

February 26, 2021

EXEMPT

Altadis U.S.A. LLC.
Attention: Rhondetta Walton, VP Regulatory Compliance
5900 North Andrews Avenue, Suite 600
Fort Lauderdale, FL 33309

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Ms. Walton:

We completed review of your EX REQs¹ 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 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 date⁶; 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 Megan Nguyen, Regulatory Health Project Manager, at (301) 796-7826 or Megan.Nguyen@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2021.02.26 10:53:34 -05'00'

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

Enclosures (if provided electronically, the Appendix is 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
New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes		
Applicant	Altadis U.S.A. LLC.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD1	GF1906962
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Romeo y Julieta Aniversario Corona	Romeo y Julieta Aniversario Corona
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	139.7 mm	139.7 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 44 (1/64 in)	Ring Gauge: 44 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	

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

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD3	GF1804185
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Romeo y Julieta Reserva Real Petite Robusto	Romeo y Julieta Reserva Real Petite Robusto
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 54 (1/64 in)	Ring Gauge: 54 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of an existing tobacco additive: • Increase in the quantity of (b) (4)	
STN	EX0001269-PD13	GF1806358
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Trinidad Maduro Belicoso	Trinidad Maduro Belicoso
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	155.7 mm	155.7 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 54 (1/64 in)	Ring Gauge: 54 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD1	GF1806376
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	H. Upmann Vintage Cameroon Petite Corona	H. Upmann Vintage Cameroon Petite Corona
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	
STN	EX0001270-PD3	GF1703460
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	H. Upmann Cedar Aged Churchill	H. Upmann Cedar Aged Churchill
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	143 mm	143 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD5	GF1806046
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Flor de Canarias Lonsdale	Flor de Canarias Lonsdale
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	
STN	EX0001270-PD7	GF1804205
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Romeo y Julieta Vintage Vintage II	Romeo y Julieta Vintage Vintage II
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD9	GF1703489
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Montecristo Classic Collection Toro	Montecristo Classic Collection Toro
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 52 (1/64 in)	Ring Gauge: 52 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) • Addition of (b) (4)	
STN	EX0001270-PD11	GF1806057
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Hoffman House Short Perfecto	Hoffman House Short Perfecto
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD13	GF1806057
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Hoffman House Short Perfecto	Hoffman House Short Perfecto
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4)	
STN	EX0001271-PD1	GF1806046
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Flor de Canarias Lonsdale	Flor de Canarias Lonsdale
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD15	GF1907639
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name ⁷	Trinidad Fundador	Trinidad Fundador
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	190.5 mm	190.5 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of an existing tobacco additive: • Increase in the quantity of (b) (4)	
STN	EX0001293-PD1	GF1806357
Submission date	September 4, 2020	Not Applicable
Receipt date	September 4, 2020	Not Applicable
Product name ⁷	H. Upmann Petite Churchill	H. Upmann Petite Churchill
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	114.3 mm	114.3 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring gauge 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001293-PD3	GF1906681
Submission date	September 4, 2020	Not Applicable
Receipt date	September 4, 2020	Not Applicable
Product name ⁷	Nat Sherman Morgan	Nat Sherman Morgan
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Package type	Cellophane Wrap	Cellophane Wrap
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter	Not provided	Not provided
Additional property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	

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