

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000538 – EX0000548**

EX0000538: Complete Full Flavor Deluxe 100s Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4) • Deletion of soft pack container closure system • Addition of hard pack container closure system
EX0000539: Complete Full Flavor Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)
EX0000540: Complete High Air Filter Deluxe 100s Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4) • Deletion of soft pack container closure system • Addition of hard pack container closure system
EX0000541: Complete High Air Filter Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Ventilation	35%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)

¹ FSC: Fire Standards Compliant

EX0000542: Complete Menthol Deluxe 100s Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4) • Deletion of soft pack container closure system • Addition of hard pack container closure system
EX0000543: Complete Menthol Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)
EX0000544: Complete Menthol High Air Filter Deluxe 100s Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4) • Deletion of soft pack container closure system • Addition of hard pack container closure system
EX0000545: Complete Menthol High Air Filter Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)

EX0000546: Complete Non-Filter Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)
EX0000547: Complete Ultra High Air Filter Deluxe 100s Box	
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4) • Deletion of soft pack container closure system • Addition of hard pack container closure system
EX0000548: Complete Ultra High Air Filter Deluxe Kings Box	
Length	84 mm
Diameter	7.9 mm
Ventilation	35%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target: (b)(4)
Common Attributes of Exemption Requests	
Applicant	Skookum Creek Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered: EX0000538 – EX0000545, EX0000547, and EX0000548 Combusted Non-Filtered: EX0000546
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.06.28 11:53:39 -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 Glen D. Jones -S
Date: 2019.06.28 11:57:48 -04'00'

For 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

EX0000538: Complete Full Flavor Deluxe 100s Box	
Product Name	Complete Full Flavor Deluxe 100s
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
EX0000539: Complete Full Flavor Deluxe Kings Box	
Product Name	Complete Full Flavor Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
EX0000540: Complete High Air Filter Deluxe 100s Box	
Product Name	Complete Lights Filter Deluxe 100s
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000541: Complete High Air Filter Deluxe Kings Box	
Product Name	Complete Lights Filter Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	35%
Characterizing Flavor	None

EX0000542: Complete Menthol Deluxe 100s Box	
Product Name	Complete Menthol Deluxe 100s
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000543: Complete Menthol Deluxe Kings Box	
Product Name	Complete Menthol Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000544: Complete Menthol High Air Filter Deluxe 100s Box	
Product Name	Complete Menthol Lights Filter Deluxe 100s
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	Menthol
EX0000545: Complete Menthol High Air Filter Deluxe Kings Box	
Product Name	Complete Menthol Lights Filter Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	Menthol
EX0000546: Complete Non-Filter Deluxe Kings Box	
Product Name	Complete Non-Filter Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Characterizing Flavor	None

EX0000547: Complete Ultra High Air Filter Deluxe 100s Box	
Product Name	Complete Ultra Lights Filter Deluxe 100s
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000548: Complete Ultra High Air Filter Deluxe Kings Box	
Product Name	Complete Ultra Lights Filter Deluxe Kings Box
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	35%
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 May 14, 2019, FDA received Exemption Requests (EX0000538-EX0000548) from Skookum Creek Tobacco Company. On May 22, 2019, FDA issued an Acknowledgement letter to the applicant. On June 4, 2019, FDA received two amendments, EX0000576 and EX0000577, in response to June 4, 2019 requests from the Office of Compliance Enforcement (OCE).

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 (b)(4)
- Addition of FSC paper (b)(4)
- Deletion of soft pack container closure system for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547
- Addition of hard pack container closure system for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547

2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on May 22, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

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 June 21, 2019, conclude that the original tobacco products are grandfathered products.

4. SCIENTIFIC REVIEW

A scientific review was completed by Jason Hsieh on June 26, 2019.

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 Shannon Hanna on June 10, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 10, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 10, 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)
- Deletion of soft pack container closure system for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547
- Addition of hard pack container closure system for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547

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

deletion of non-FSC cigarette paper and the addition of FSC cigarette paper is an addition/deletion of a tobacco additive. Based on information submitted by the applicant, there is an additional modification of a change in container closure system for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547 only, i.e., from soft pack in the original product to hard pack in the new product. I, as TPL, find that the container closure systems in the original and new products meet the definition of ‘additive’ because they are substances used in the packaging of the tobacco products. In addition, I find that this modification is minor because this modification does not affect the characteristics of the consumable portion of the tobacco products. 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. As TPL, for EX0000538, EX0000540, EX0000542, EX0000544, and EX0000547 only, I also find that the change in container closure system is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. 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 from Substantial Equivalence 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 EX0000538 – EX0000548 as identified on the cover page of this review.