

**Technical Project Lead (TPL) Review:
Exemption Request EX0000207**

EX0000207: Kent III Silver Soft Pack	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	52%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of a complex purchased flavor (b) (4) • Deletion of tipping paper (b) (4) • Addition of tipping paper (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing quantity of glycerin • Increasing quantity of water
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	Soft Pack
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.01.16 09:46:09 -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: 2018.01.16 13:51:05 -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

EX0000207	
Product Name	Kent III Ultra Lights Kings
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	52%
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 EX0000207 on November 22, 2017. FDA issued the applicant an Acknowledgement letter for this Exemption Request on November 30, 2017.

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 a complex purchased flavor (b) (4)
- Increasing quantities of existing tobacco additives (glycerin and water)
- Deletion of tipping paper (b) (4) offline)
- Addition of tipping paper (b) (4) online)

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Lea Lakes on November 30, 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 legally marketed. The OCE review, dated December 28, 2017, 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.¹

4. SCIENTIFIC REVIEW

A chemistry review was completed by Selena Russell on January 16, 2018. The review states that the new tobacco product has been modified by adding and deleting tobacco additives and increasing the quantities of existing tobacco additives. These substances, used in the manufacturing of the original tobacco product, are additives because their intended use is expected to result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of the tobacco product. [REDACTED] is removed in the new product and this is accompanied by minor increases in glycerin and water. The removal of [REDACTED], along with minor increases in glycerin and water, is not expected to materially affect the product's composition or HPHC yields, thus these modifications are minor. Additionally, the applicant replaced the [REDACTED] [REDACTED] tipping paper of the original product with a [REDACTED] tipping paper that contained the same quantities of ingredients and inks. The characteristics of the new tipping paper, including filter ventilation, are the same as the tipping paper in the original product. The difference in the tipping paper is that in the original tobacco product the tipping paper was [REDACTED] while the tipping paper for the new tobacco product was [REDACTED] during the manufacturing process. This is a more modern method of achieving ventilation on current-day cigarette making equipment and does not have significant effects on product chemistry. Given that there is no difference in ventilation between the original and new tobacco product, the change in tipping paper is not expected to have a significant impact on HPHC yields. 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 January 12, 2018. The FONSI was supported by an environmental assessment prepared by FDA on January 12, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of a complex purchased flavor [REDACTED] (b) (4)
- Increasing quantities of existing tobacco additives (glycerin and water)

¹ 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.

- Deletion of tipping paper ([REDACTED] offline)
- Addition of tipping paper ([REDACTED] online)

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 characteristics 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 chemistry reviewer that the deletion of the complex purchased [REDACTED] with minor increases in glycerin and water adds and deletes tobacco additives to the new product and increases quantities of existing tobacco additives. Additionally, I concur that the deletion of one tipping paper for another tipping paper with the same quantities of ingredients and inks adds and deletes a tobacco additive to the new product.

The removal of [REDACTED] is accompanied by minor increases in glycerin and water. The removal of [REDACTED] along with minor increases in glycerin and water, is not expected to materially affect the product’s composition or HPHC yields, thus I agree with the chemistry review that this modification is a minor modification of the original tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features). Furthermore, I agree with the chemistry review that the replacement of the tipping paper with another tipping paper that contains the same quantities of ingredients and inks is a minor modification and I find that it is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product including HPHC yields. The difference in the tipping paper is that the original tobacco product contained tipping paper that was [REDACTED] while the tipping paper for the new tobacco product was [REDACTED] during the manufacturing process. This is a more modern method of achieving ventilation on current-day cigarette making equipment while maintaining the same ventilation [REDACTED] between the original and new tobacco product. Given that there is no difference in ventilation between the original and new tobacco product, the modification is not expected to have a significant impact on HPHC yields. Thus, I also concur with the chemistry 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. In addition, it is my conclusion that, 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 (see section 905(j)(3)(A)(ii) of the FD&C Act) and 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 for modification through the exemption from substantial equivalence 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 as of February 15, 2007).

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

An exempt order letter should be issued for the new tobacco product in EX0000207 as identified on the cover page of this review.