

**Technical Project Lead (TPL) Review of Exemption Requests:  
EX0000984 – EX0000987**

Common Attributes of EX Requests		
Applicant	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0000984	GF1501231
Product name	Vantage Classic 100 Soft Pack	Vantage 100s Soft Pack
Eligibility status	Not Applicable	Grandfathered
Marketing order date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	51%	51%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	

Tobacco Product	New	Original
Submission tracking number	EX0000985	GF1501230
Product name	Vantage Classic Soft Pack	Vantage King Soft Pack
Eligibility status	Not Applicable	Grandfathered
Marketing order date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package Type	Soft Pack	Soft Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	39%	39%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of cork tipping (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	
Tobacco Product	New	Original
Submission tracking number	EX0000986	EX0000219
Product name	Vantage Classic Menthol 100 Soft Pack	Vantage Classic Menthol 100 Soft Pack
Eligibility status	Not Applicable	Previously found EX
Marketing order date	Not Applicable	June 18, 2018
Abbreviated report date	Not Applicable	August 6, 2018
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.9 mm	7.9 mm
Ventilation	45%	45%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	

Tobacco Product	New	Original
Submission tracking number	EX0000987	GF1501293
Product name	Vantage Classic Menthol Soft Pack	Vantage Menthol King Soft Pack
Eligibility status	Not Applicable	Grandfathered
Marketing order date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	39%	39%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of non-porous plug wrap (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	
<b>Recommendation</b>		
Issue Exempt (EX) order.		

**Technical Project Lead (TPL):**

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Date: 2020.03.17 11:59:09 -04'00'

Matthew J. Walters, Ph.D., MPH  
CDR, US 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: 2020.03.17 12:56:13 -04'00'

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

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## **1. BACKGROUND**

### **1.1. ORIGINAL TOBACCO PRODUCTS**

The original tobacco products are combusted, filtered cigarettes manufactured by the applicant as indicated on the cover page of this review.

### **1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

On February 11, 2020, FDA received Exemption Requests EX0000984 - EX0000987 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter on February 13, 2020.

### **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 modification compared to the corresponding original tobacco products:

- Deletion of cork tipping paper for EX0000984, EX0000985, and EX0000987
- Addition of cork tipping paper for EX0000984, EX0000985, and EX0000987
- Deletion of filter tow for EX0000984, EX0000985, and EX0000987
- Addition of filter tow for EX0000984, EX0000985, and EX0000987
- Deletion of non-porous plug wrap for all EX Requests
- Addition of non-porous plug wrap for all EX Requests

## **2. REGULATORY REVIEW**

Regulatory reviews were completed by Tacheka M. Bailey on February 13, 2020. The reviews conclude that the Exemption Requests are administratively complete.

## **3. COMPLIANCE REVIEW**

The Office of Compliance and Enforcement (OCE) completed a review for EX0000984, EX0000985, and EX0000987 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 review dated March 16, 2020 concludes that the original tobacco products are grandfathered products. The original tobacco product in EX0000986 was determined by FDA under EX0000219 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. A report under section 905(j)(1)(A)(ii) (Abbreviated Report) was submitted under AS0000058, and at least 90 days have elapsed since FDA receipt of the Abbreviated

Report . Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.<sup>1</sup>

#### 4. SCIENTIFIC REVIEW

A chemistry review was completed by Rachael Lerebours on March 9, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Tipping paper (cork),<sup>2</sup> plug wrap, and filter tow<sup>2</sup> 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 EX0000984, EX0000985, and EX0000987, that the deletion of cork tipping paper and the addition of an alternate 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 all EX Requests, 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 EX0000984, EX0000985, and EX0000987, 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. The filter tow of the new products include a 16% decrease in <sup>(b) (4)</sup> compared to the original product and possess the same amounts of <sup>(b) (4)</sup>. 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.

#### 5. ENVIRONMENTAL DECISION

An environmental review was completed by Bria Martin on March 3, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 12, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 12, 2020.

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<sup>1</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.

<sup>2</sup> EX0000984, EX0000985, and EX0000987 only

## 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of cork tipping paper for EX0000984, EX0000985, and EX0000987
- Addition of cork tipping paper for EX0000984, EX0000985, and EX0000987
- Deletion of filter tow for for EX0000984, EX0000985, and EX0000987
- Addition of filter tow for EX0000984, EX0000985, and EX0000987
- Deletion of non-porous plug wrap for all EX Requests
- Addition of non-porous plug wrap for all EX Requests

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 (cork),<sup>2</sup> plug wrap, and filter tow,<sup>2</sup>) and the addition of tobacco additives (tipping paper (cork),<sup>2</sup> plug wrap, and filter tow<sup>2</sup>). 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 EX0000984, EX0000985, and EX0000987, the applicant proposes the deletion of cork tipping paper and the addition of an alternate cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. For all EX Requests, 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 EX0000984, EX0000985, and EX0000987, 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 16% 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. 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 tobacco products for EX0000984, EX0000985, and EX0000987 are grandfathered products; i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007. Additionally, the original tobacco product for EX0000986 is previously found Exempt by FDA, an Abbreviated Report was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Report.

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

An exempt order should be issued for the new tobacco products in EX0000984 – EX0000987, as identified on the cover page of this review.