

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs) and Static Product ID (PDs)	EX0001268 (PD1, PD3, PD5, PD7, PD9, PD11, PD13, PD15, PD17, PD19, and PD21) and EX0001292 (PD1, PD3, PD5, and PD7)
Common Attributes	
Submission date	September 2, 2020, September 4, 2020
Receipt date	September 2, 2020, September 4, 2020
Applicant	Altadis U.S.A. LLC.
Product manufacturer	Altadis U.S.A. LLC.
Product category	Cigar
Product subcategory	Leaf-Wrapped
Cross-Referenced Submissions	
EX0001268 and EX0001292	None
Supporting FDA Memoranda Relied Upon in this Review	
EX0001268 and EX0001292	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.12.14 14:54:33 -05'00'

Charles Feng, Ph.D.
Chemistry Branch II Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.12.14 15:42:24 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND.....	3
1.1. NEW AND ORIGINAL TOBACCO PRODUCTS	3
1.2. REGULATORY ACTIVITY	3
1.3. SCOPE OF REVIEW	3
2. COMPLIANCE REVIEW	3
3. TOBACCO ADDITIVE MODIFICATION.....	3
4. SCIENTIFIC REVIEW.....	4
5. ENVIRONMENTAL DECISION	4
6. CONCLUSION AND RECOMMENDATION	4
7. APPENDICES.....	7

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	Sarah Amyot	9/23/2020
chemistry	Abdur-Rafay Shareef	11/19/2020
environmental science	Thomas Creaven	11/10/2020

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 reviews dated November 18, 2020, November 19, 2020, and November 20, 2020 conclude that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.¹

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 EX0001268 (PD1, PD3, PD5, PD9, PD11, PD15, PD17, PD19, and PD21)
- adding an additive (b) (4) in EX0001268 (PD15)
- deleting an additive (b) (4) adhesive in EX0001268 (PD7) and EX0001292 (PD1, PD3, PD5, and PD7)
- deleting an additive (b) (4) in EX0001268 (PD13) and EX0001292 (PD3)
- increasing the quantity of an existing additive (b) (4) adhesive in EX0001268 (PD7) and EX0001292 PD1, PD3, PD5, and PD7

¹ 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.

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.

In EX0001268-PD1, PD3, PD5, PD9, PD11, PD17, PD19, and PD21, (b) (4) was added. In EX0001268-PD13, (b) (4) was deleted. In EX0001268-PD15, (b) (4) were added. In EX0001268-PD7 and EX0001292-PD1, PD3, PD5, and PD7, (b) (4) adhesive was deleted and (b) (4) adhesive was increased. In EX0001292-PD3, (b) (4) adhesive and (b) (4) were deleted and (b) (4) adhesive was increased. The review concludes that these are minor modifications because these changes do not have negative impact on smoke composition. (b) (4) are ingredients added or deleted from the combustible portion of cigar wrapper. Deletion reduces the amount of combustible materials, and the proposed amounts to be added in this case are too small to have measurable impact on smoke yields. (b) (4) is a (b) (4) and its quantity was increased to replace (b) (4)) with the same quantity. However, these adhesives are applied at the head of the cigar, which is cut prior to lighting by the user or under laboratory testing conditions, and therefore, not in the combustible portion of the cigar. Therefore, this change is unlikely to impact the mainstream smoke chemistry. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

The final environmental review found that the applicant did not provide sufficient market volume information for the original and new 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 a minor modification 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. In EX0001268-PD1, PD3, PD5, PD9, PD11, PD17, PD19, and PD21, (b) (4) was added. In EX0001268-PD13, (b) (4) was deleted. In EX0001268-PD15, (b) (4) and (b) (4) were added. In EX0001268-PD7 and EX0001292-PD1, PD5, and PD7, (b) (4) adhesive was deleted and (b) (4) adhesive was increased. In EX0001292-PD3, (b) (4) adhesive and (b) (4) were deleted and (b) (4) adhesive was increased. The review concludes that these are minor modifications because these changes do not have negative impact on smoke composition. (b) (4) are ingredients added or deleted from the combustible portion of cigar wrapper. Deletion reduces the amount of combustible materials, and the proposed amounts to be

added in this case are too small to have measurable impact on smoke yields. (b) (4) is a (b) (4) and its quantity was increased to replace (b) (4) in the same quantity. However, these adhesives are applied at the head of the cigar, which is cut prior to lighting by the user or under laboratory testing conditions, and therefore, not in the combustible portion of the cigar. Therefore, this change is unlikely to impact the mainstream smoke chemistry. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. 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, 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. All of your EX Requests lack information on the current market volume and the first- and fifth-year market projection volumes for the new tobacco products and the corresponding original products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. Provide the current market volume and the first- and fifth-year market projection volumes for the new tobacco products and the corresponding original products. If you deem any of this information confidential, mark it as such so that it can be placed in a confidential appendix to the public EA document.

New and Original Tobacco Products Market Volumes (Number of Cigar Pieces)						
STN	Current Year Market Volumes		Projected Market Volumes			
	Original Product	New Product	First Year		Fifth Year	
			Original Product	New Product	Original Product	New Product
EX0001268-PD1						
EX0001268-PD3						
EX0001268-PD5						
EX0001268-PD7						
EX0001268-PD9						
EX0001268-PD11						
EX0001268-PD13						
EX0001268-PD15						
EX0001268-PD17						

EX0001268-PD19						
EX0001268-PD21						
EX0001292-PD1						
EX0001292-PD3						
EX0001292-PD5						
EX0001292-PD7						

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	September 2, 2020 and September 4, 2020	
Receipt date	September 2, 2020 and September 4, 2020	
Applicant	Altadis U.S.A. LLC.	
Product manufacturer	Altadis U.S.A. LLC.	
Product category	Cigar	
Product subcategory	Leaf-Wrapped	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1806455
Static Product ID	PD1	Not applicable
Product name	La Aroma de Cuba Holts H2 Double Corona ²	La Aroma de Cuba Holts H2 Double Corona ²
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 millimeters (mm)	190.5 mm
Diameter	Not provided	Not provided
Wrapper material	Whole Leaf	Whole Leaf
Additional property	Ring Gauge: 52 (1/64 in), Shape: Parejo	Ring Gauge: 52 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4) milligram (mg)/cigar	

² Brand/sub-brand or other commercial name used in commercial distribution.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1806018
Static Product ID	PD3	Not applicable
Product name	Big Butt El Camaron ²	Big Butt El Camaron ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	146.05 mm	146.05 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 50 (1/64 in), Shape: Parejo	Ring Gauge: 50 (1/64 in), Shape: Parejo
Product modifications	Addition of tobacco additives: Addition of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1805543
Static Product ID	PD5	Not applicable
Product name	Quintero Churchill ²	Quintero Churchill ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	184.15 mm	184.15 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1805522
Static Product ID	PD7	Not applicable
Product name	Por Larranaga Cuban Grade Double Corona Maduro ²	Por Larranaga Cuban Grade Double Corona Maduro ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	177.8 mm	177.8 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: - Deletion of (b) (4) mg/cigar) Increasing/Decreasing the quantity of existing tobacco additives: - Increase in the quantity of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1908739
Static Product ID	PD9	Not applicable
Product name	La Flor de Copan Lonsdale ²	La Flor de Copan Lonsdale ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	171.45 mm	171.45 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 48 (1/64 in), Shape: Parejo	Ring Gauge: 48 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1806392
Static Product ID	PD11	Not applicable
Product name	La Flor de Copan Short Corona ²	La Flor de Copan Short Corona ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	120.65 mm	120.65 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 42 (1/64 in), Shape: Parejo	Ring Gauge: 42 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1805675
Static Product ID	PD13	Not applicable
Product name	Saint Luis Rey Serie G Maduro Rothchilde ²	Saint Luis Rey Serie G Maduro Rothchilde ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 56 (1/64 in), Shape: Parejo	Ring Gauge: 56 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1805670
Static Product ID	PD15	Not applicable
Product name	Saint Luis Rey Maduro Rothchilde ²	Saint Luis Rey Maduro Rothchilde ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) mg/cigar) • Addition of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1908731
Static Product ID	PD17	Not applicable
Product name	La Flor de Copan Robusto ²	La Flor de Copan Robusto ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001268	GF1805670
Static Product ID	PD19	Not applicable
Product name	Saint Luis Rey Maduro Rothchilde ²	Saint Luis Rey Maduro Rothchilde ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	NEW EX0001268	GF1805555
Static Product ID	PD21	Not applicable
Product name	La Corona Corona Cubana ²	La Corona Corona Cubana ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	146.05 mm	146.05 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 42 (1/64 in), Shape: Parejo	Ring Gauge: 42 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001292	GF1806019
Static Product ID	PD1	Not applicable
Product name	Big Butt Gordito ²	Big Butt Gordito ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	120.65 millimeters (mm)	120.65 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 54 (1/64 in), Shape: Parejo	Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: - Deletion of (b) (4) (b) (4) mg/cigar) Increasing/Decreasing the quantity of existing tobacco additives: - Increase in the quantity of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001292	GF1805675
Static Product ID	PD3	Not applicable
Product name	Saint Luis Rey Serie G Maduro Rothchilde ²	Saint Luis Rey Serie G Maduro Rothchilde ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 56 (1/64 in), Shape: Parejo	Ring Gauge: 56 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: - Deletion of (b) (4) mg/cigar) - Deletion of (b) (4) mg/cigar) Increasing/Decreasing the quantity of existing tobacco additives: - Increase in the quantity of (b) (4) mg/cigar)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001292	GF1805525
Static Product ID	PD5	Not applicable
Product name	Por Larranaga Cuban Grade Robusto ²	Por Larranaga Cuban Grade Robusto ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 48 (1/64 in), Shape: Parejo	Ring Gauge: 48 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: - Deletion of (b) (4) mg/cigar) Increasing/Decreasing the quantity of existing tobacco additives: - Increase in the quantity of (b) (4) mg/cigar)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001292	GF1806390
Static Product ID	PD7	Not applicable
Product name	La Flor de Copan Petite Corona ²	La Flor de Copan Petite Corona ²
Eligibility status	Not applicable	Grandfathered
Marketing Authorization Date	N/A	N/A
Abbreviated Report Date	N/A	N/A
Package Type	Cellophane Wrap	Cellophane Wrap
Package Quantity	1 Cigar	1 Cigar
Characterizing Flavor	None	None
Length	114.3 mm	114.3 mm
Diameter	Not Provided	Not Provided
Wrapper Material	Whole Leaf	Whole Leaf
Additional Properties	Ring Gauge: 44 (1/64 in), Shape: Parejo	Ring Gauge: 44 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: - Deletion of (b) (4) mg/cigar) Increasing/Decreasing the quantity of existing tobacco additives: - Increase in the quantity of (b) (4) mg/cigar)	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
November 5, 2020	November 5, 2020	EX0001320	All	Yes	Active	Response to October 30, 2020 FDA OCE Information Request