

**Technical Project Lead (TPL) Review:
Exemption Request EX0000825**

EX0000825: Camel Vintage North Star Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of cork tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of 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	Box
Recommendation	
Issue Exempt order letter.	

¹ FSC: Fire Standards Complaint

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.12.04 10:12:18 -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: 2019.12.04 13:44:14 -05'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000825: Camel Vintage North Star Box	
Product Name	Marshall McGearty North Star
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 30, 2019, FDA received an exemption request (EX0000825) from RAI Services Company, submitted on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter on October 31, 2019. On November 5, 2019, FDA received amendments (EX0000829 and EX0000830) following Office of Compliance and Enforcement's (OCE) request for information for predicate eligibility determination. The amendments contained notice of a clerical error within the original application and correction to the characterizing flavor of the original and new tobacco products.

1.3. SCOPE OF REVIEW

This review captures all regulatory, 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 tipping paper (b) (4)
- Addition of cork tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Jennifer Schmitz on October 31, 2019. 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 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 November 25, 2019, concludes that the original tobacco product is a grandfathered product. Therefore, the original product is eligible for modifications under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on November 20, 2019.

The review states that the new tobacco product has been modified by adding or deleting tobacco additives. Cigarette paper, tipping paper, and filter tow are used in the manufacturing of the original tobacco product 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 product. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). 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. The change from non-FSC to FSC cigarette paper may result in increased harmful and potentially harmful constituents (HPHC) yields; however, the reduction in 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 the FSC cigarette paper, as outlined in the July 17, 2017, toxicology memo. The review also concludes that the deletion of cork tipping paper and the addition of cork tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the

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.

May 16, 2017, social science memo. Finally, 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 product. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation remains the same when comparing the new and original tobacco product.

5. ENVIRONMENTAL DECISION

Environmental review was completed by Ronald Edwards on November 20, 2019³.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 25, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 25, 2019.

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 tipping paper (b) (4)
- Addition of cork tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)

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 (non-FSC cigarette paper, cork tipping paper, and filter tow), and the addition of tobacco additives (FSC cigarette paper, alternate filter tow, and cork tipping paper). 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 protection of the 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 tobacco blend, design parameters such as ventilation), 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

³ An addendum review was completed on December 2, 2019, to correct an error in the conclusion. The addendum review does not change the conclusion of the Environmental review dated November 20, 2019.

occur from the use of FSC paper. The applicant also proposed the deletion of cork tipping paper and the addition of cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. The review finally 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 product. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation of the new and original tobacco product remains the same. Lastly, FDA finds, based on the 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 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 modifications through the Exemption Request pathway because it is 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 EX0000825 as identified on the cover page of this review.