

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0002010.PD1 - EX0002023.PD1
Common Attributes	
Submission date	June 2, 2021
Receipt date	June 2, 2021
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 Submission	
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):

For Jeffrey Ammann
Digitally signed by Jeannie H. Jeong-im -S
Date: 2022.06.27 15:26:13 -04'00'

Jeffrey R. Ammann, Ph.D.
Chemistry Team Supervisor
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil
-S
Date: 2022.06.28 09:16:29 -04'00'

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

¹ Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

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

1.2. REGULATORY ACTIVITY

See appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1	
Discipline	Reviewer(s)	Review Date
Regulatory	Michael Jokoh	10/27/2021
Chemistry	Norman Fraley	5/26/2022
Environmental science	William Brenner	5/12/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated May 24, 2022, conclude that the evidence submitted by the applicant is adequate to demonstrate original products are grandfathered products.

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

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (b) (4) in all the EX Requests
- deleting an additive (b) (4) in all the EX Requests
- deleting an additive (b) (4) in EX0002017.PD1, EX0002019.PD1, and EX0002023.PD1
- deleting an additive (b) (4) in EX0002019.PD1
- increasing the quantity of an existing additive (b) (4) in all the EX Requests

² Any 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 products. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic (FD&C Act).

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on May 19, 2022. The FONSI was supported by an environmental assessment prepared by FDA on May 19, 2022.

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 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 products to be marketed would be appropriate for the protection of the public health. The applicant proposes to increase (b) (4) in the new products of all the EX Requests by (b) (4) in the adhesive applied to the head of the cigar binder and wrapper of the new products. However, an (b) (4) amount of (b) (4) is being deleted from this adhesive in the original products of all EX Requests. (b) (4) and (b) (4) are both (b) (4) with identical functions as binding agents. Also, the head of the cigar is removed before use. Therefore, these changes are not anticipated to impact harmful and potential harmful constituent (HPHC) yields. (b) (4) is being deleted from the new products of EX0002017.PD1 ((b) (4)), EX0002019.PD1 (at (b) (4)), and EX0002023.PD1 (at (b) (4)) and (b) (4) (at (b) (4)) is being deleted from the new products of all EX Requests. The applicant indicated that (b) (4) are often used as a treatment on the cigar wrapper during the manufacturing process of premium cigars and that (b) (4) is used to ensure uniform color. Furthermore, the deletion of (b) (4) (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 product of EX0002019.PD1 at (b) (4) cigar. The applicant indicated that (b) (4) is used as a treatment on the cigar wrapper during the manufacturing process cigars to ensure uniform color of the cigars. 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original 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 products exempt and made a finding of no significant impact.

An exempt order should be issued for the new products, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original products³

Common Attributes of EX REQs		
Submission date	June 2, 2021	
Receipt date	June 2, 2021	
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 Product	Original Product
STN	EX0002010.PD1	GF1805610
Product name	Altadis 47 x 6 Parejo	Royal Jamaica Gold Park Lane
Eligibility status	Not applicable (N/A)	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 millimeters (mm)	152.4 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 47 (1/64 in)	Ring Gauge: 47 (1/64 in)
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)	

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

⁴ Although the applicant did not provide the diameter, values for diameter may be calculated from the ring gauge values provided by the applicant (see Additional Property).

Attributes	New Product	Original Product
STN	EX0002011.PD1	GF1906561
Product name	Montecristo Corona Grande	Montecristo Corona Grande
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	146.05 mm	146.05 mm
Diameter ⁴	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: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002012.PD1	GF1805639
Product name	VegaFina Corona	VegaFina Corona
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	146.05 mm	146.05 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 43 (1/64 in)	Ring Gauge: 43 (1/64 in)
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)	

Attributes	New Product	Original Product
STN	EX0002013.PD1	GF1804369
Product name	Altadis 44 x 4 1/4 Parejo	Montecristo No 444
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 44 (1/64 in)	Ring Gauge: 44 (1/64 in)
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)	
Attributes	New Product	Original Product
STN	EX0002014.PD1	GF1806367
Product name	Altadis 47 x 5 Parejo	H. Upmann H2000 #7 Habano
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 47 (1/64 in)	Ring Gauge: 47 (1/64 in)
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)	

Attributes	New Product	Original Product
STN	EX0002015.PD1	GF1907650
Product name	Altadis 40 x 4 Parejo	VegaFina No. 5
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	101.6 mm	101.6 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of additive: (b) (4) • Deletion of additive: (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002016.PD1	GF1702946
Product name	Altadis 39 x 6 3/4 Parejo	Montecristo Fancytals
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	171.45 mm	171.45 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 39 (1/64 in)	Ring Gauge: 39 (1/64 in)
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)	

Attributes	New Product	Original Product
STN	EX0002017.PD1	GF1804149
Product name	Altadis 48 x 6 Parejo	Onyx Black Prince
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Diameter ⁴	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: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002018.PD1	GF1906667
Product name	Altadis 32 x 6 Parejo	Nat Sherman #65 Gotham West Side
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	152.4 mm	152.4 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 32 (1/64 in)	Ring Gauge: 32 (1/64 in)
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)	

Attributes	New Product	Original Product
STN	EX0002019.PD1	GF1805645
Product name	Altadis 47 x 5 Parejo	Trinidad Corona
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 45 (1/64 in)	Ring Gauge: 45 (1/64 in)
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 existing tobacco additives: • Increase in the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002020.PD1	GF1806376
Product name	Altadis 47 x 5 Parejo	H. Upmann Vintage Cameroon Petite Corona
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 40 (1/64 in)	Ring Gauge: 40 (1/64 in)
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)	

Attributes	New Product	Original Product
STN	EX0002021.PD1	GF1702948
Product name	Altadis 47 x 4 1/4 Parejo	Montecristo Half Corona
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Diameter ⁴	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: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002022.PD1	GF1804208
Product name	Altadis 60 x 6 1/2 Parejo	Romeo y Julieta Vintage Vintage VI
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter ⁴	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: • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	

Attributes	New Product	Original Product
STN	EX0002023.PD1	GF1805632
Product name	Altadis 55 x 5 Parejo	Trinidad Maduro Robusto
Eligibility status	N/A	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter ⁴	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property	Ring Gauge: 55 (1/64 in)	Ring Gauge: 55 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)	