



June 13, 2022

EXEMPT

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

FDA Submission Tracking Numbers (STNs): EX0002041.PD1 – EX0002048.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
-S

Digitally signed by Todd L.
Cecil -S
Date: 2022.06.13 16:06:50
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Todd 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 6, 2021	
Receipt date	June 6, 2021	
Applicant	Tabacalera de Garcia S.A.S.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped Cigar	
Attributes	New Product	Original Product
STN	EX0002041.PD1	GF1804167
Product name	Altadis 60 x 5 1/2 Figurado	Onyx Reserve Torbusto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	139.7 mm	139.7 mm
Diameter	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)
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"> • Increasing the quantity of (b) (4) 	

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

Attributes	New Product	Original Product
STN	EX0002042.PD1	GF1805480
Product name	Altadis 42 x 5 1/16 Parejo	Don Diego Privada Petite Corona
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	128.52 mm	128.52 mm
Diameter	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)
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"> • Increasing the quantity of (b) (4) 	
Attributes	New Product	Original Product
STN	EX0002043.PD1	GF1907622
Product name	Altadis 48 x 61/2 Figurado	Seijas' Signature Series Perfecto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter	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)
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) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) 	

Attributes	New Product	Original Product
STN	EX0002044.PD1	GF1906697
Product name	Altadis 42 x 6 7/8 Parejo	Por Larranaga Cetros
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	174.63 mm	174.63 mm
Diameter	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)
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"> • Increasing the quantity of (b) (4) 	
Attributes	New Product	Original Product
STN	EX0002045.PD1	GF1806057
Product name	Altadis 46 x 4 1/4 Figurado	Hoffman House Short Perfecto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Diameter	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)
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) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) 	

Attributes	New Product	Original Product
STN	EX0002046.PD1	GF1805479
Product name	Altadis 42 x 5 9/16 Parejo	Don Diego Privada #4
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	141.29 mm	141.29 mm
Diameter	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)
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"> • Increasing the quantity of (b) (4) 	
Attributes	New Product	Original Product
STN	EX0002047.PD1	GF1804376
Product name	Altadis 52 x 5 Figurado	Montecristo Serie V Mini Belicoso
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter	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: <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"> • Increasing the quantity of (b) (4) 	

Attributes	New Product	Original Product
STN	EX0002048.PD1	GF1805274
Product name	Altadis 48 x 7 1/2 Parejo	Butera Royal Vintage Capo Grande
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	190.5 mm	190.5 mm
Diameter	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)
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"> Increasing the quantity of (b) (4) to 	

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