

June 28, 2022

EXEMPT

Tabacalera de Garcia S.A.S.
Attention: Rhondetta Walton, Vice President Regulatory Compliance
Altadis USA LLC
5900 North Andrews Avenue, Suite 600
Fort Lauderdale, FL 33309

FDA Submission Tracking Numbers (STNs): EX0002010.PD1 – EX0002023.PD1

Dear Rhondetta 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 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 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 Michael Jokoh, Regulatory Health Project Manager, at (301) 796-0502 or Michael.Jokoh@fda.hhs.gov.

Sincerely,

Todd L. Cecil Digitally signed by Todd L. Cecil -S
-S Date: 2022.06.28 09:17:25 -04'00'

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

Enclosures:

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 A⁷
New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes		
Submission date	June 2, 2021	
Receipt date	June 2, 2021	
Applicant	Tabacalera de Garcia S.A.S.	
Product Manufacturer	Tabacalera de Garcia S.A.S.	
Product Category	Cigar	
Product subcategory	Unfiltered, Leaf-Wrapped	
	New Tobacco Product	Original Tobacco Product
	EX0002010.PD1	GF1805610
Product Name:	Altadis 47x 6 Parejo	Royal Jamaica Gold Park Lane
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	Not applicable (N/A)	Grandfathered
Length:	152.4 millimeters (mm)	152.4 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 47 (1/64 in)	Ring Gauge: 47 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing 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 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).

	New Tobacco Product	Original Tobacco Product
	EX0002011.PD1	GF1906561
Product Name:	Montecristo Corona Grande	Montecristo Corona Grande
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	146.05 mm	146.05 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 46 (1/64 in)	Ring Gauge: 46 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002012.PD1	GF1805639
Product Name:	VegaFina Corona	VegaFina Corona
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	146.05 mm	146.05 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 43 (1/64 in)	Ring Gauge: 43 (1/64 in)
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) 		

	New Tobacco Product	Original Tobacco Product
	EX0002013.PD1	GF1804369
Product Name:	Altadis 44 x 4 1/4 Parejo	Montecristo No 444
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	107.95 mm	107.95 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 44 (1/64 in)	Ring Gauge: 44 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increasing/Decreasing in the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002014.PD1	GF1806367
Product Name:	Altadis 47 x 5 Parejo	H. Upmann H2000 #7 Habano
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	127 mm	127 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 47 (1/64 in)	Ring Gauge: 47 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0002015.PD1	GF1907650
Product Name:	Altadis 40 x 4 Parejo	VegaFina No. 5
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	101.6 mm	101.6 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002016.PD1	GF1702946
Product Name:	Altadis 39 x 6 3/4 Parejo	Montecristo Fancytales
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	171.45 mm	171.45 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 39 (1/64 in)	Ring Gauge: 39 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0002017.PD1	GF1804149
Product Name:	Altadis 48 x 6 Parejo	Onyx Black Prince
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	152.4 mm	152.4 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 48 (1/64 in)	Ring Gauge: 48 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002018.PD1	GF1906667
Product Name:	Altadis 32 x 6 Parejo	Nat Sherman #65 Gotham West Side
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	152.4 mm	152.4 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 32 (1/64 in)	Ring Gauge: 32 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0002019.PD1	GF1805645
Product Name:	Altadis 45 x 5 Parejo	Trinidad Corona
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	127 mm	127 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 45 (1/64 in)	Ring Gauge: 45 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002020.PD1	GF1806376
Product Name:	Altadis 40 x 5 Parejo	H. Upmann Vintage Cameroon Petite Corona
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	127 mm	127 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0002021.PD1	GF1702948
Product Name:	Altadis 42 x 4 1/4 Parejo	Montecristo Half Corona
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	107.95 mm	107.95 mm
Diameter:⁸	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)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0002022.PD1	GF1804208
Product Name:	Altadis 60 x 6 1/2 Parejo	Romeo y Julieta Vintage Vintage VI
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	165.1 mm	165.1 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 60 (1/64 in)	Ring Gauge: 60 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0002023.PD1	GF1805632
Product Name:	Altadis 55 x 5 Parejo	Trinidad Maduro Robusto
Package Type:	Cellophane	Cellophane
Package Quantity:	1 Cigar	1 Cigar
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	127 mm	127 mm
Diameter:⁸	Not Provided	Not Provided
Wrapper Material:	Whole leaf tobacco	Whole leaf tobacco
Additional Property:	Ring Gauge: 55 (1/64 in)	Ring Gauge: 55 (1/64 in)
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) 		
Increase/Decrease in the quantity of existing additives:		
<ul style="list-style-type: none"> • 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