FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review.[1]	
STNs	EX0001310.PD25, EX0001310.PD31, EX0001310.PD33, and EX0001310.PD37
Common Attributes	
Submission date	October 22, 2020
Receipt date	October 22, 2020
Applicant	Empresas Victor Sinclair Dominicana
Product manufacturer	Empresas Victor Sinclair Dominicana
Product category	Cigars
Product subcategory	Unfiltered, Leaf-Wrapped Cigar
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Characterizing Flavor Differences in EX Requests and SE Reports (September 21, 2020)
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jenna F. Dumond -S
Date: 2022.10.24 15:01:55 -04'00'

Jenna F. DuMond, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.10.24 16:16:26 -04'00'

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

[1] Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

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

1.2. REGULATORY ACTIVITY

On October 22, 2020, FDA received Exemption Requests (EX REQs) from Empresas Victor Sinclair Dominicana. On April 7, 2021, FDA issued an Acceptance letter. On April 14, 2021, FDA issued a Correction letter to update the text included in Appendix A of the Acceptance letter. On June 25, 2021, FDA issued a Deficiency letter.

See appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1		Cycle 2	
Discipline Table	**Reviewer(s)**	**Review Date**	**Reviewer(s)**	**Review Date**
Chemistry	Mona Shrestha	4/30/2021	Scott Wasdo	2/11/2022
Environmental Science	Thomas Creaven	5/4/2021	Thomas Creaven	2/9/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated May 11, 2021, conclude that the evidence submitted by the applicant is adequate to demonstrate original products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway..[2]

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive ((b) (4)) in all the EX Requests
- adding an additive ((b) (4)) in EX0001310.PD25
- adding an additive ((b) (4)) in EX0001310.PD31
- adding an additive ((b) (4)) in EX0001310.PD33

[2] Any tobacco product that can be sold under the FD&C Act (i.e., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

- adding an additive (b) (4)) in EX0001310.PD37

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 products. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on February 14, 2022. The FONSI was supported by an environmental assessment prepared by FDA on February 14, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are a minor modification of a 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 products to be marketed would be appropriate for the protection of the public health.

For all EX Requests, the applicant proposes to modify the original products by deleting the flavor additive, (b) (4) ", and add an equivalent amount of a different flavor additive. The new products add the flavor additives (b) (4) " in EX0001310.PD25, (b) (4) " in EX0001310.PD31, "(b) (4) " in EX0001310.PD33, and "(b) (4) " in EX0001310.PD37 (See Appendix Table A). For EX0001310.PD25, EX0001310.PD31, EX0001310.PD33, and EX0001310.PD37, the applicant provided quantitative lists of the single ingredients comprising the complex flavor additives used in the new and original products. The total quantity of flavor ingredients used in the new and original products is identical; however, the complex flavor additives used in the new products of these EX Requests are compositionally distinct and different from that used in the flavor of the original product. The complex flavor additives used in the corresponding new products in these EX Requests contain some single ingredients that are not present in the original product flavor. The flavor additives in the new products also incorporate some of the same single ingredients as the flavor additives in the corresponding original products, but in all cases where the corresponding new and original product share common ingredients, the new product uses significantly different quantities of these ingredients than the original product. During product use, flavor ingredients may transfer directly to the smoke or thermally decompose and release degradation products including harmful and potentially harmful constituents (HPHCs). However, the majority of the adequately identified single ingredients (i.e., where the applicant provided appropriate quantitative lists) added to the new products in these EX Requests are volatile or semi-volatile, and therefore these specific compounds are expected to transfer largely intact to the smoke and are not expected to measurably affect the relative HPHC yield of the new and original products. Of the other identified single ingredients in these EX Requests, they are present at

low levels and are not expected to significantly contribute to the total HPHC yield of the new products compared to the original products. As combustion of the ~8 g of tobacco in the new and original products is expected to generate substantial yields of several HPHCs including tobacco specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), and carbonyls, the anticipated quantity of HPHCs generated by the known single ingredients used in the new products is not expected to meaningfully contribute to the total HPHC burden of the new products compared to that of the original. Therefore, the modifications to the original products in EX0001310.PD25, EX0001310.PD31, EX0001310.PD33, and EX0001310.PD37 are minor modifications in accordance with section 905(j)(3)(A)(i) of the FD&C Act from a chemistry perspective. 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

Research suggests that enjoyment of flavor has been associated with initiation and continued use of tobacco products (e.g., smokeless tobacco products), particularly among youth and young adults.[3],[4]

However, there are no changes from a non-characterizing flavor to a characterizing flavor in the new and original tobacco products based on the labeling and identifying information stated by the applicant in these applications. As such, these changes in characterizing flavors are not of concern, from a social science perspective, to FDA at this time.[5]

The original 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 as of February 15, 2007.

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

An exempt order should be issued for the new products, as identified on the cover page of this review.

[3] 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.
[4] Ben Taleb Z, Breland A, Bahelah R, et al. Flavored Versus Nonflavored Waterpipe Tobacco: A Comparison of Toxicant Exposure, Puff Topography, Subjective Experiences, and Harm Perceptions. Nicotine Tob Res. 2019;21(9):1213-1219.
[5] CTP internal memo: Characterizing Flavor Differences in EX Requests and SE Reports (September 21, 2020)

7. APPENDICES

Appendix A. New and original products.

Common Attributes		
Submission date	October 22, 2020	
Receipt date	October 22, 2020	
Applicant	Empresas Victor Sinclair Dominicana	
Product manufacturer	Empresas Victor Sinclair Dominicana	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-wrapped Cigar	
Attributes	**New Product**	**Original Product**
STN	**EX0001310.PD25**	**Not applicable (N/A)**
Product name	POINT BREAK FLAVORS BLUEBERRY CORONA TUBO[6]	SMOKIN ASS KONA COFFEE CORONA TUBO[6]
Eligibility status	N/A	Grandfathered
Nicotine source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[7]	Cellophane[7]
Package quantity	1 Cigar	1 Cigar
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF	Blueberry	Coffee
Length	5.5 inches (in)	5.5 in
Diameter	Not Provided	Not Provided
Wrapper material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of flavor additive "(b) (4) [redacted] • Addition of flavor additive "(b) (4) [redacted]	
Attributes	**New Product**	**Original Product**
STN	**EX0001310.PD31**	**N/A**
Product name	POINT BREAK FLAVORS CINNAMON CORONA TUBO[6]	SMOKIN ASS KONA COFFEE CORONA TUBO[6]
Eligibility status	N/A	Grandfathered
Nicotine source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[7]	Cellophane[7]
Package quantity	1 Cigar	1 Cigar

[6] Brand/sub-brand or other commercial name used in commercial distribution.
[7] The applicant did not provide information on the ingredient makeup of Cellophane

Characterizing flavor (CF)	Flavored	Flavored
Flavored CF	Cinnamon	Coffee
Length	5.5 in	5.5 in
Diameter	Not Provided	Not Provided
Wrapper material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of flavor additive "(b) (4) [redacted] • Addition of flavor additive "(b) (4) [redacted]	
Attributes	**New Product**	**Original Product**
STN	**EX0001310.PD33**	**N/A**
Product name	POINT BREAK FLAVORS GRAPE CORONA TUBO[6]	SMOKIN ASS KONA COFFEE CORONA TUBO[6]
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[7]	Cellophane[7]
Package quantity	1 Cigar	1 Cigar
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF	Grape	Coffee
Length	5.5 in	5.5 in
Diameter	Not Provided	Not Provided
Wrapper material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of flavor additive "(b) (4) [redacted]" • Addition of flavor additive "(b) (4) [redacted]"	
Attributes	**New Product**	**Original Product**
STN	**EX0001310.PD37**	**N/A**
Product name	POINT BREAK FLAVORS KEY LIME PIE CORONA TUBO[6]	SMOKIN ASS KONA COFFEE CORONA TUBO[6]
Eligibility status	N/A	Grandfathered
Nicotine source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[7]	Cellophane[7]
Package quantity	1 Cigar	1 Cigar
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF	Key Lime Pie	Coffee
Length	5.5 in	5.5 in
Diameter	Not Provided	Not Provided

Wrapper material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of flavor additive "(b) (4) • Addition of flavor additive "(b) (4)	

Appendix B
Amendments Received for These Applications

Submission Date	Receipt Date	Amendment	Applications Being Amended	Reviewed	Brief Description
April 26, 2021	April 26, 2021	EX0001895	All	Yes	Response to April 21, 2021, FDA Information Request
April 29, 2021	April 29, 2021	EX0001901	All	Yes	Response to April 23, 2021, and April 28, 2021, FDA Information Requests
May 4, 2021	May 4, 2021	EX0001971	All	Yes	Response to May 3, 2021, and May 4, 2021, FDA Information Requests
July 23, 2021	July 23, 2021	EX0002184	All	Yes	Response to June 25, 2021, Deficiency letter
August 25, 2021	August 25, 2021	EX0002239	All	Yes	Additional response to June 25, 2021, Deficiency Letter