



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

September 21, 2022

EXEMPT

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

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

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,

Digitally signed by Todd L. Cecil
-S
Date: 2022.09.21 15:42:49
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Todd L. Cecil -S

Todd L. Cecil, Ph.D.
Acting 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 28, 2021, July 8, 2021, and July 14, 2021	
Receipt date	June 28, 2021, July 8, 2021, and July 14, 2021	
Applicant	Tabacalera de Garcia S.A.S.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped	
Attributes	New Product	Original Product
STN	EX0002089.PD1	GF1805269
Product name	Blender's Gold Dominican Maduro Churchill	Blender's Gold Dominican Maduro Churchill
Eligibility status	Not Applicable (N/A)	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 50 (1/64 in)	Ring Gauge: 50 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) • (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)

⁹ 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>

Attributes	New Product	Original Product
STN	EX0002090.PD1	GF1804183
Product name	Altadis 28 x 4 ¾ Parejo	Romeo y Julieta 1875 Julietas
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	123.95 mm	123.95 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 28 (1/64 in)	Ring Gauge: 28 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	
Attributes	New Product	Original Product
STN	EX0002091.PD1	GF1806025
Product name	Altadis 36 x 6 ½ Parejo	Blenders Gold Dominican Panetella
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 36 (1/64 in)	Ring Gauge: 36 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	

Attributes	New Product	Original Product
STN	EX0002143.PD1	GF1806024
Product name	Altadis 43 x 6 ¹ / ₁₆ Parejo	Blenders Gold Dominican Lonsdale
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	153.92 mm	153.92 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 43 (1/64 in)	Ring Gauge: 43 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	
Attributes	New Product	Original Product
STN	EX0002144.PD1	GF1804186
Product name	Altadis 36 x 7 Parejo	Romeo y Julieta Reserva Real Porto Real
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cedar-lined aluminum Tube	Cedar-lined aluminum Tube
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 36 (1/64 in)	Ring Gauge: 36 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (b)(4) 	

Attributes	New Product	Original Product
STN	EX0002146.PD1	GF1702857
Product name	Altadis 42 x 5 ⁵ / ₈ Parejo	Montecristo No. 10
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Box	Box
Package quantity	25 Cigars	25 Cigars
Characterizing flavor	None	None
Length	143 mm	143 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (b)(4) 	
Attributes	New Product	Original Product
STN	EX0002147.PD1	GF1702858
Product name	Altadis 38 x 6 ⁷ / ₈ Parejo	Montecristo No. 20
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Box	Box
Package quantity	25 Cigars	25 Cigars
Characterizing flavor	None	None
Length	174.75 mm	174.75 mm
Diameter ⁸	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine source ⁹	Tobacco	Tobacco
Additional Property	Ring Gauge: 38 (1/64 in)	Ring Gauge: 38 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (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