

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001260-EX0001266
Common Attributes	
Submission date	August 31, 2020
Receipt date	August 31, 2020
Applicant	Cheyenne International LLC
Product manufacturer	Cheyenne International LLC
Product category	Cigars
Product subcategory	Filtered, Sheet-Wrapped Cigar
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.10.29 20:43:48 -04'00'

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.10.30 08:43:06 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

The applicant submitted information for the new and original tobacco products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines Reviewed

Discipline	Cycle 1: Reviewers	Review Date
regulatory	Kristopher Van Amburg	9/14/2020
chemistry	Jason Hsieh	10/29/2020
environmental science	Hermes Reyes Caballero	10/2/2020

Table 2. Consult

Discipline	Reviewers	Review Date
engineering	Rashele Moore	10/13/2020

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review 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 October 13, 2020¹ and October 19, 2020² conclude that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.³

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original tobacco products compared to the corresponding new tobacco products are the result of:

- deleting an additive (acetate filter (b) (4)) with plug wrap) in EX0001260-EX0001263, and EX0001265

¹ For EX0001261

² For EX0001260 and EX0001262-EX0001266

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.

- deleting an additive (acetate filter (b) (4)) with plug wrap) in EX0001264
- adding an additive (acetate filter (b) (4) with plug wrap) in EX0001260-EX0001265
- deleting an additive (acetate filter (b) (4) with plug wrap) in EX0001266
- adding an additive (acetate filter (b) (4) with plug wrap) in EX0001266

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 4) 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.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on October 20, 2020. The FONSI was supported by an environmental assessment prepared by FDA on October 20, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 4) are a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. 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 the protection of the public health. In EX0001260-EX0001263 and EX0001265, the filters of the new tobacco products have 60% higher (b) (4), 87% higher (b) (4), and 108% higher (b) (4) compared to the corresponding original tobacco products. In EX0001264, the filter of the new tobacco product in EX0001264 has 60% higher (b) (4), 95% higher (b) (4), and 114% higher (b) (4), and 11% lower (b) (4) (b) (4). Also, a (b) (4) in the (b) (4) filter is present in the original tobacco product, but deleted in the new tobacco product. In EX0001266, the filter of the new tobacco product has 68% higher (b) (4) (b) (4) g/100 rods), 108% higher (b) (4) (b) (4) g/100 rods), and 5% lower (b) (4) (b) (4) g/100 rods), and 111% higher (b) (4) (b) (4) g/100 rods) compared to the original tobacco product. These differences may lead to a change in the smoke profile between the new and corresponding original products. The applicant provided pressure drop of filter tow of the new products, which is 8-50% higher (EX0001260-EX0001263, and EX0001265), 31-48% higher (EX0001264), and 36-60% higher (EX0001266). Studies have shown that a filter tow with higher pressure drop generally has higher filtration efficiency for particle removal. However, the measured filter efficiency increased between 0.4% to 3.3% for EX0001260-EX0001264 and decreased for EX0001265 and EX0001266 by 2% and 1%, respectively. Furthermore, the applicant indicated that the new and corresponding original tobacco products have the same ventilation at 0% (EX0001260-EX0001265) and 35% (EX0001266). Therefore, the filter modification in the new products are collectively considered a minor modification. In all of the above EX Requests, the change in these additives are not expected to affect or alter smoke yields between the new and original tobacco products. Additionally, the modifications are not expected to materially affect any

other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Lastly, I find that an exemption for this modification is 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 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.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco products in EX0001260-EX0001266, as identified in Appendix of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	August 31, 2020	
Receipt date	August 31, 2020	
Applicant	Cheyenne International LLC	
Product manufacturer	Cheyenne International LLC	
Product category	Cigars	
Product subcategory	Filtered, Sheet-Wrapped Cigar	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001260	GF2009807
Product name	Cheyenne Cigars Xotic Berry	Cheyenne Little Cigars Xotic Berry Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	Berry	Berry
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of ^{(b) (4)} filter with plug wrap ^{(b) (4)} target: ^{(b) (4)} g/100 rods) • Addition of ^{(b) (4)} filter with plug wrap ^{(b) (4)} target: ^{(b) (4)} g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001261	GF2009805
Product name	Cheyenne Cigars Full Flavor	Cheyenne Little Cigars Full Flavor Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of ^{(b) (4)} filter with plug wrap ^{(b) (4)} target: ^{(b) (4)} g/100 rods) 	

	<ul style="list-style-type: none"> • Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001262	GF2009804
Product name	Cheyenne Cigars Peach	Cheyenne Little Cigars Peach Flavor Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	Peach	Peach
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) • Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001263	GF2009809
Product name	Cheyenne Cigars Vanilla	Cheyenne Little Cigars Vanilla Flavor Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	Vanilla	Vanilla
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) • Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001264	GF2009803
Product name	Cheyenne Cigars Menthol	Cheyenne Little Cigars Menthol Flavor Box 100's
Eligibility status	Not applicable	Grandfathered

Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	Menthol	Menthol
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) • Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001265	GF2009808
Product name	Cheyenne Cigars Wild Cherry	Cheyenne Little Cigars Wild Cherry Flavor Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	Cherry	Cherry
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) • Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001266	GF2009806
Product name	Cheyenne Cigars Classic	Cheyenne Little Cigars Light Flavor Box 100's
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 cigars	20 cigars
Characterizing flavor	None	None
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm

Ventilation	35%	35%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none">• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
September 28, 2020	September 28, 2020	EX0001302	All EX Requests	Yes	Active	Response to September 25, 2020 FDA Information Request