

Technical Project Lead (TPL) Review:
Exemption Requests EX0000721 – EX0000725

| EX0000721: Kent Classic Soft Pack | |
|---------------------------------------|--|
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 33% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of FSC¹ cigarette paper (b) (4) (b) (4) target: (b) mg/cig Addition of alternate FSC cigarette paper (b) (4) (b) (4) target: (b) mg/cig Deletion of printed monogram ink (blue) on cigarette barrel |
| EX0000722: Kent Classic 100 Soft Pack | |
| Length | 99 mm |
| Diameter | 7.9 mm |
| Ventilation | 32% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of FSC cigarette paper (b) (4) (b) (4) target: (b) mg/cig Addition of FSC cigarette paper (b) (4) (b) (4) target: (b) mg/cig Deletion of filter tow (b) (4) target: (b) mg/cig Addition of filter tow (b) (4) target: (b) mg/cig Deletion of printed monogram ink (blue) on cigarette barrel |

¹ FSC: Fire Standard Compliant

| EX0000723: Kent Classic 100 Soft Pack | |
|---|--|
| Length | 99 mm |
| Diameter | 7.9 mm |
| Ventilation | 32% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4) ; (b) (4) ; target: (b) mg/cig) • Addition of FSC cigarette paper (b) (4) ; (b) (4) target: (b) mg/cig) • Deletion of printed monogram ink (blue) on cigarette barrel |
| EX0000724: Kent Classic Soft Pack | |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 33% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4) ; (b) (4) ; target: (b) mg/cig) • Addition of FSC cigarette paper (b) (4) ; (b) (4) target: (b) mg/cig) • Deletion of filter tow (b) (4) target: (b) mg/cig) • Addition of filter tow (b) (4) target: (b) mg/cig) • Deletion of printed monogram ink (blue) on cigarette barrel |
| EX0000725: Camel Gold | |
| Length | 83 mm |
| Diameter | 7.8 mm |
| Ventilation | 29% |
| Characterizing Flavor | None |
| Product Modifications | <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cig) • Addition of cork tipping paper (b) (4) target: (b) (4) mg/cig) • Deletion of filter tow (b) (4) ; target: (b) mg/cig)² • Addition of filter tow (b) (4) target: (b) mg/cig) |
| 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: EX0000721 – EX0000724 Box: EX0000725 |

² The chemistry review dated September 9, 2019 had a typo in the target value and should be (b) mg/cig as reported in this TPL review.

Recommendation

Issue Exempt order letters.

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.09.13 09:05:20 -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: 2019.09.13 09:44:21 -04'00'

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 Products

| EX0000721: Kent Classic Soft Pack | |
|--|---------------|
| Product Name | Kent Kings |
| Package Type | Soft Pack |
| Package Quantity | 20 Cigarettes |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 33% |
| Characterizing Flavor | None |
| EX0000722: Kent Classic 100 Soft Pack | |
| Product Name | Kent 100s |
| Package Type | Soft Pack |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.9 mm |
| Ventilation | 32% |
| Characterizing Flavor | None |
| EX0000723: Kent Classic 100 Soft Pack | |
| Product Name | Kent 100s |
| Package Type | Soft Pack |
| Package Quantity | 20 Cigarettes |
| Length | 99 mm |
| Diameter | 7.9 mm |
| Ventilation | 32% |
| Characterizing Flavor | None |
| EX0000724: Kent Classic Soft Pack | |
| Product Name | Kent Kings |
| Package Type | Soft Pack |
| Package Quantity | 20 Cigarettes |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 33% |
| Characterizing Flavor | None |

| EX0000725: Camel Gold | |
|------------------------------|---------------|
| Product Name | Camel Gold |
| Package Type | Box |
| Package Quantity | 20 Cigarettes |
| Length | 83 mm |
| Diameter | 7.8 mm |
| Ventilation | 29% |
| Characterizing Flavor | None |

The applicant manufactures the original tobacco products and claims that they are previously found substantially equivalent (SE0002164 for EX0000721 and EX0000724; and SE0002159 for EX0000722 and EX0000723 on April 4, 2019; and SE0013007 for EX0000725 on June 16, 2016).

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 31, 2019, FDA received Exemption Requests (EX0000721-EX0000725) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On August 8, 2019, FDA issued an Acknowledgment letter to the applicant.

1.3. SCOPE OF REVIEW

This review captures all regulatory, 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 FSC cigarette paper (b) (4) for EX0000721 – EX0000724
- Addition of FSC cigarette paper (b) (4) for EX0000721 – EX0000724
- Deletion of filter tow (b) (4) for EX0000722, EX0000724, and EX0000725
- Addition of filter tow (b) (4) for EX0000722, EX0000724, and EX0000725
- Deletion of cork tipping paper (b) (4) for EX0000725
- Addition of cork tipping paper (b) (4) for EX0000725
- Deletion of printed monogram ink (blue) on cigarette barrel for EX0000721 – EX0000724

2. REGULATORY REVIEW

Regulatory reviews were completed by Nia White on August 7, 2019. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000721-EX0000725 were previously determined to be substantially equivalent. Additionally, the original tobacco product for EX0000725 is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA as shown in the table below.

| EX Request | Original Tobacco Product | Original Tobacco Product Found SE Under: | Date |
|------------------------|--------------------------|--|---------------|
| EX0000721 EX0000724 | Kent Kings | SE0002164 | April 4, 2019 |
| EX0000722 EX0000723 | Kent 100s | SE0002159 | April 4, 2019 |
| EX0000725 | Camel Gold | SE0013007 | June 16, 2016 |

Therefore, the original products are eligible for modifications under the Exemption Request pathway³.

4. SCIENTIFIC REVIEW

A scientific review was completed by Karina Zuck on September 9, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper,⁴ tipping paper,⁵ filter tow,⁶ and monogram ink² are used in the manufacturing of the original tobacco products, 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 products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. For EX0000721 – EX0000724, the review concludes the substitution of an original FSC cigarette paper with an alternative FSC cigarette paper is a minor modification. The differences in the quantity of (b) (4) and (b) (4) in the FSC cigarette paper between the new and original tobacco products are very minor. These minor quantity differences are not expected to have a significant impact on the product performance or HPHC yields. The review also concludes for EX0000725 only that the deletion of cork tipping paper and the addition of an alternate cork tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, for EX0000721 - EX0000724, the review concludes that the deletion of monogram ink (blue) on the cigarette barrel is a minor modification and this removal of the monogram ink is not expected to materially affect any other characteristic (i.e., materials, ingredients, design, composition, heating source, or other features) of the tobacco products and may potentially decrease HPHC yields. Finally, for EX0000722, EX0000724, and EX0000725, the review concludes that the deletion of filter tow and the addition of an alternative filter tow is a minor modification and is not expected to materially affect any other characteristic (i.e., materials, ingredients, design, composition, heating

³ 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.

⁴ EX0000721 – EX0000724 only

⁵ EX0000725 only

⁶ EX0000722, EX0000724, and EX0000725 only

source, or other features) of the tobacco products. The filter tow can influence the ventilation of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on September 3, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 12, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 11, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of FSC cigarette paper (b) (4) for EX0000721 – EX0000724
- Addition of FSC cigarette paper (b) (4) for EX0000721 – EX0000724
- Deletion of filter tow (b) (4) for EX0000722, EX0000724, and EX0000725
- Addition of filter tow (b) (4) for EX0000722, EX0000724, and EX0000725
- Deletion of cork tipping paper (b) (4) for EX0000725
- Addition of cork tipping paper (b) (4) for EX0000725
- Deletion of printed monogram ink (blue) on cigarette barrel for EX0000721 – EX0000724

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 (FSC cigarette paper,³ cork tipping paper,⁴ filter tow,⁵ and monogram ink on cigarette barrel³), and the addition of tobacco additives (alternate FSC cigarette paper,³ alternative filter tow,⁵ and cork tipping paper⁴). 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 products to be marketed would be appropriate for protection of the public health. For EX0000721 – EX0000724, the substitution of an original FSC cigarette paper with an alternative FSC cigarette paper is a minor modification. The differences in quantity of (b) (4) (b) (4) and (b) (4) in the FSC cigarette paper between the new and original tobacco products are very minor. These minor quantity differences are not expected to have a significant impact on the product performance or HPHC yields. For EX000725 only, 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. Furthermore, the review concludes for EX0000721 – EX0000724 that the deletion of monogram ink (blue) on the cigarette

barrel is a minor modification and is not expected to materially affect any other characteristic (i.e., materials, ingredients, design, composition, heating source, or other features) of the tobacco products and may potentially decrease HPHC yields. The review finally concludes that for EX000722, EX0000724, and EX0000725, the deletion of filter tow and the addition of an alternative filter tow is a minor modification and is not expected to materially affect any other characteristic (i.e., materials, ingredients, design, composition, heating source, or other features) of the tobacco products. The filter tow can influence the ventilation of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. Lastly, FDA finds, based on the information contained in the Exemption Requests 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 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 are eligible for modifications through the Exemption Request pathway because they are legally marketed in the United States. The original tobacco products were previously found SE by FDA under SE0002164 for EX0000721 and EX0000724; under SE0002159 for EX0000722 and EX0000723; and under SE0013007 for EX0000725. Additionally, the original tobacco product in EX0000725 is in compliance with the FD&C Act.

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 products in EX0000721 - EX0000725 as identified on the cover page of this review.