

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, EX0001267-PD21
Common Attributes	
Submission date	September 2, 2020
Receipt date	September 2, 2020
Applicant	Altadis U.S.A. LLC. ¹
Product manufacturer	Fabrica de Tabacos La Flor de Copan S. de R.L. de C.V.
Product category	Cigars
Product subcategory	Unfiltered, Leaf-Wrapped
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Date: 2021.01.15 13:37:12 -05'00'

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

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.01.15 15:12:52 -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: Reviewers	Review Date
regulatory	Sequoia Bacon	9/28/2020
chemistry	Jason Hsieh	12/14/2020
environmental science	Hermes Reyes Caballero	12/14/2020

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, other than exclusively in test markets, as of February 15, 2007). The OCE review dated December 15, 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:

- deleting an additive (b)(4) in EX0001267-PD1, EX0001267-PD9, EX0001267-PD11, and EX0001267-PD21
- deleting an additive (b)(4) in EX0001267-PD3, EX0001267-PD17, and EX0001267-PD19
- adding an additive (b)(4) in EX0001267-PD5, EX0001267-PD7, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, and EX0001267-PD21
- adding an additive (b)(4) in EX0001267-PD7

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.

EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21

- adding an additive (b)(4) in EX0001267-PD15
- increasing the quantity of an existing additive (b)(4) in EX0001267-PD3, EX0001267-PD17, and EX0001267-PD19.

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 DECISION

The final environmental review found that the applicant did not provide current market volumes or the first- and fifth-year market volume projections for the original tobacco products, and the current and fifth-year market volume projection of the original tobacco products. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or finding of no significant impact (FONSI).

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 proposes to modify the original tobacco products by deleting (b)(4) in EX0001267-PD1 (b)(4) mg/cigar), EX0001267-PD9 (b)(4) mg/cigar), EX0001267-PD11 (b)(4) mg/cigar), and EX0001267-PD21 (72.9 mg/cigar) (b)(4) is often used as a treatment on the cigar wrapper during the cigar manufacturing process and to ensure uniform color. (b)(4) is used as a processing aid that is deleted in the new tobacco products of EX0001267-PD1, EX0001267-PD9, EX0001267-PD11, and EX0001267-PD21; therefore, it is not expected to alter the smoke chemistry significantly. The applicant proposes to modify the original tobacco products by adding: (b)(4) in EX0001271-PD15 (b)(4) mg/cigar); (b)(4) in EX0001267-PD5 (b)(4) mg/cigar), EX0001267-PD7 (b)(4) mg/cigar), EX0001267-PD11 (2.1 mg/cigar), EX0001267-PD13 (b)(4) mg/cigar), EX0001267-PD15 (b)(4) mg/cigar), and EX0001267-PD21 (b)(4) mg/cigar); and (b)(4) in EX0001267-PD7 (b)(4) mg/cigar). (b)(4) and (b)(4) are used as a treatment on the cigar wrapper during the manufacturing process to ensure uniform color. These changes are 0.43% of the total mass of the new tobacco products. Therefore, this proposed change is not expected to impact harmful and potentially harmful constituents (HPHC) yields. The applicant proposes to modify the original tobacco products by deleting (b)(4) mg/cigar) and increasing an equal quantity of (b)(4) mg/cigar) in EX0001267-PD3, EX0001267-PD17, and EX0001267-PD19. (b)(4) and (b)(4) are both polysaccharides commonly used as adhesives in the manufacture of cigars.

(b)(4)

(b)(4)

(b)(4)

Therefore, these changes are not anticipated to have a measurable effect on tobacco smoke or impact HPHC yields. Lastly, I find that an exemption for these modifications are 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, other than exclusively in test markets, as of February 15, 2007.

FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA may be precluded or delayed from issuing an EX order.

An Environmental Information Request letter should be issued requesting the following information:

1. Your EX Requests lack sufficient market volume information for the original and new tobacco products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new tobacco products as compared to the original tobacco products. Provide the current market volume for the original and new tobacco products, the first- and fifth-year projected market volume for the original tobacco products, and the fifth-year projected market volume for the new tobacco products in Table 2.

Table 2. Market Volume for the New and Corresponding Original Products

STN	Units	Current-Year Market Volume	Projected Market Volume	
			First-Year	Fifth-Year
EX0001267/PD1	cigars		(b)(4)	
Original Product to EX0001267/PD1 (GF1805673)	cigars			
EX0001267/PD3	cigars		(b)(4)	
Original Product to EX0001267/PD3 (GF1805676)	cigars			
EX0001267/PD5	cigars		(b)(4)	
Original Product to EX0001267/PD5 (GF1805674)	cigars			
EX0001267/PD7	cigars		(b)(4)	
Original Product to EX0001267/PD7 (GF1805674)				
EX0001267/PD9	cigars		(b)(4)	
Original Product to EX0001267/PD9 (GF1805674)				
EX0001267/PD11	cigars		(b)(4)	
Original Product to EX0001267/PD11 (GF1805674)				
EX0001267/PD13	cigars		(b)(4)	

EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21

Original Product to EX0001267/PD13 (GF1806447)	cigars			
EX0001267/PD15	cigars		(b)(4)	
Original Product to EX0001267/PD15 (GF1806447)				
EX0001267/PD17	cigars		(b)(4)	
Original Product to EX0001267/PD17 (GF1806447)				
EX0001267/PD19	cigars		(b)(4)	
Original Product to EX0001267/PD19 (GF1805549)	cigars			

If the applicant adequately responds to the request and an EIS or FONSI is completed, an exempt order should be issued for the new tobacco products in EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21, as identified on the cover page of this review.

7. APPENDIX**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.	
Product manufacturer	Fabrica de Tabacos La Flor de Copan S. de R.L. de C.V.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001267-PD1	GF1805673
Product name	Saint Luis Rey Serie G Maduro Churchill	Saint Luis Rey Serie G Maduro Churchill
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 58	Ring gauge (1/64 in): 58
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) 	
STN	EX0001267-PD3	GF1805676
Product name	Saint Luis Rey Titan	Saint Luis Rey Titan
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	139.7 mm	139.7 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 60	Ring gauge (1/64 in): 60
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) Increasing/Decreasing the quantity of an existing tobacco additive: <ul style="list-style-type: none"> Increase in the quantity of (b)(4) 	
STN	EX0001267-PD5	GF1805674
Product name	Saint Luis Rey Serie G Maduro No. 6	Saint Luis Rey Serie G Maduro No. 6
Eligibility status	Not applicable	Grandfathered

EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21

Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 60	Ring gauge (1/64 in): 60
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) 	
STN	EX0001267-PD7	GF1805674
Product name	Saint Luis Rey Serie G Maduro No. 6	Saint Luis Rey Serie G Maduro No. 6
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 60	Ring gauge (1/64 in): 60
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) • Addition of (b)(4) 	
STN	EX0001267-PD9	GF1805674
Product name	Saint Luis Rey Serie G Maduro No. 6	Saint Luis Rey Serie G Maduro No. 6
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 60	Ring gauge (1/64 in): 60
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) 	
STN	EX0001267-PD11	GF1805674
Product name	Saint Luis Rey Serie G Maduro No. 6	Saint Luis Rey Serie G Maduro No. 6
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable

EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21

Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 60	Ring gauge (1/64 in): 60
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Addition of (b)(4) 	
STN	EX0001267-PD13	GF1806447
Product name	Las Cabrillas Maximillian Natural	Las Cabrillas Maximillian Natural
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 56	Ring gauge (1/64 in): 56
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) 	
STN	EX0001267-PD15	GF1806447
Product name	Las Cabrillas Maximillian Natural	Las Cabrillas Maximillian Natural
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 56	Ring gauge (1/64 in): 56
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) • Addition of (b)(4) 	
STN	EX0001267-PD17	GF1806447
Product name	Las Cabrillas Maximillian Natural	Las Cabrillas Maximillian Natural
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar

EX0001267-PD1, EX0001267-PD3, EX0001267-PD5, EX0001267-PD7, EX0001267-PD9, EX0001267-PD11, EX0001267-PD13, EX0001267-PD15, EX0001267-PD17, EX0001267-PD19, and EX0001267-PD21

Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 56	Ring gauge (1/64 in): 56
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) Increasing/Decreasing the quantity of an existing tobacco additive: <ul style="list-style-type: none"> • Increase in the quantity of (b)(4) 	
STN	EX0001267-PD19	GF1805549
Product name	Quintero Toro	Quintero Toro
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 56	Ring gauge (1/64 in): 56
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) Increasing/Decreasing the quantity of an existing tobacco additive: <ul style="list-style-type: none"> • Increase in the quantity of (b)(4) 	
STN	EX0001267-PD21	GF1805675
Product name	Saint Luis Rey Serie G Maduro Rothchilde	Saint Luis Rey Serie G Maduro Rothchilde
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Cellophane	Cellophane
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Wrapper material	Natural whole leaf	Natural whole leaf
Additional property	Ring gauge (1/64 in): 56	Ring gauge (1/64 in): 56
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b)(4) • Addition of (b)(4) 	