

March 04, 2021

EXEMPT

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

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

Dear Ms. Walton:

We completed review of your EX REQ¹s 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 Assessments (EAs) 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 Regulatory Health Project Manager, Megan Nguyen at (301) 796-7826 or Megan.Nguyen@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2021.03.04 13:31:16 -05'00'

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

Enclosures:

- Appendix A – New and 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 A⁷

New and Original Tobacco Products Subject of This Letter

Common Attributes		
Submission date	September 2, 2020	
Receipt date	September 2, 2020	
Applicant	Altadis U.S.A. LLC.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped Cigar	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD5	GF1806358
Product name	H. Upmann Petite Corona	H. Upmann 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 ⁸	Ring Gauge (1/64 in): 44	Ring Gauge (1/64 in): 44
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Deletion of (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD7	GF1805647
Product name	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	155.6 mm	155.6 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter ⁸	Ring Gauge (1/64 in): 54	Ring Gauge (1/64 in): 54
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Deletion of (b)(4) • Deletion of (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b)(4) 	

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

⁸ Diameter provided as ring gauge.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD9	GF1804185
Product name	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 ⁸	Ring Gauge (1/64 in): 54	Ring Gauge (1/64 in): 54
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD11	GF1805269
Product name	Blender's Gold Dominican Maduro Churchill	Blender's Gold Dominican Maduro 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	165.1 mm	165.1 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter ⁸	Ring Gauge (1/64 in): 50	Ring Gauge (1/64 in): 50
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD15	GF1806358
Product name	H. Upmann Petite Corona	H. Upmann 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 ⁸	Ring Gauge (1/64 in): 44	Ring Gauge (1/64 in): 44
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD17	GF1703489
Product name	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 ⁸	Ring Gauge (1/64 in): 52	Ring Gauge (1/64 in): 52
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD15	GF1804205
Product name	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 ⁸	Ring Gauge (1/64 in): 46	Ring Gauge (1/64 in): 46
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD17	GF1805633
Product name	Trinidad Maduro Toro	Trinidad Maduro 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 ⁸	Ring Gauge (1/64 in): 55	Ring Gauge (1/64 in): 55
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD3	GF1906561
Product name	Montecristo Corona Grande	Montecristo Corona Grande
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	146.05 mm	146.05 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter ⁸	Ring Gauge (1/64 in): 46	Ring Gauge (1/64 in): 46
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of (b)(4) (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD5	GF1804216
Product name	Romeo y Julieta Vintage Vintage IV	Romeo y Julieta Vintage Vintage IV
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 ⁸	Ring Gauge (1/64 in): 48	Ring Gauge (1/64 in): 48
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) • Addition of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD7	GF1907639
Product name	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 ⁸	Ring Gauge (1/64 in): 40	Ring Gauge (1/64 in): 40
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Deletion of (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD9	GF1602085
Product name	Romeo y Julieta 1875 Exhibicion #1	Romeo y Julieta 1875 Exhibicion #1
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	215.9 mm	215.9 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter ⁸	Ring Gauge (1/64 in): 52	Ring Gauge (1/64 in): 52
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD11	GF1804173
Product name	Romeo y Julieta 1875 Cedro Deluxe #1	Romeo y Julieta 1875 Cedro Deluxe #1
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 ⁸	Ring Gauge (1/64 in): 44	Ring Gauge (1/64 in): 44
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD13	GF1908832
Product name	Seijas' Signature Series Toro	Seijas' Signature Series 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	155.6 mm	155.6 mm
Wrapper material	Whole Leaf	Whole Leaf
Diameter ⁸	Ring Gauge (1/64 in): 52	Ring Gauge (1/64 in): 52
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Deletion of (b)(4) • Deletion of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD17	GF1907649
Product name	VegaFina Lonsdale	VegaFina 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 ⁸	Ring Gauge (1/64 in): 43	Ring Gauge (1/64 in): 43
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion 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