U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001248-PD1 – EX0001250-PD1
Common Attributes	
Submission date	August 14, 2020
Receipt date	August 14, 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 Matthew J. Walters -S3
Date: 2021.02.01 09:11:55 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Division Director
Division of Product Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.02.01 09:21:54 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

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

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

	Cycle 1		Cycle 2	
Discipline	**Reviewers**	**Review Date**	**Reviewers**	**Review Date**
regulatory	Kristopher Van Amburg	8/25/2020	N/A	N/A
chemistry	Jason Hsieh	10/29/2020	Sandra Salido	1/21/2021
environmental science	Hermes Reyes Caballero	10/2/2020	Thomas Creaven	1/21/2021

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 as of February 15, 2007). The OCE review dated October 13, 2020, concludes 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.[1]

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:

- increasing the quantity of an existing additive (b)(4) in EX0001248-PD1
- deleting an additive (b)(4) in EX0001248-PD1
- deleting an additive (b)(4)) in EX0001249-PD1 and EX0001250-PD1
- adding an additive (b)(4)) in EX0001250-PD1

[1] 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.

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) 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 January 25, 2021. The FONSI was supported by an environmental assessment prepared by FDA on January 25, 2021.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications 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. The applicant proposes for EX0001248-PD1 to increase the quantity of the existing additive (b)(4), which also results in a deletion of the additive (b)(4); this is not expected to have any significant effects on product chemistry or a change in characterizing flavor. This modification of these ingredients are not expected to significantly alter the HPHC smoke chemistry. Additionally, for EX0001249-PD1 and EX0001250-PD1, the applicant proposes to delete the additive flavor (b)(4) and for EX0001250-PD1 only, add the additive flavor (b)(4). The change in these flavor additives are not expected to impact HPHC smoke yields or result in measurable HPHC yield differences. Changes in user perception are also not expected when removing characterizing flavor (EX0001249-PD1) or when changing a characterizing flavor (EX0001250-PD1). Additionally, research suggests that enjoyment of flavor has been associated with initiation and continued use of tobacco products, particularly among youth and young adults.[2] Since the differences in flavor between the new and original tobacco products are not changed between characterizing flavors and removes a charactering flavor, as indicated by the use of flavor descriptors in the new and original tobacco products, based on current scientific evidence, these changes in flavor descriptors are not of concern to FDA at this time. In all of the above EX Requests, the change in these additives resulted in small changes in total quantity of additives in the new tobacco products and 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 these modifications 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.

[2] Couch ET, Darius EF, Walsh MM, Chaffee BW. ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. *Health Educ Res.* 2017;32(6):537-545.

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 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 EX0001248-PD1 – EX0001250-PD1, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes of EX REQs		
Submission date	August 14, 2020	
Receipt date	August 14, 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	**EX0001248-PD1**	**GF2009803**
Product name	Cheyenne Little Cigars Extreme 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: • Addition of (b)(4) [redacted] Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b)(4) [redacted]	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001249-PD1	GF2009809
Product name	Cheyenne Little Cigars Sweet Tip	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	None	Vanilla
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of complex ingredient (b)(4) [redacted]	
STN	EX0001250-PD1	GF2009809
Product name	Cheyenne Little Cigars Grape	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	Grape	Vanilla
Length	99 mm	99 mm
Diameter	7.90 mm	7.90 mm
Ventilation	0%	0%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of complex ingredient (b)(4) [redacted] • Addition of complex ingredient (b)(4) [redacted]	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
September 28, 2020	September 28, 2020	EX0001320	All EX Requests	Yes	Response to September 25, 2020, FDA Information Request
December 4, 2020	December 4, 2020	EX0001374	EX0001250-PD1	Yes	Response to November 5, 2020, Deficiency Letter
December 4, 2020	December 4, 2020	EX0001375	EX0001248-PD1	Yes	Response to November 5, 2020, Deficiency Letter
December 4, 2020	December 4, 2020	EX0001376	EX0001249-PD1	Yes	Response to November 5, 2020, Deficiency Letter