

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)
Common Attributes	
Submission date	September 2, 2020 and September 4, 2020
Receipt date	September 2, 2020 and September 4, 2020
Applicant	Tabacalera de Garcia S.A.S.
Product manufacturer	Tabacalera de Garcia S.A.S.
Product category	Cigars
Product subcategory	Unfiltered, Leaf-Wrapped
Cross-Referenced Submissions	
All new products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new products	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: 2020.12.11 14:35:54 -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 Matthew R. Holman -S
Date: 2020.12.11 15:17:18 -05'00'

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

For

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 amendment.

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	Jennifer M. Schmitz and Tachea M. Bailey	9/14/2020 and 9/17/2020
Chemistry	Rachel Lerebours	11/13/2020
Environmental Science	Hermes Reyes-Caballero	11/17/2020

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 reviews dated November 18, 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:

- deleting an additive (b) (4) in EX0001269-PD1, EX0001270-PD11, EX0001270-PD13 EX0001271-PD15
- adding an additive (b) (4) in EX0001270-PD9
- deleting an additive (b) (4) (b) (4) in EX0001269-PD3, EX0001269-PD13, EX0001270-PD1, EX0001270-PD3, EX0001270-PD5, EX0001270-PD13, EX0001271-PD15, EX0001293-PD1, EX0001293-PD3
- deleting an additive (b) (4) in EX0001269-PD3, EX0001271-PD15, EX0001293-PD1, EX0001293-PD3

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.

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

- increasing the quantity of an existing additive (b) (4) in EX0001269-PD3, EX0001271-PD15, EX0001293-PD1, EX0001293-PD3
- deleting an additive (b) (4) in EX0001269-PD13, EX0001270-PD11, EX0001270-PD13, EX0001271-PD15
- adding an additive (b) (4) in EX0001270-PD7, EX0001270-PD9, EX0001271-PD1

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 EX0001269-PD3, EX0001293-PD1 and EX0001293-PD13, (b) (4) were deleted and (b) (4) was increased. In EX0001269-PD13, (b) (4) were deleted. In EX0001270-PD9, (b) (4) were added. In EX0001270-PD11, (b) (4) were deleted. In EX0001270-PD13, (b) (4) were deleted. In EX0001271-PD15, (b) (4) were deleted and (b) (4) 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) and its quantity was increased to replace (b) (4) in the same quantity. (b) (4), the head of cigar (where these adhesives are applied) is cut by the user prior to lighting and these adhesives are not in the combustible portion of the cigar, and therefore, unlikely to impact 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 EX0001269-PD3, EX0001293-PD1 and EX0001293-PD13, (b) (4) were deleted and (b) (4) was increased. In EX0001269-PD13, (b) (4) were deleted. In EX0001270-PD9, (b) (4) were added. In EX0001270-PD11, (b) (4) were deleted. In EX0001270-PD13, (b) (4) were deleted. In EX0001271-PD15, (b) (4) were deleted and (b) (4) was increased. (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 of these ingredients to be added are too small to have measurable impact on smoke yields. (b) (4) its quantity was increased to replace (b) (4) in the same quantity. (b) (4) can generate formaldehyde, acrolein and acetaldehyde, the head of cigar (where these adhesives are applied) is cut by the user prior to lighting and these adhesives are not in the combustible portion of the cigar, and therefore, unlikely to impact mainstream smoke chemistry. Therefore, all these proposed modifications are minor modifications. 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 this modification 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 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 products as compared to the original 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 1.

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Table 1. Market Volume for the New and Corresponding Original Products

STN	Units (cigars)	Current Year Market Volume	Projected Market Volume	
			First- Year	Fifth- Year
EX0001269-PD1	cigars		(b) (4)	
Original Product to EX0001269-PD1 (GF1906962)				
EX0001269-PD3	cigars			
Original Product to EX0001269-PD3 (GF1804185)				
EX0001269-PD13	cigars			
Original Product to EX0001269-PD13 (GF1805647)				
EX0001270-PD1	cigars			
Original Product to EX0001270-PD1 (GF1806376)				
EX0001270-PD3	cigars			
Original Product to EX0001270-PD3 (GF1703460)				
EX0001270-PD5	cigars			
Original Product to EX0001270-PD5 (GF1806046)				
EX0001270-PD7	cigars			
Original Product to EX0001270-PD7 (GF1804205)				
EX0001270-PD9	cigars			
Original Product to EX0001270-PD9 (GF1703489)				
EX0001270-PD11	cigars			
Original Product to EX0001270-PD11 (GF1806057)				
EX0001270-PD13	cigars			
Original Product to EX0001270-PD13 (GF1806057) ²				
EX0001271-PD1	cigars			
Original Product to EX0001271-PD1 (GF1806046) ²				
EX0001271-PD15	cigars			
Original Product to EX0001271-PD15 (GF1907639)				
EX0001293-PD1	cigars			
Original Product to EX0001293-PD1 (GF1806357)				
EX0001293-PD3	cigars			
Original Product to EX0001293-PD3 (GF1906681)				
Total				

² Provide the market volume for the original product only one time if it is repeated in the table.

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
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 Tobacco Product	Original Tobacco Product
STN	EX0001269-PD1	GF1906962
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Romeo y Julieta Aniversario Corona ³	Romeo y Julieta Aniversario Corona ³
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	139.7 mm	139.7 mm
Wrapper material	Whole Leaf	Whole Leaf
Additional property	Premium, Ring Gauge: 44 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 44 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	

³ Brand/sub-brand or other commercial name used in commercial distribution.

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD3	GF1804185
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Romeo y Julieta Reserva Real Petite Robusto ³	Romeo y Julieta Reserva Real Petite Robusto ³
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
Additional property	Premium, Ring Gauge: 54 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 54 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of an existing tobacco additive: • Increase in the quantity of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001269-PD13	GF1806358
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Trinidad Maduro Belicoso ³	Trinidad Maduro Belicoso ³
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	155.7 mm	155.7 mm
Wrapper material	Whole Leaf	Whole Leaf
Additional property	Premium, Ring Gauge: 54 (1/64 in), Shape: Figurado	Premium, Ring Gauge: 54 (1/64 in), Shape: Figurado
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD1	GF1806376
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	H. Upmann Vintage Cameroon Petite Corona ³	H. Upmann Vintage Cameroon Petite Corona ³
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
Additional property	Premium, Ring Gauge: 40 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 40 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD3	GF1703460
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	H. Upmann Cedar Aged Churchill ³	H. Upmann Cedar Aged Churchill ³
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	143 mm	143 mm
Wrapper material	Whole Leaf	Whole Leaf
Additional property	Premium, Ring Gauge: 46 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 46 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD5	GF1806046
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Flor de Canarias Lonsdale ³	Flor de Canarias Lonsdale ³
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
Additional property	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Deletion of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD7	GF1804205
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Romeo y Julieta Vintage Vintage II ³	Romeo y Julieta Vintage Vintage II ³
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
Additional property	Premium, Ring Gauge: 46 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 46 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: Addition of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD9	GF1703489
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Montecristo Classic Collection Toro ³	Montecristo Classic Collection Toro ³
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
Additional property	Premium, Ring Gauge: 52 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 52 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) • Addition of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD11	GF1806057
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Hoffman House Short Perfecto ³	Hoffman House Short Perfecto ³
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
Additional property	Premium, Ring Gauge: 46 (1/64 in), Shape: Figurado	Premium, Ring Gauge: 46 (1/64 in), Shape: Figurado
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001270-PD13	GF1806057
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Hoffman House Short Perfecto ³	Hoffman House Short Perfecto ³
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
Additional property	Premium, Ring Gauge: 46 (1/64 in), Shape: Figurado	Premium, Ring Gauge: 46 (1/64 in), Shape: Figurado
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD1	GF1806046
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Flor de Canarias Lonsdale ³	Flor de Canarias Lonsdale ³
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
Additional property	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001271-PD15	GF1907639
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product name	Trinidad Fundador ³	Trinidad Fundador ³
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
Additional property	Premium, Ring Gauge: 40 (1/64 in), Shape: Parejo	Premium, Ring Gauge: 40 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of an existing tobacco additive: • Increase in the quantity of (b) (4)	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001293-PD1	GF1806357
Submission date	September 4, 2020	Not Applicable
Receipt date	September 4, 2020	Not Applicable
Product name	H. Upmann Petite Churchill ³	H. Upmann Petite Churchill ³
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	114.3 mm	114.3 mm
Wrapper material	Whole Leaf	Whole Leaf
Additional property	Premium Ring gauge 46 (1/64 in), Shape: Parejo.	Premium Ring Gauge: 46 (1/64 in), Shape: Parejo
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	

EX0001269 (PD1, PD3, PD13), EX0001270 (PD1, PD3, PD5, PD7, PD9, PD11, PD13), EX0001271 (PD1, PD15), EX0001293 (PD1, PD3)

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001293-PD3	GF1906681
Submission date	September 4, 2020	Not Applicable
Receipt date	September 4, 2020	Not Applicable
Product name	Nat Sherman Morgan ³	Nat Sherman Morgan ³
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
Additional property	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo.	Premium, Ring Gauge: 42 (1/64 in), Shape: Parejo.
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	

Appendix B. Amendment

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
November 5, 2020	November 5, 2020	EX0001321	All	Yes	Active	Response to October 29, 2020 FDA Information Request