

**Technical Project Lead (TPL) Review:  
Exemption Request EX0000883-EX0000886**

EX0000883: Monarch Classic Gold 100 Soft Pack	
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"> <li>• Deletion of cork-on-white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cig)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cig)</li> <li>• Deletion of the box container closure system</li> <li>• Addition of a soft pack container closure system</li> </ul>
EX0000884: Monarch Classic Blue 100 Soft Pack	
Length	98 mm
Diameter	7.8 mm
Ventilation	59%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of alternate white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of the box container closure system</li> <li>• Addition of a soft pack container closure system</li> </ul>
EX0000885: Monarch Classic Red 100 Soft Pack	
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"> <li>• Deletion of cork-on-white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of alternate cork-on-white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> </ul>

	<ul style="list-style-type: none"> <li>• Deletion of the box container closure system</li> <li>• Addition of a soft pack container closure system</li> </ul>
<b>EX0000886: Pall Mall Vintage Gold 100 Soft Pack</b>	
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"> <li>• Deletion of cork-on-white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of alternate plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cig)</li> <li>• Addition of alternate filter tow (b) (4) target: (b) (4) mg/cig)</li> <li>• Deletion of the box container closure system</li> <li>• Addition of a soft pack container closure system</li> </ul>
<b>Common Attributes of Exemption Requests</b>	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 Cigarettes
Package Type	Soft Pack
<b>Recommendation</b>	
Issue an Exempt order letter.	

**Technical Project Lead (TPL):**

**Todd L. Cecil -S** Digitally signed by Todd L. Cecil  
-S  
Date: 2020.01.17 16:30:27 -05'00'

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 Glen D. Jones -S  
Date: 2020.01.21 16:04:37 -05'00'

For 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 Product**

<b>EX0000883: Monarch Classic Gold 100 Soft Pack</b>	
<b>EX0000886: Pall Mall Vintage Gold 100 Soft Pack</b>	
<b>Product Name</b>	Doral Light 100s Box
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.8 mm
<b>Ventilation</b>	34%
<b>Characterizing Flavor</b>	None
<b>EX0000884: Monarch Classic Blue 100 Soft Pack</b>	
<b>Product Name</b>	Doral Classic Silver 100
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.8 mm
<b>Ventilation</b>	59%
<b>Characterizing Flavor</b>	None
<b>EX0000885: Monarch Classic Red 100 Soft Pack</b>	
<b>Product Name</b>	Doral Classic Red 100
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.8 mm
<b>Ventilation</b>	17%
<b>Characterizing Flavor</b>	None

The applicant manufactures the original tobacco products and claims that they are previously found exempt<sup>1</sup> or grandfathered<sup>2</sup>.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 20, 2019, FDA received Exemption Requests (EX0000883-EX0000886) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On November 27, 2019, FDA held a teleconference with the applicant to request clarifying information regarding the submission of Abbreviated Reports for the original products subject of referenced in EX0000884 and EX0000885. On December 3, 2019, FDA received an amendment from the applicant with a statement that Abbreviated Reports had not yet been submitted and their intent to provide

<sup>1</sup> EX0000884 and EX0000885

<sup>2</sup> EX0000883 and EX0000886

Abbreviated Reports no later than December 31, 2019 (EX0000900). FDA issued an Acceptance Letter to the applicant for EX0000883 and EX0000886 on December 6, 2019, and EX0000884 and EX0000885 on December 27, 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-on-white tipping paper (b) (4) (EX0000883, EX0000886)
- Deletion of cork-on-white tipping paper (b) (4) (EX0000885)
- Addition of cork-on-white tipping paper (b) (4) (EX0000885)
- Deletion of white tipping paper (b) (4) (EX0000884)
- Addition of white tipping paper (b) (4) (EX0000883, EX0000884, EX0000886)
- Deletion of plug wrap (b) (4) (EX0000883, EX0000886)
- Addition of plug wrap (b) (4) (EX0000883, EX0000886)
- Deletion of filter tow (b) (4) (EX0000883, EX0000886)
- Addition of filter tow (b) (4) (EX0000883, EX0000886)
- Deletion of the box container closure system
- Addition of a soft pack container closure system

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Camille Hayslett on December 6, 2019 for EX0000883 and EX0000886; and on December 27, 2019 for EX0000884-EX0000885. 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 product in EX0000883 and EX0000886 is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated December 17, 2019, concludes that the original tobacco product is a grandfathered product.

The original tobacco products in EX0000884 and EX0000885 were determined by FDA under EX0000766 and EX0000765 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; and Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were received on December 10, 2019.

Therefore, the original products subject of EX0000883 and EX0000886 are eligible for modification under the Exemption Request pathway<sup>3</sup> while the original products subject of EX0000884 and EX0000885 are eligible for modification under the Exemption Request pathway on March 9, 2020, the date when 90 days will elapse since FDA receipt of the Abbreviated Reports.

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Jiu Ai on January 17, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Tipping paper, plug wrap<sup>2</sup> and filter tow<sup>2</sup> 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 modification 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 on white tipping paper and the addition of cork on white tipping paper is a minor modification. Further, deletion of cork on white 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 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 alternate non-porous plug wrap paper is a minor modification<sup>2</sup>. The plug wrap used in the new and corresponding original tobacco product differ in small quantities of (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 alternate 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<sup>2</sup>. 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 product relative to the original tobacco product. 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

1. An environmental review was completed by Dilip Venugopal on January 17, 2020. All of your EX Requests indicate that the original tobacco products will continue to be manufactured and

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<sup>3</sup> 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.

marketed after 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 Requests. However, the overall market volumes from concurrent marketing of the new tobacco products and the original tobacco products is unclear as there is conflicting information provided. Your EX Requests include both 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.” Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and predicate tobacco products. For the original tobacco products, provide the projected market volumes in the first and fifth years of marketing the new tobacco products. You may provide the information in Table 1.

<b>Table 1</b>			
<b>Original Tobacco Product Market Volumes</b>			
<b>Original Tobacco Product</b>	<b>Unit</b>	<b>First-Year Market Volume</b>	<b>Fifth-Year Market Volume</b>
Doral Classic Silver 100 (EX0000766)			
Doral Classic Red 100 (EX0000765)			
Doral Light 100s Box (GF1501289)			

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order letter should be issued for the new tobacco products in EX0000883 – EX0000886, as identified on the cover page of this review.