

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000374 – EX0000403**

<b>EX0000374: Smokin Joes Red 100 Box FSC</b>	
<b>Length</b>	99 mm
<b>Diameter</b>	7.91 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC<sup>1</sup> paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000375: Smokin Joes Red King Box FSC</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.91 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000376: Smokin Joes Gold 100 Box FSC</b>	
<b>Length</b>	99 mm
<b>Diameter</b>	7.91 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000377: Smokin Joes Gold King Box FSC</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.91 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000378: Smokin Joes Blue 100 Box FSC</b>	
<b>Length</b>	99 mm
<b>Diameter</b>	7.91 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

<sup>1</sup> Fire Standards Compliant

EX0000379: Smokin Joes Blue King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000380: Smokin Joes Menthol 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000381: Smokin Joes Menthol King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul>
EX0000382: Smokin Joes Menthol Gold 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000383: Smokin Joes Menthol Gold King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

EX0000384: Smokin Joes Non Filter King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	Not Applicable
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000385: SJ Natural Purple 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000386: SJ Natural Purple King Box FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul>
EX0000387: SJ Natural Red 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000388: SJ Natural Red King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

EX0000389: SJ Natural Silver 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000390: SJ Natural Silver King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000391: SJ Natural White 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000392: SJ Natural White King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000393: SJ Natural Menthol 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

EX0000394: SJ Natural Menthol King Box FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000395: SJ Natural Menthol Gold 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000396: SJ Natural Menthol Gold King Box FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000397: SJ Natural Non Filter King Soft Pack FSC	
Length	84 mm
Diameter	7.91 mm
Ventilation	Not Applicable
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
EX0000398: Smokin Joes Red 100 Soft Pack FSC	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

<b>EX0000399: Smokin Joes Red King Soft Pack FSC</b>	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000400: Smokin Joes Gold 100 Soft Pack FSC</b>	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000401: Smokin Joes Gold King Soft Pack FSC</b>	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000402: Smokin Joes Blue 100 Soft Pack FSC</b>	
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>
<b>EX0000403: SJ Natural Purple King Soft Pack FSC</b>	
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of non-FSC paper (b) (4)</li> <li>• Addition of FSC paper (b) (4)</li> </ul>

<b>Attributes of Exemption Requests</b>	
<b>Applicant</b>	Joseph Anderson DBA Smokin Joes
<b>Product Category</b>	Cigarette
<b>Product Sub-Category</b>	Combusted Filtered: EX0000374 – EX0000383, EX0000385 – EX0000396, and EX0000398 – EX0000403 Combusted Non-Filtered: EX0000384 and EX0000397
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box: EX0000374 – EX0000378, EX0000386, EX0000394, and EX0000396 Soft Pack: EX0000379 – EX0000385, EX0000387 – EX0000393, EX0000395, and EX0000397 – EX0000403
<b>Recommendation</b>	
Issue Exempt order letters.	

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2019.02.15 10:12:17 -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: 2019.02.15 11:26:23 -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>EX0000374: Smokin Joes Red 100 Box FSC</b>	
Product Name	Smokin Joes Full Flavor 100 Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000375: Smokin Joes Red King Box FSC</b>	
Product Name	Smokin Joes Full Flavor King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000376: Smokin Joes Gold 100 Box FSC</b>	
Product Name	Smokin Joes Light 100 Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000377: Smokin Joes Gold King Box FSC</b>	
Product Name	Smokin Joes Light King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None

<b>EX0000378: Smokin Joes Blue 100 Box FSC</b>	
Product Name	Smokin Joes Ultra Light 100 Box
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000379: Smokin Joes Blue King Soft Pack FSC</b>	
Product Name	Smokin Joes Ultra Light King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000380: Smokin Joes Menthol 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Menthol 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000381: Smokin Joes Menthol King Soft Pack FSC</b>	
Product Name	Smokin Joes Menthol King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000382: Smokin Joes Menthol Gold 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Menthol Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol

<b>EX0000383: Smokin Joes Menthol Gold King Soft Pack FSC</b>	
Product Name	Smokin Joes Menthol Light King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000384: Smokin Joes Non Filter King Soft Pack FSC</b>	
Product Name	Smokin Joes Non Filter King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	Not Applicable
Characterizing Flavor	None
<b>EX0000385: SJ Natural Purple 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Full Flavor 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000386: SJ Natural Purple King Box FSC</b>	
Product Name	Smokin Joes Natural Full Flavor King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000387: SJ Natural Red 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Medium 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None

<b>EX0000388: SJ Natural Red King Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Medium King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000389: SJ Natural Silver 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000390: SJ Natural Silver King Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Light King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000391: SJ Natural White 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Ultra Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000392: SJ Natural White King Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Ultra Light King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None

<b>EX0000393: SJ Natural Menthol 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Menthol 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000394: SJ Natural Menthol King Box FSC</b>	
Product Name	Smokin Joes Natural Menthol King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000395: SJ Natural Menthol Gold 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Menthol Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000396: SJ Natural Menthol Gold King Box FSC</b>	
Product Name	Smokin Joes Natural Menthol Light King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	Menthol
<b>EX0000397: SJ Natural Non Filter King Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Non Filter King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	Not Applicable
Characterizing Flavor	None

<b>EX0000398: Smokin Joes Red 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Full Flavor 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000399: Smokin Joes Red King Soft Pack FSC</b>	
Product Name	Smokin Joes Full Flavor King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000400: Smokin Joes Gold 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000401: Smokin Joes Gold King Soft Pack FSC</b>	
Product Name	Smokin Joes Light King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None
<b>EX0000402: Smokin Joes Blue 100 Soft Pack FSC</b>	
Product Name	Smokin Joes Ultra Light 100 Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None

<b>EX0000403: SJ Natural Purple King Soft Pack FSC</b>	
Product Name	Smokin Joes Natural Full Flavor King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.91 mm
Ventilation	0%
Characterizing Flavor	None

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

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 21, 2018, FDA received Exemption Requests EX0000374 – EX0000403 from Smokin Joes. On December 31, 2018, FDA issued Acknowledgement letters to the applicant. On January 17, 2019, FDA requested clarification on Environmental Assessment (EA) for Exemption Requests. On January 23, 2019 FDA received an amendment containing the information under EX0000423. On January 22, 2019, FDA requested additional information to complete grandfathered status review. On January 25, 2019, FDA received an amendment containing the information under EX0000428. On February 5, 2019, FDA requested additional information needed for the Office of Compliance and Enforcement to complete the review for EX0000394 and EX0000396. On February 8, 2019 FDA received an amendment containing the information under EX000451.

## 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 original tobacco products:

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC paper (b) (4)

## 2. REGULATORY REVIEW

Regulatory reviews were completed by James Lumalcuri on December 31, 2018. These 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 legally marketed. The OCE reviews, dated February 13, 2019, 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 products are eligible for modification under the Exemption Request pathway.<sup>2</sup>

### 4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Coraggio on February 6, 2019. The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper is used in the manufacturing of the original tobacco products, and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in its 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 17, 2017, toxicology memo.

### 5. ENVIRONMENTAL DECISION

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on January 24, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 13, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 13, 2019.

### 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC paper (b) (4)

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

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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.



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 modifications are the deletion of non-FSC cigarette paper and the addition of FSC cigarette paper. 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 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 paper. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP’s scientific understanding, that exemptions 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 products are grandfathered products (i.e., was 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.

Exempt order letters should be issued for the new tobacco products in EX0000374-EX0000403 as identified on the cover page of this review.