

## Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review <sup>1</sup>	
STNs	EX0001309.PD37, EX0001309.PD39, and EX0001309.PD45
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):

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Date: 2022.10.26 11:44:28 -04'00'

Delshanee Kotandeniya, Ph.D.  
Chemistry Team Supervisor  
Office of Science/ 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: 2022.10.26 15:04:38 -04'00'

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

<sup>1</sup> 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 an Acceptance 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

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Maliha Choudhury	4/7/2021	N/A	N/A
Chemistry	Salome Bhagan	5/3/2021	Ethan Englund	2/16/2022
Environmental Science	Chad Baisden	5/13/2021	Chad Baisden	2/15/2022

## 2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews 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.<sup>2</sup>

## 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 EX0001309.PD37
- deleting an additive (b) (4) in EX0001309.PD39 and EX0001309.PD45
- adding an additive (b) (4) in EX0001309. PD37 and EX0001309.PD39
- adding an additive (b) (4) in EX0001309.PD45

<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.

#### 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 October 25, 2022. The FONSI was supported by an environmental assessment prepared by FDA on February 22, 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 a flavor additive and adding an equivalent amount of a different flavor additive. The new products in EX0001309.PD37, EX0001309.PD39, and EX0001309.PD45 are modified by deleting the complex flavors “(b) (4)” (EX0001309.PD37) and “(b) (4)” (EX0001309.PD39 and EX0001309.PD45) and replacing these complex flavors with equivalent amounts of complex flavors such as “(b) (4)” (EX0001309.PD37 and EX0001309.PD39) and “(b) (4)” (EX0001309.PD45) [see Appendix A]. The applicant’s response to the Deficiency letter dated June 25, 2021, contains updated quantities of complex flavoring ingredients in the new and corresponding original products for all EX Requests. The total quantity of complex 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. For example, modifications of complex flavors resulted in decreased quantities of single ingredients such as (b) (4) mg/cigar decrease in EX0001309.PD37) or decreased (b) (4) in EX0001309.PD39 (↓ (b) (4) mg/cigar) and EX0001309.PD45 (↓ (b) (4) mg/cigar) respectively. The proposed modification of adding complex flavor “(b) (4)” in EX0001309.PD37 involved adding chemicals such as alcohols ((b) (4), (b) (4) mg/cigar), aldehydes (e.g., (b) (4), (b) (4) mg/cigar), organic acids (e.g., (b) (4), (b) (4) mg/cigar), and esters (e.g., (b) (4), (b) (4) mg/cigar or (b) (4), (b) (4) mg/cigar). The complex flavor modification of the new product in EX0001309.PD39 results in addition of ingredients such as (b) (4) (b) (4) mg/cigar, (b) (4) (b) (4) mg/cigar, (b) (4) (b) (4) mg/cigar, (b) (4) (b) (4) mg/cigar and (b) (4) mg/cigar) and increases in ingredients such as (b) (4)

(b) (4) (↑<sup>(b) (4)</sup> mg/cigar, 1200% increase), and decreases in chemicals like (b) (4) (↓<sup>(b) (4)</sup> mg/cigar, 67% decrease). The modifications of the new product in EX0001309-PD45 results in the addition of ingredients such as (b) (4) (<sup>(b) (4)</sup> mg/cigar), (b) (4) (<sup>(b) (4)</sup> mg/cigar), and (b) (4) (<sup>(b) (4)</sup> mg/cigar) and increases or decreases in ingredients such as (b) (4) (↑<sup>(b) (4)</sup> mg/cigar, 3400% increase), (b) (4) (↑<sup>(b) (4)</sup> mg/cigar, 820% increase), and decrease in (b) (4) (↓<sup>(b) (4)</sup> mg/cigar, 72% decrease). During product use, flavor ingredients may transfer directly to the smoke or undergo thermal degradation during pyrolysis to release degradation products including harmful and potentially harmful constituents (HPHCs).<sup>3</sup> However, the majority of the ingredients added to the new products in these EX Requests, described above, are volatile and semi-volatile, and these specific compounds are expected to transfer largely intact to the smoke. The rest of the flavor ingredients are present in small quantities compared to the total cigar weights and are not expected to significantly contribute to the total HPHC yield. Both of these single ingredient types (volatile or semi-volatile organic compounds) would not be expected to measurably affect the relative HPHC yield of the new and original products. Combustion of the 1.913 g (EX0001309.PD37) and 15.306 g (both EX0001309.PD39 and EX0001309.PD45) of tobacco in the new and original products is expected to generate several HPHCs including tobacco specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), and carbonyls. Comparatively, the anticipated quantity of HPHCs generated by the additional 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 products. Additionally, the modifications are not expected to materially affect any other characteristics (materials, design, ingredients, composition, heating source, or other features) of the tobacco products. 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.<sup>4,5</sup> 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.<sup>6</sup> The new and original products in EX0001309.PD37, EX0001309.PD39, and EX0001309.PD45, are packaged in cellophane wrappers. The applicant does not provide any other information about packaging such as the individual ingredient makeup of cellophane packaging. However, since the

<sup>3</sup> (a) Baker RR, Massey ED, Smith G. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. *Food Chem Toxicol.* 2004; 42 Suppl:S53-83. (b) Wilson, SA. Theoretical Aspects of Menthol Migration and Transfer. In *Recent Advances in Tobacco Science*, Vol. 19 ; Symposium Proceedings, 47th Meeting of Tobacco Chemists' Research Conference, Gatlinburg, TN, October 18-21; 1993; pp 129-153. (c) Chemical composition of alcoholic beverages, additives and contaminants. *IARC Monogr Eval Carcinog Risks Hum.* 1988; 44:71-99. (d) Lafontaine S, Caffrey A, Dailey J, et al. Evaluation of Variety, Maturity, and Farm on the Concentrations of Monoterpene Diglycosides and Hop Volatile/Nonvolatile Composition in Five *Humulus lupulus* Cultivars. *J Agric Food Chem.* Apr 21, 2021;69(15):4356-4370. (e) Brendel S, Hofmann T, Granvogl M. Characterization of Key Aroma Compounds in Pellets of Different Hop Varieties (*Humulus lupulus* L.) by Means of the Sensomics Approach. *J Agric Food Chem.* Oct 30, 2019;67(43):12044-12053. (f) FDA. Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list> (Last accessed January 24, 2022). (g) (b) (4). (h) Brezinsky K, Pecullan M, Glassman I. Pyrolysis and Oxidation of Phenol. *J Phys Chem A.* Oct 1, 1998;102(44):8614-8619. (i) a (b) (4). (j) Francis GW, Christy AA, Oygarden J. Pyrolytic formation of polycyclic aromatic hydrocarbons from sesquiterpenes. *Food Chem.* Dec 1, 2012;135(3):1316-22.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> CTP internal memo: Characterizing Flavor Differences in EX Requests and SE Reports (September 21, 2020)

new and their corresponding original products are in identical packaging, we have determined that in this case alone, further information is not necessary for packaging details. 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

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.

## 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	EX0001309.PD37	Not Applicable (N/A)
Product name	TABANERO COFFEE LIQUEUR MINI <sup>7</sup>	CUBAN DELIGHTS FLAVORS AMARETTO MINI <sup>7</sup>
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 <sup>8</sup>	Cellophane <sup>8</sup>
Package quantity	1 Cigar	1 Cigar
Characterizing Flavor (CF)	Flavored	Flavored
Flavored CF	Coffee Liqueur	Amaretto
Length	3.25 inches (in)	3.25 in
Diameter <sup>9</sup>	Not provided	Not provided
Wrapper Material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 26 (1/64 in)	Ring Gauge: 26 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of flavor additive "(b) (4) [REDACTED]"</li> <li>• Addition of flavor additive "(b) (4) [REDACTED]"</li> </ul>	

<sup>7</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<sup>8</sup> The applicant did not provide information on the ingredient makeup of Cellophane

<sup>9</sup> Although the applicant did not provide the diameter, values for diameter may be calculated from the ring gauge values provided by the applicant (see Additional Property)

Attributes	New Product	Original Product
STN	EX0001309.PD39	N/A
Product name	CAFE LATTE BELICOSO <sup>7</sup>	BIG DOG SWEET TIP TORPEDO <sup>7</sup>
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 <sup>8</sup>	Cellophane <sup>8</sup>
Package quantity	1 Cigar	1 Cigar
Characterizing Flavor (CF)	Flavored	Flavored
Characterizing flavor	Coffee	Sweet
Length	6.5 in	6.5 in
Diameter <sup>9</sup>	Not provided	Not provided
Wrapper Material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 52 (1/64 in)	Ring Gauge: 52 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of flavor additive "(b) (4) [REDACTED]"</li> <li>• Addition of flavor additive "(b) (4) [REDACTED]"</li> </ul>	
Attributes	New Product	Original Product
STN	EX0001309.PD45	N/A
Product name	POINT BREAK FLAVORS KEY LIME PIE TORPEDO <sup>7</sup>	BIG DOG SWEET TIP TORPEDO <sup>7</sup>
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 <sup>8</sup>	Cellophane <sup>8</sup>
Package quantity	1 Cigar	1 Cigar
Characterizing Flavor (CF)	Flavored	Flavored
Flavored CF	Key Lime Pie	Sweet
Length	6.5 in	6.5 in
Diameter <sup>9</sup>	Not provided	Not provided
Wrapper Material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional property	Ring Gauge: 52 (1/64 in)	Ring Gauge: 52 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of flavor additive "(b) (4) [REDACTED]"</li> <li>• Addition of flavor additive "(b) (4) [REDACTED]"</li> </ul>	



**APPENDIX B. AMENDMENTS**

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 28, 2021, FDA Information Request
May 4, 2021	May 4, 2021	EX0001902	All	Yes	Response to May 3, 2021, and May 4, 2021, FDA Information Request
July 23, 2021	July 23, 2021	EX0002184 <sup>10</sup>	All	Yes	Response to June 25, 2021, Deficiency letter
August 25, 2021	August 25, 2021	EX0002239	All	Yes	Updated response to June 25, 2021, Deficiency letter

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<sup>10</sup> This amendment does not include EX0001309.PD37 on the cover letter, however this STN.PD is subject of the amendment.