Technical Project Lead (TPL) Review: Exemption Request EX0000189 – EX0000191

<table>
<thead>
<tr>
<th>EX0000189: Newport Kings</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>84 mm</td>
</tr>
<tr>
<td>Diameter</td>
<td>7.9 mm</td>
</tr>
<tr>
<td>Filter Ventilation</td>
<td>0.0%</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>Menthol</td>
</tr>
<tr>
<td>Product Modifications</td>
<td>Substitution/Removal of tobacco additives: substitution of original FSC cigarette paper with alternate FSC cigarette paper</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EX0000190: Newport Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
</tr>
<tr>
<td>Diameter</td>
</tr>
<tr>
<td>Filter Ventilation</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
</tr>
<tr>
<td>Product Modifications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EX0000191: Newport Box 100s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
</tr>
<tr>
<td>Diameter</td>
</tr>
<tr>
<td>Filter Ventilation</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
</tr>
<tr>
<td>Product Modifications</td>
</tr>
</tbody>
</table>

Common Attributes of Exemption Requests

<table>
<thead>
<tr>
<th>Applicant</th>
<th>R.J. Reynolds Tobacco Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Category</td>
<td>Cigarette</td>
</tr>
<tr>
<td>Product Sub-Category</td>
<td>Combusted Filtered</td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Package Type</td>
<td>Soft Pack: EX0000189 Box: EX0000190 and EX0000191</td>
</tr>
</tbody>
</table>

Recommendation

Issue an Exempt order letter.

1 Fire Standards Complaint
Technical Project Lead (TPL):

Matthew J. Walters -S
2017.10.13 14:35:53 -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: 2017.10.13 14:37:36 -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 Product

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Package Quantity</th>
<th>Package Type</th>
<th>Length</th>
<th>Diameter</th>
<th>Filter Ventilation</th>
<th>Characterizing Flavor</th>
</tr>
</thead>
<tbody>
<tr>
<td>New port Menthol Kings</td>
<td>20 cigarettes</td>
<td>Soft Pack</td>
<td>84 mm</td>
<td>7.9 mm</td>
<td>0%</td>
<td>Menthol</td>
</tr>
<tr>
<td>New port Menthol Box</td>
<td>20 cigarettes</td>
<td>Box</td>
<td>80 mm</td>
<td>7.9 mm</td>
<td>0%</td>
<td>Menthol</td>
</tr>
<tr>
<td>New port Menthol Box 100s</td>
<td>20 cigarettes</td>
<td>Box</td>
<td>99 mm</td>
<td>7.9 mm</td>
<td>0%</td>
<td>Menthol</td>
</tr>
</tbody>
</table>

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 EX0000189 – EX0000191 on August 7, 2017. FDA issued the applicant an Acknowledgement letter for these Exemption Requests on August 14, 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 modification compared to the corresponding tobacco product:

- Substitution of substitution of an original FSC cigarette paper with an alternate FSC cigarette paper

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Crystal Caesar on August 14, 2017. The review concludes that the Exemption Requests are 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, concludes that the original tobacco product is a grandfathered product. Therefore, the original September 14, 2017 product is eligible for modification under the Exemption Request pathway.2

4. SCIENTIFIC REVIEW

A scientific review was completed by Jikun Liu on October 10, 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 FD&C Act. The review concludes the substitution of an original FSC cigarette paper with an alternative FSC cigarette paper is a minor modification. The differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only difference in the base paper weight (e.g. \( b^{(4)}\)) between the two FSC cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 13, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 13, 2017.

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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.
6. CONCLUSION AND RECOMMENDATION

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

- Substitution of substitution of an original FSC cigarette paper with an alternate FSC cigarette paper

I concur with the chemistry reviewer that the substitution of an original FSC cigarette paper with an alternative 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. The differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only difference in the base paper weight (e.g. (b) (4)) between the two FSC cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields. 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 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 EX0000189 – EX0000191 as identified on the cover page of this review.