition of filter center line adhesive (b)(4)) for EX0000905
- Deletion of tipping paper adhesive (b)(4)) for EX0000913
- Addition of tipping paper adhesive (b)(4) for EX0000913

I concur with the conclusion of the scientific review that these modifications are minor modifications 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 changes represent the deletion of tobacco additives (tipping paper (white, cork, or white-on-cork),² plug wrap,³ filter tow,⁴ filter center line adhesive,⁵ and tipping paper adhesive⁶) and the addition of tobacco additives (tipping paper (white or cork),² plug wrap,³ filter tow,⁴ filter center line adhesive,⁵ and tipping paper adhesive⁶). 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. For EX0000905 – EX0000912, the applicant proposes the deletion of white, cork, or white-on-cork tipping paper and the addition of an alternate white or cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. For EX0000909 – EX0000911, 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 tobacco 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. For EX0000905, and EX0000907 – EX0000911, 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 products. The filter tow in the new products include a 17% decrease in (b)(4) compared to the original product and possess the same amounts of (b)(4) . 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. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. In addition, for EX0000905, the deletion of filter center line adhesive in the original product and the addition of an alternate filter center line adhesive in the new product is a minor modification. Because the filter centerline adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. Finally, for EX0000913, the deletion of tipping paper adhesive in the original product and the addition of an alternate tipping paper adhesive in the new product is a minor modification. Because the tipping paper adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, 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. 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.

Some of the original tobacco products are eligible for modification through the Exemption Request pathway because they are legally marketed in the United States. For EX0000908-EX0000911, the original products were found grandfathered. For EX0000905 and EX0000907, the original products were previously found Exempt by FDA and 90 days have elapsed since FDA receipt of the Abbreviated Reports. EX0000906, EX0000912, and EX0000913, the original products were previously found Exempt by FDA and Abbreviated Reports were received on December 10, 2019. Therefore, EX0000906, EX0000912, and EX0000913 are eligible for modification through the Exemption Request pathway when found exempt and 90 days after FDA receipt of the Abbreviated Reports, i.e., March 9, 2020.

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 EX0000905 - EX0000913 as identified on the cover page of this review.