

**Technical Project Lead (TPL) Review:
Exemption Request EX0000193 – EX0000196, EX0000198 –
EX0000200**

EX0000193: True Blue 100	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	54.0 %
Characterizing Flavor	None
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} and increase in quantity of tobacco additives (glycerin and water in the casing)
EX0000194: True Menthol Green 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	54.0 %
Characterizing Flavor	Menthol
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} and increase in quantity of tobacco additives (glycerin and water in the casing)
EX0000195: True Blue Soft Pack	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	None
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} and increase in quantity of tobacco additives (glycerin and water in the casing)
EX0000196: True Blue	
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	None
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} and increase in quantity of tobacco additives (glycerin and water in the casing)
EX0000198: True Blue 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	54.0 %
Characterizing Flavor	None
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} and increase in quantity of tobacco additives (glycerin and water in the casing)

EX0000199: True Menthol Green Soft Pack	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	Menthol
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} [REDACTED] and increase in quantity of tobacco additives (glycerin and water in the casing)
EX0000200: Kent III Silver 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	55.0 %
Characterizing Flavor	None
Product Modifications	Deletion/Increase of tobacco additives: deletion of a tobacco additive (Casing Flavor ^{(b) (4)} [REDACTED] and increase in quantity of tobacco additives (glycerin and water in the casing)
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	Box: EX0000193 and EX0000196 Soft Pack: EX0000194, EX0000195 and EX0000198 – EX0000200
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.11.29 09:11:10 -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: 2017.11.29 09:17:17 -05'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Product

EX0000193	
Product Name	True Box 100s
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	54.0 %
Characterizing Flavor	None
EX0000194	
Product Name	True Menthol 100s
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	54.0 %
Characterizing Flavor	Menthol
EX0000195	
Product Name	True Kings
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	None
EX0000196	
Product Name	True Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	None

EX0000198	
Product Name	True 100s
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	54.0 %
Characterizing Flavor	None
EX0000199	
Product Name	True Menthol Kings
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	61.0 %
Characterizing Flavor	Menthol
EX0000200	
Product Name	Kent III Ultra Lights 100s
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	55.0 %
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Requests EX0000193 – EX0000196, and EX0000198 – EX0000200 on September 29, 2017. FDA issued an Acknowledgement letter for these Exemption Requests on October 6, 2017.

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

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

- Deletion of Casing Flavor (b) (4) and increased quantity of two existing tobacco additives (glycerin and water)

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Nia White on October 6, 2017. The review concludes that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products are legally marketed. The OCE reviews, dated November 9, 2017, conclude 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). Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A chemistry review was completed by Changyu Chae on November 28, 2017. The review concludes that the proposed new tobacco product have been modified by adding or deleting tobacco additives or increasing or decreasing the quantity of an existing tobacco additive. The review also concludes that the modifications are a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. This is because the removal of Casing Flavor (b) (4) along with minor increases in glycerin and water are not expected to materially affect the product's composition or HPHC yields.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 28, 2017. The FONSI was supported by an environmental assessment prepared by FDA on November 28, 2017.

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.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of a tobacco additive and increase in quantity of tobacco additives: deletion of Casing Flavor (b) (4) and increased quantities of two existing tobacco additives (glycerin and water)

I concur with the chemistry reviewer that the removal of the complex ingredient Casing Flavor (b) (4) with an increase in two existing tobacco additives (glycerin and water) deletes a tobacco additive and increases the quantities of tobacco additives in the new tobacco products. 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), . . .” Casing Flavor (b) (4) glycerin and water are ingredients used in the manufacture of the original tobacco products, and thus are additives. I also concur that these modifications are a minor modification of the original tobacco products in accordance with section 905(j)(3)(A)(i) of the FD&C Act. This is because these modifications are not expected to have a significant impact on the original tobacco products’ composition or HPHC yields. Further, the removal of the complex ingredient - Casing Flavor (b) (4) - and increasing the quantities of glycerin and water do not create any toxicological or other concerns because these changes are not expected to materially affect the products’ composition or HPHC yields. Accordingly, SE Reports are not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health (section 905(j)(3)(A)(ii) of the FD&C Act). Additionally, for these same reasons, an exemption is 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 meet statutory requirements for modification through the exemption from substantial equivalence pathway because they are legally marketed in the United States. The original products are grandfathered products (i.e., were 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.

Exempt order letters should be issued for the new tobacco product in EX0000193 – EX0000196 and EX0000198 – EX0000200 as identified on the cover page of this review.