

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17
Common Attributes	
Submission date	September 2, 2020
Receipt date	September 2, 2020
Applicant	Altadis U.S.A. LLC. ¹
Product manufacturer	Tabacalera de Garcia S.A.S.
Product category	Cigars
Product subcategory	Unfiltered, Leaf-Wrapped Cigar
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2021.02.04 16:11:15 -05'00'

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.02.05 14:11:03 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

¹ On November 19, 2020 a Transfer of Ownership was issued acknowledging the transfer of the new and original tobacco products from ITG Cigars to Altadis U.S.A. LLC.

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

The applicant submitted information for the new and original tobacco products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewer(s)	Review Date
regulatory	Jennifer Schmitz	9/14/2020
chemistry	Jason Hsieh	11/18/2020
environmental science	Hermes Reyes Caballero	11/16/2020

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated November 20, 2020 concludes that the evidence submitted by the applicant is adequate to demonstrate the original tobacco products are grandfathered products.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.²

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original tobacco products compared to the corresponding new tobacco products are the result of:

- adding an additive (b)(4) in EX0001269-PD5 and EX0001269-PD7.
- increasing the quantity of an existing additive (b)(4) in EX0001269-PD5 and EX0001269-PD7.
- deleting an additive (b)(4) in EX0001269-PD7, EX0001269-PD11, EX0001270-PD17, EX0001271-PD7, and EX0001271-PD13
- deleting an additive (b)(4) in EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001271-PD13, and EX0001271-PD17.

² Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

- adding an additive (b)(4) in EX0001271-PD3, EX0001271-PD5, EX0001271-PD9, and EX0001271-PD11
- adding an additive (b)(4) in EX0001271-PD5
- deleting an additive (b)(4) in EX0001271-PD7 and EX0001271-PD13

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION³

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on January 28, 2021. The FONSI was supported by an environmental assessment prepared by FDA on January 27, 2021.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are "additives" as defined in section 900(1) of the FD&C Act. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for the protection of the public health. The applicant proposed to increase (b)(4) in EX0001269-PD5 and EX0001269-PD7 by 250% or (b)(4) mg/cigar in the adhesive applied to the head of the cigar binder and wrapper of the new products. However, an equal quantity of (b)(4) is being deleted from this adhesive (b)(4) and (b)(4). (b)(4) are both polysaccharides with identical functions as binding agents. Also, the head of the cigar is removed before use. Therefore, these changes are not anticipated to impact HPHC yields. (b)(4) is being deleted from the new products of EX0001269-PD7, EX0001269-PD11, EX0001270-PD17, EX0001271-PD7, and EX0001271-PD13 and (b)(4) is being deleted from EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001271-PD13, and EX0001271-PD17. The applicant indicated that (b)(4) and (b)(4) are often used as a treatment on the cigar wrapper during the manufacturing process of premium cigar and that (b)(4) is used to ensure uniform color. Furthermore, the deletion of (b)(4) and (b)(4) in the cigar wrapper represents a small quantity difference and does not result in a measurable change to the finished tobacco products. Also, (b)(4) is deleted from the new products of EX0001271-PD7 and EX0001271-PD13 at 0.34 mg/cigar. Therefore, the modification of deleting (b)(4) and (b)(4) from the cigar wrapper in the new tobacco products is not expected to significantly alter the main stream smoke chemistry. (b)(4)

³ On December 8, 2020, FDA issued an Environmental Information Request letter to the applicant prior to finalization of this TPL review, which conveyed the requested information. The applicant provided an amendment on January 8, 2021 with the market volume information.

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

(b)(4) is added to the cigar wrapper in EX0001271-PD3, EX0001271-PD5, EX0001271-PD9, and EX0001271-PD11 to ensure uniform color. (b)(4) contains (b)(4) % of (b)(4) and (b)(4) of other ingredients including (b)(4). Thus, the amount of ingredients other than (b)(4) added to the tobacco product constitutes approximately (b)(4) mg/cigar. Also, (b)(4) is added in EX0001271-PD5 0.34 mg/cigar. Since these quantities are small, any modification on this scale is not anticipated to have a measurable change to the tobacco smoke chemistry. Lastly, I find that an exemption for these modifications is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are grandfathered products; i.e., were commercially marketed in the United States as of February 15, 2007.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco products in EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, aEX0001271-PD17 as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	September 2, 2020	
Receipt date	September 2, 2020	
Applicant	Altadis U.S.A. LLC. ¹	
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 ⁴	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) 	
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 ⁴	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) 	

⁴ Ring gauge was provided instead of diameter by the applicant.

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

	<ul style="list-style-type: none"> Deletion of (b)(4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> Increase in the quantity of (b)(4) 	
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 ⁴	Ring Gauge (1/64 in): 54	Ring Gauge (1/64 in): 54
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of (b)(4) 	
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 ⁴	Ring Gauge (1/64 in): 50	Ring Gauge (1/64 in): 50
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of apple (b)(4) 	
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 ⁴	Ring Gauge (1/64 in): 44	Ring Gauge (1/64 in): 44

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b)(4)	
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 ⁴	Ring Gauge (1/64 in): 52	Ring Gauge (1/64 in): 52
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b)(4)	
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 ⁴	Ring Gauge (1/64 in): 46	Ring Gauge (1/64 in): 46
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b)(4)	
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 ⁴	Ring Gauge (1/64 in): 55	Ring Gauge (1/64 in): 55
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b)(4)	
STN	EX0001271-PD3	GF1906561

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

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 ⁴	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) 	
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 ⁴	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) 	
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 ⁴	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) 	
STN	EX0001271-PD9	GF1602085
Product name	Romeo y Julieta 1875 Exhibicion #1	Romeo y Julieta 1875 Exhibicion #1

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

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 ⁴	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) 	
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 ⁴	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) 	
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 ⁴	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) 	
STN	EX0001271-PD17	GF1907649
Product name	VegaFina Lonsdale	VegaFina Lonsdale

EX0001269-PD5, EX0001269-PD7, EX0001269-PD9, EX0001269-PD11, EX0001269-PD15, EX0001269-PD17, EX0001270-PD15, EX0001270-PD17, EX0001271-PD3, EX0001271-PD5, EX0001271-PD7, EX0001271-PD9, EX0001271-PD11, EX0001271-PD13, EX0001271-PD17

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 ⁴	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. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
November 5, 2020	November 5, 2020	EX0001321	All STNs	Yes	Response to October 29, 2020 FDA Information Request
January 6, 2021	January 8, 2021	EX0001464	All STNs	Yes	Response to December 8, 2020 FDA Environmental Information Request