

**Technical Project Lead (TPL) Review:
Exemption Request EX0000893-EX0000899**

EX0000893: Monarch Classic Menthol Soft Pack	
Length	83 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <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) • Deletion of box container closure system • Addition of soft pack container closure system
EX0000894: Monarch Classic Menthol Gold Soft Pack	
Length	83 mm
Diameter	7.8 mm
Ventilation	26%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Addition of white 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) • Deletion of box container closure system • Addition of soft pack container closure system
EX0000895: Camel Gold 100 Box	
Length	98 mm
Diameter	7.8 mm
Ventilation	38%
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) target: (b) (4) mg/cigarette) • Addition of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)

	<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))
EX0000896: Monarch Classic Menthol Gold 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	28%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of plug wrap (b) (4) target: (b) (4) mg/cigarette) • Addition of plug wrap (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)
EX0000897: Kamel Red Genuine Original Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	23%
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) 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)
EX0000898: Monarch Classic Menthol 100 Soft Pack	
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <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)

	<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
EX0000899: Kamel Red Genuine Smooth Taste Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
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) target: (b) (4) mg/cigarette) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette) • Deletion of plug wrap (b) (4) target: (b) (4) mg/cigarette) • Addition of plug wrap (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)
Common 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 (EX0000895, EX0000897, EX0000899) and Soft Pack (EX0000893, EX0000894, EX0000896, EX0000898)
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Todd L. Cecil -S Digitally signed by Todd L. Cecil -
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Date: 2020.04.13 07:28:41 -04'00'

Todd L. Cecil, Ph.D.
Associate 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: 2020.04.13 08:13:07 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND6

1.1. ORIGINAL TOBACCO PRODUCTS 6

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW..... 7

1.3. SCOPE OF REVIEW..... 7

1.4. TOBACCO ADDITIVE MODIFICATION..... 7

2. REGULATORY REVIEW8

3. COMPLIANCE REVIEW8

4. SCIENTIFIC REVIEW8

5. ENVIRONMENTAL DECISION.....9

6. CONCLUSION AND RECOMMENDATION9

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Product

EX0000893: Monarch Classic Menthol Soft Pack	
Product Name	Doral Full Flavor Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
EX0000894: Monarch Classic Menthol Gold Soft Pack	
Product Name	Doral Light Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	26%
Characterizing Flavor	Menthol
EX0000895: Camel Gold 100 Box	
Product Name	Camel Gold 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	38%
Characterizing Flavor	None
EX0000896: Monarch Classic Menthol Gold 100 Soft Pack	
Product Name	Doral Light Menthol 100s Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	28%
Characterizing Flavor	Menthol
EX0000897: Kamel Red Genuine Original Box	
Product Name	Red Kamel Originals Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm

Ventilation	23%
Characterizing Flavor	None
EX0000898: Monarch Classic Menthol 100 Soft Pack	
Product Name	Doral Full Flavor Menthol 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	17%
Characterizing Flavor	Menthol
EX0000899: Kamel Red Genuine Smooth Taste Box	
Product Name	Red Kamel Lights
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are previously found substantially equivalent¹ or grandfathered².

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 6, 2019, FDA received Exemption Requests (EX0000893-EX0000899) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance Letter to the applicant for these Exemption Requests on December 12, 2019.

1.3. SCOPE OF REVIEW

This memo 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 cork tipping paper (b) (4) (EX0000893, EX0000895 - EX0000898)
- Addition of cork tipping paper (b) (4) (EX0000893, EX0000895, EX0000897, EX0000898)
- Deletion of white tipping paper (b) (4) (EX0000894, EX0000899)

¹ EX0000895

² EX0000893-EX0000894 and EX0000896-EX0000899

- Addition of white tipping paper (b) (4) (EX0000894, EX0000896, EX0000899)
- Deletion of filter tow (b) (4) (EX0000893-EX0000899)
- Addition of filter tow (b) (4) (EX0000893-EX0000899)
- Deletion of plug wrap (b) (4) (EX0000896, EX0000899)
- Addition of plug wrap (b) (4) (EX0000896, EX0000899)
- Deletion of box container closure system (EX0000893-EX0000894, EX0000898)
- Addition of soft pack container closure system (EX0000893-EX0000894, EX0000898)

2. REGULATORY REVIEW

Regulatory reviews were completed by Jennifer Schmitz on December 12, 2019. The reviews conclude that these 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 EX0000893-EX0000894 and EX0000896-EX0000899 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 9, 2020 and January 10, 2020, conclude that the original tobacco products are grandfathered products.

The original tobacco product in EX0000895 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0013016.

Therefore, the original products are eligible for modification under the Exemption Request pathway.³

4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Corragio on February 4, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Tipping paper, plug wrap⁴ and filter tow used in the manufacturing of the original tobacco products, 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 scientific review concludes that the deletion of cork tipping paper and the addition of cork tipping paper is a minor modification. Further, deletion of cork tipping paper and the addition of white tipping paper and the deletion of white tipping paper and the addition of white tipping paper are minor modifications. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo and because the tipping paper is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these

³ 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 EX0000896, EX0000899

ingredients in the tipping paper are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. The review also concludes that the deletion of non-porous plug wrap and addition of an alternative non-porous plug wrap paper is a minor modification. The plug wrap used in the new and corresponding original tobacco products differ in small quantities of (b) (4) and (b) (4) that are not expected to cause a change in the function of the cigarette component. In addition, the plug wrap is not a combusted component of a cigarette. Replacing the plug wrap is unlikely to affect the smoke chemistry of the cigarette. Furthermore, the review concludes that, the deletion of filter tow and the addition of an alternative filter tow 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 differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the filter tow 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 products relative to the original tobacco products. Therefore, the collective modifications are a minor modification as defined under the requirements in section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Bria Martin on January 7, 2020, for EX0000895 and January 15, 2020, for EX0000893, EX0000894, and EX0000896-EX0000899.

For EX0000895, a finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 14, 2020. The FONSI was supported by an environmental assessment prepared by FDA on January 16, 2020.

For EX0000893, EX0000894, and EX0000896-EX0000899, the final environmental review found that the applicant did not provide the overall market volumes from concurrent marketing of the new and original tobacco products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or a FONSI.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of cork tipping paper (b) (4) (EX0000893, EX0000895 - EX0000898)
- Addition of cork tipping paper (b) (4) (EX0000893, EX0000895, EX0000897, EX0000898)
- Deletion of white tipping paper (b) (4) (EX0000894, EX0000899)

- Addition of white tipping paper (b) (4) (EX0000894, EX0000896, EX0000899)
- Deletion of filter tow (b) (4) (EX0000893-EX0000899)
- Addition of filter tow (b) (4) (EX0000893-EX0000899)
- Deletion of plug wrap (b) (4) (EX0000896, EX0000899)
- Addition of plug wrap (b) (4) (EX0000896, EX0000899)
- Deletion of box container closure system (EX0000893-EX0000894, EX0000898)

Addition of soft pack container closure system (EX0000893-EX0000894, EX0000898)

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 tipping paper, plug wrap⁴ and filter tow are additions/deletions of tobacco additives and/or increases/decreases of the quantity of existing tobacco additives. 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. I concur that the changes to the tipping paper from cork to cork, cork to white, and white to white are minor modifications. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo and because the tipping paper 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. I also agree with the conclusion of the scientific review that the deletion of non-porous plug wrap and addition of an alternative non-porous plug wrap paper is a minor modification. The plug wrap used in the new and corresponding original tobacco products differ in small quantities of (b) (4) and (b) (4) that are not expected to cause a change in the function of the cigarette component. In addition, the plug wrap is not a combusted component of a cigarette. Replacing the plug wrap is unlikely to affect the smoke chemistry of the cigarette. Additionally, I agree with the review’s conclusion that the deletion of filter tow and the addition of an alternative filter tow are minor modifications and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the corresponding original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. Based on information submitted by the applicant, there is an additional modification of a change in container closure system for some⁵ of the EX REQs, i.e., from box in the original products to soft packs in the new products. I find that the container closure systems in the original and new products meet the definition of ‘additive’ because the intended use of a container closure system 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. In addition, I find that this modification is minor because this modification does not affect the characteristics of the consumable portion of the tobacco products in this case, because a change in the container closure system for cigarettes is not expected to impact stability or HPHC yields when consumed. Lastly, FDA finds, based on the

⁵ EX0000893, EX0000894, and EX0000898

information contained in the Exemption Request 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 from Substantial Equivalence pathway because they can be legally marketed in the United States. The original products in EX0000893-EX0000894 and EX0000896-EX0000899 are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The original product in EX0000895 was determined to be substantially equivalent and in compliance with the FD&C Act by FDA under SE0013016.

For EX0000895, 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 product in EX0000895 as identified on the cover page of this review.

For EX0000893-EX0000894, and EX0000896-EX0000899, FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Environmental Information Request letter should be issued requesting the following information:

1. All of your EX REQs indicate that the original tobacco products will continue to be manufactured and marketed upon receiving marketing orders for the new tobacco products. The current market volumes of the original tobacco products, and the projected market volumes in the first and fifth years for the new tobacco products are included in your EX REQs. However, there is conflicting information regarding the overall market volumes from concurrent marketing of the new and original tobacco products.

Your EX REQs include statements indicating that "if the EX REQ for the new product is granted, the new product will replace current market volume" and "will replace some portion of the current in-market volume of the product." For the original tobacco products, provide the projected market volumes in the first year and the fifth year of marketing the new tobacco products. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. The information may be provided in Table 1.

Table 1. Original Tobacco Product Market Volumes and Projections		
Original Tobacco Product	Projections	
	First Year (# of Cigarettes)	Fifth Year (# of Cigarettes)
Doral Full Flavor Menthol Box		
Doral Light Menthol Box		
Doral Light Menthol 100s Soft Pack		
Red Kamel Originals Box		
Doral Full Flavor Menthol 100s Box		
Red Kamel Lights		

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000893-EX0000894, and EX0000896-EX0000899, as identified on the cover page of this review.