U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 8, 2022

EXEMPT

Empresas Victor Sinclair Dominicana
Attention: Beth G. Oliva, Esq.
Fox Rothschild LLP
101 Park Avenue, Floor 17
New York, NY 10178

FDA Submission Tracking Numbers (STNs): EX0001309.PD37, EX0001309.PD39, and EX0001309.PD45

Dear Beth G. Oliva:

We completed review of your EX REQs[1] and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.[2]

Our finding does not mean we "approved" the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being "approved" by FDA (see Section 301(tt) of the FD&C Act).

To market the new tobacco products that are the subject of these EX REQs, the following must be met:

1. **Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
2. **Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix B for FDA's recommended format for submitting of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] Requests for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Maliha Choudhury, M.H.S., Regulatory Health Project Manager, at (240) 402-4549 or Maliha.Choudhury@fda.hhs.gov.

Sincerely,

Todd L. Cecil -S

Digitally signed by Todd L. Cecil -S
Date: 2022.11.08 15:20:53 -05'00'

Todd L. Cecil, Ph.D.
Acting Director
Office of Science
Center for Tobacco Products

Enclosures (if provided electronically, the Appendices are not included in physical mail):

Appendix A – New and Corresponding Original Tobacco Products Subject of This Letter
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal

[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

[5] For more information about eSubmitter, see http://www.fda.gov/ForIndustry/FDAeSubmitter

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A[7,8,9,10,11]

New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs		
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	CUBAN DELIGHTSFLAVORS AMARETTO MINI
Eligibility status	N/A	Grandfathered[11]
Nicotine Source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[9]	Cellophane[9]
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[10]	Not provided	Not provided
Wrapper Material	Whole Leaf Tobacco	Whole Leaf Tobacco
Additional Property	Ring Gauge: 26 (1/64 in)26 (Ring Gauge 1/64 in)	Ring Gauge: 26 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of flavor additive "(b) (4) [redacted]" • Addition of flavor additive "(b) (4) [redacted]"	

[7] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification. https://www.congress.gov/bill/117th-congress/house-bill/2471

[8] Brand/sub-brand or other commercial name used in commercial distribution.

[9] The applicant did not provide information on the ingredient makeup of Cellophane.

[10] 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)

[11] FDA updated the term "grandfathered tobacco product" (GF) to "pre-existing tobacco product" (PTP). This update will not affect review of pending submissions and STNs will not change retroactively. You may continue to use the STN (GF or PX) assigned in the FDA Acceptance letter confirming receipt of your submission. Refer to FDA's website for more information on the GF to PTP update.

Attributes	New Product	Original Product
STN	**EX0001309.PD39**	**N/A**
Product name	CAFE LATTE BELICOSO	BIG DOG SWEET TIP TORPEDO
Eligibility status	N/A	Grandfathered[11]
Nicotine Source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[9]	Cellophane[9]
Package quantity	1 Cigar	1 Cigar
Characterizing flavor (CF)	Flavored	Flavored
Flavored CF	Coffee	Sweet
Length	6.5 in	6.5 in
Diameter[10]	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: • Deletion of flavor additive "(b) (4) [redacted] • Addition of flavor additive "(b) (4) [redacted]"	
STN	**EX0001309.PD45**	**N/A**
Product name	POINT BREAK FLAVORS KEY LIME PIE TORPEDO	BIG DOG SWEET TIP TORPEDO
Eligibility status	N/A	Grandfathered[11]
Nicotine Source	Tobacco	Tobacco
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane[9]	Cellophane[9]
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[10]	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: • Deletion of flavor additive (b) (4) [redacted]" • Addition of flavor additive "(b) (4) [redacted]"	

Appendix B

FDA's Recommended Format for Submitting an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe **[ink or digital signature]**
Vice President
Mock-Up Tobacco Company