



Technical Project Lead (TPL) Review: Exemption Request EX0000174

EX0000174: Vantage Silver	
Length	83 mm
Diameter	7.8 mm
Filter Ventilation	51%
Characterizing Flavor	None
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
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	Hard Pack
Recommendation	
Issue an Exempt order letter.	

¹ Fire Standards Compliant

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.08.18 13:00:10 -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: 2017.08.18 13:13:06 -04'00'

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

EX0000174	
Product Name	Vantage Ultra Light Box
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.8 mm
Filter Ventilation	51%
Characterizing Flavor	None

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 EX0000174, on March 23, 2017. FDA issued the applicant an Acknowledgement letter for the Exemption Request on April 5, 2017 and an Advice/Information Request (A/I) letter for this Exemption Request on May 23, 2017. In response, the applicant submitted an amendment (EX0000179) to the Exemption Request.

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 modification compared to the original tobacco product:

- Substitution of non-FSC cigarette paper with FSC cigarette paper

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Jennifer Schmitz on April 5, 2017. 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 as of February 15, 2007). The OCE review dated April 21, 2017, concludes that the original tobacco product is a grandfathered product. Therefore, the original product is eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Jeffrey Ammann on August 18, 2017. The review concludes that the modification is a minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic (FD&C) Act. The review concludes the substitution of non-FSC cigarette paper to FSC cigarette paper is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased 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 14, 2017 toxicology memo.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 18, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 18, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- Substitution of non-FSC cigarette paper with FSC cigarette paper

I concur with the chemistry reviewer that the substitution of non-FSC cigarette paper with FSC cigarette paper adds and deletes a tobacco additive to the new product. I also concur that this modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. In addition, it is my conclusion and 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

² Any tobacco product that can be sold under the FD&C Act (i.e., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

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. Thus, the modification proposed in this Exemption Request 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 meets statutory requirements 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 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 EX0000174 as identified on the cover page of this review.