

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000863 – EX0000882**

<b>EX0000863: Native Menthol 100's Hard Pack (Green)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC<sup>1</sup> cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000864: Native Menthol 100's Soft (Green)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000865: Native Menthol King Soft (Green)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000866: Native Menthol King Hard Pack (Green)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>

<sup>1</sup> FSC: Fire Standards Compliant

<b>EX0000867: Native 100's Soft (Ultra)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000868: Native King Hard Pack (Ultra)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000869: Native King Hard Pack (Blue)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000870: Native King Soft (Ultra)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>

<b>EX0000871: Native King Soft (Blue)</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000872: Native 100's Hard Pack (Ultra)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000873: Native Menthol King Soft</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000874: Native Menthol King Hard Pack</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>

<b>EX0000875: Native Menthol 100's Soft</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000876: Native Menthol 100's Hard Pack</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000877: Native 100's Hard Pack (Blue)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000878: Native 100's Soft (Blue)</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>

<b>EX0000879: Native Full Flavor 100's Hard Pack</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000880: Native Full Flavor King Soft</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000881: Native Full Flavor King Hard Pack</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>
<b>EX0000882: Native Full Flavor 100's Soft</b>	
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC cigarette paper (b) (4)</li> <li>• Addition of FSC cigarette paper (b) (4)</li> </ul>

<b>Common Attributes of Exemption Requests</b>	
Applicant	Native Trading Associates, LLC
Product Category	Cigarettes
Product Sub-Category	Filtered Combusted
Package Quantity	20 Cigarettes
Package Type	Hard Pack: EX0000863, EX0000866, EX0000868, EX0000869, EX0000872, EX0000874, EX0000876, EX0000877, EX0000879, and EX0000881 Soft Pack: EX0000864, EX0000865, EX0000867, EX0000870, EX0000871, EX0000873, EX0000875, EX0000878, EX0000880, and EX0000882
<b>Recommendation</b>	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -5  
Date: 2020.01.06 16:04:18 -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 -5  
Date: 2020.01.06 16:52:20 -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 Products**

<b>EX0000863: Native Menthol 100's Hard Pack (Green)</b>	
<b>Product Name</b>	Native Menthol Lights 100's Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000864: Native Menthol 100's Soft (Green)</b>	
<b>Product Name</b>	Native Menthol Lights 100's Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000865: Native Menthol King Soft (Green)</b>	
<b>Product Name</b>	Native Menthol Lights King Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000866: Native Menthol King Hard Pack (Green)</b>	
<b>Product Name</b>	Native Menthol Lights King Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol



<b>EX0000867: Native 100's Soft (Ultra)</b>	
<b>Product Name</b>	Native Ultra Lights 100's Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>EX0000868: Native King Hard Pack (Ultra)</b>	
<b>Product Name</b>	Native Ultra Lights King Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>EX0000869: Native King Hard Pack (Blue)</b>	
<b>Product Name</b>	Native Lights King Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>EX0000870: Native King Soft (Ultra)</b>	
<b>Product Name</b>	Native Ultra Lights King Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>EX0000871: Native King Soft (Blue)</b>	
<b>Product Name</b>	Native Lights King Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None

<b>EX0000872: Native 100's Hard Pack (Ultra)</b>	
<b>Product Name</b>	Native Ultra Lights 100's Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>EX0000873: Native Menthol King Soft</b>	
<b>Product Name</b>	Native Menthol King Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000874: Native Menthol King Hard Pack</b>	
<b>Product Name</b>	Native Menthol King Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000875: Native Menthol 100's Soft</b>	
<b>Product Name</b>	Native Menthol 100's Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000876: Native Menthol 100's Hard Pack</b>	
<b>Product Name</b>	Native Menthol 100's Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	Menthol

<b>EX0000877: Native 100's Hard Pack (Blue)</b>	
<b>Product Name</b>	Native Lights 100's Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>EX0000878: Native 100's Soft (Blue)</b>	
<b>Product Name</b>	Native Lights 100's Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>EX0000879: Native Full Flavor 100's Hard Pack</b>	
<b>Product Name</b>	Native Full Flavor 100's Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>EX0000880: Native Full Flavor King Soft</b>	
<b>Product Name</b>	Native Full Flavor King Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None
<b>EX0000881: Native Full Flavor King Hard Pack</b>	
<b>Product Name</b>	Native Full Flavor King Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Hard Pack
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None

<b>EX0000882: Native Full Flavor 100's Soft</b>	
<b>Product Name</b>	Native Full Flavor 100's Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Soft Pack
<b>Length</b>	100 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	4%
<b>Characterizing Flavor</b>	None

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

### **1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

On November 19, 2019, FDA received Exemption Requests (EX0000863-EX0000882) from Troutman Sanders LLP on behalf of Native Trading Associates, LLC. On November 21, 2019, FDA held a teleconference with the applicant to request clarification on the company name and the name of the new tobacco product cigarette paper for EX0000872. On November 26, 2019, FDA issued an Acceptance letters to the applicant. On November 26, 2019, the Office of Compliance and Enforcement (OCE) requested additional information on the original tobacco products for EX0000865, EX0000871, EX0000873, and EX0000874. In response, the applicant submitted amendments (EX0000889, and EX0000891) on November 25, 2019 and December 2, 2019.

### **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 non-FSC cigarette paper
- Addition of FSC cigarette paper

## **2. REGULATORY REVIEW**

Regulatory reviews were completed by Kristopher Van Amburg on November 26, 2019. The reviews conclude 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 grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets as of February 15, 2007). The OCE reviews dated December 16, 2019 for EX0000863-EX0000867, EX0000876-EX0000880 and December 17, 2019 for EX0000868-EX0000875, EX0000881-EX0000882, conclude that the original tobacco product is a grandfathered product. Therefore, the original products are eligible for modification under the Exemption Request pathway.<sup>2</sup>

### 4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on January 6, 2020.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Cigarette paper is 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. The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new products 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

An environmental review was completed by Bria Martin on December 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 17, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 17, 2019.

### 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper

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.

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<sup>2</sup> 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.

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 deletion of non-FSC cigarette paper and the addition of FSC cigarette paper is an addition/deletion of a tobacco additive. 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. 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 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 cigarette 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 cigarette paper. 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 modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, 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 products in EX0000863 – EX0000882 as identified on the cover page of this review.