

**Technical Project Lead (TPL) Review:
Exemption Request EX0000219**

EX0000219: Vantage Classic Menthol 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	45%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4) • Deletion of cork-on-white tipping paper (b) (4) • Addition of alternate cork-on-white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4)
Attributes of Exemption Request	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Soft Pack
Recommendation	
Issue an Exempt order letter.	

¹ Fire Standards Compliant

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.06.18 10:22:08 -04'00'

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: 2018.06.18 12:22:12 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND4

1.1. ORIGINAL TOBACCO PRODUCT 4

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO 4

1.3. SCOPE OF MEMO 4

1.4. TOBACCO ADDITIVE MODIFICATION..... 4

2. REGULATORY REVIEW5

3. COMPLIANCE REVIEW5

4. SCIENTIFIC REVIEW5

5. ENVIRONMENTAL DECISION.....5

6. CONCLUSION AND RECOMMENDATION6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000219: Vantage Classic Menthol 100 Soft Pack	
Product Name	Vantage Menthol 100s Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	45%
Characterizing Flavor	Menthol
Additional Properties	<ul style="list-style-type: none"> • Non-FSC¹ cigarette paper (b) (4) • Cork-on-white tipping paper (b) (4) • Filter tow (b) (4)

The applicant manufactures the original tobacco product and claims that it is grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Request EX0000219 on April 27, 2018. FDA issued the applicant an Acknowledgement letter for this Exemption Request on May 2, 2018.

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of cork-on-white tipping paper (b) (4)
- Addition of alternate cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of alternate filter tow (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Crystal Caesar on May 2, 2018. The review concludes that the Exemption Request is 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 is legally marketed. The OCE review, dated May 29, 2018, concludes that the original tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). Therefore, the original product is eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A chemistry review was completed by Melis Coraggio on June 18, 2018. The review states that the new tobacco product has been modified by adding and deleting tobacco additives. The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new product is a minor modification because the benefit of using FSC paper to reduce cigarette-related household fires is anticipated to outweigh any potential increased health risks caused by the small increases in HPHC exposures that may occur from the use of the FSC paper (See July 17, 2017 toxicology memo.). The applicant also proposed the deletion of a cork-on-white tipping paper with the addition of an alternative cork-on-white tipping paper which is not expected to have any significant effects on product chemistry or consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change 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 product. The filter tow can influence the ventilation of a product, however, the ventilation of the new and original tobacco products remains the same at 45%. Thus, the review concludes that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 13, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 13, 2018.

² 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.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of cork-on-white tipping paper (b) (4)
- Addition of alternate cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of alternate filter tow (b) (4)

I concur with the scientific reviewer that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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 product to be marketed would be appropriate for the protection of public health. At this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation, etc.), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. Additionally, the applicant also proposed the deletion of cork-on-white tipping paper followed by the addition of an alternative cork-on-white tipping paper which is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change 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 product. The filter tow can influence the ventilation of a product, however, the ventilation of the new and original tobacco product remains the same at 45%. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, that an exemption for these modifications is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco product is eligible for modification through the exemption from Substantial Equivalence pathway because it can be legally marketed in the United States. The original product is a grandfathered product (i.e., was 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 product exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco product in EX0000219 as identified on the cover page of this review.