

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0002041.PD1-EX0002048.PD1
Common Attributes	
Submission date	June 6, 2021
Receipt date	June 6, 2021
Applicant	Tabacalera de Garcia S.A.S.
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 Tricia L. Johnson -S
Date: 2022.06.13 14:15:39 -04'00'

Tricia Johnson, M.A.
Supervisory Chemist
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: 2022.06.13 15:24:07 -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	Kyle Ferguson	5/11/2022
Environmental science	Corey DeBoom	5/16/2022

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 review dated, May 24, 2022, concludes 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

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.

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 EX0002041.PD1, EX0002043.PD1, and EX0002045.PD1
- deleting additives (b) (4) in EX0002043.PD1 and EX0002045.PD1
- increasing the quantity of an existing additive (b) (4) in all the EX Requests

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 FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on May 17, 2022. The FONSI was supported by an environmental assessment prepared by FDA on May 17, 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.

For all EX Requests, the applicant proposed modifying all the original products by deleting an additive, (b) (4) (EX0002041.PD1, EX0002043.PD1, and EX0002045.PD1), (b) (4) (EX0002043.PD1 and EX0002045.PD1), (b) (4) (All EX Requests), and (b) (4) (All EX Requests) from the corresponding new products, and increasing the quantity of an existing additive, (b) (4) (All EX Requests), in all the corresponding new products. Furthermore, the design parameters (i.e., diameter, length, weight) are identical between all the new and corresponding original products.

The applicant states that (b) (4) (EX0002041.PD1, EX0002043.PD1 and EX0002045.PD1), (b) (4) (EX0002043.PD1 and EX0002045.PD1), and (b) (4) (All EX Requests) are used as

processing aids to ensure color uniformity to the wrapper in the original products. However, the applicants stated that these additives are no longer used in the manufacturing process in all the new products. (b) (4)

Therefore, the removal of the additive quantities (i.e., (b) (4)) from the wrapper in the new products is not expected to have a measurable impact on the cigar mainstream smoke yields in the new products compared to the corresponding original product. Additionally, the applicant proposed modifying all the original products by removing (b) (4) (b) (4) g/cigar) and increasing the quantity of (b) (4) (↑250%, (b) (4) g/cigar) in the wrapper in the corresponding new products. Both (b) (4) and (b) (4) are adhesives, consisting of a mixture of (b) (4) respectively. (b) (4)

However, the adhesives are not combusted during consumer use and unlikely to impact the mainstream smoke yields in the new products compared to the corresponding original products. Collectively, the proposed modifications to the original products in EX0002041.PD1-EX0002048.PD1 are minor modifications in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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 products

Common Attributes		
Submission date	June 6, 2021	
Receipt date	June 6, 2021	
Applicant	Tabacalera de Garcia S.A.S.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigars	
Product subcategory	Unfiltered, Leaf-Wrapped Cigar	
Attributes	New Product	Original Product
STN	EX0002041.PD1	GF1804167
Product name	Altadis 60 x 5 1/2 Figurado	Onyx Reserve Torbusto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	139.7 mm	139.7 mm
Diameter	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) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4)	

Attributes	New Product	Original Product
STN	EX0002042.PD1	GF1805480
Product name	Altadis 42 x 5 1/16 Parejo	Don Diego Privada Petite Corona
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	128.52 mm	128.52 mm
Diameter	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: • Increasing the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002043.PD1	GF1907622
Product name	Altadis 48 x 6 1/2 Figurado	Seijas' Signature Series Perfecto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter	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) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4)	

Attributes	New Product	Original Product
STN	EX0002044.PD1	GF1906697
Product name	Altadis 42 x 6 7/8 Parejo	Por Larranaga Cetros
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	174.63 mm	174.63 mm
Diameter	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: • Increasing the quantity of (b) (4)	

Attributes	New Product	Original Product
STN	EX0002045.PD1	GF1806057
Product name	Altadis 46 x 4 1/4 Figurado	Hoffman House Short Perfecto
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	107.95 mm	107.95 mm
Diameter	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) • Deletion of (b) (4) • Deletion of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002046.PD1	GF1805479
Product name	Altadis 42 x 5 9/16 Parejo	Don Diego Privada #4
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	141.29 mm	141.29 mm
Diameter	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: • Increasing the quantity of (b) (4)	

Attributes	New Product	Original Product
STN	EX0002047.PD1	GF1804376
Product name	Altadis 52 x 5 Figurado	Montecristo Serie V Mini Belicoso
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	127 mm	127 mm
Diameter	Not Provided	Not Provided
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional property	Ring Gauge: 52 (1/64 in)	Ring Gauge: 52 (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: - Increasing the quantity of (b) (4)	
Attributes	New Product	Original Product
STN	EX0002048.PD1	GF1805274
Product name	Altadis 48 x 7 1/2 Parejo	Butera Royal Vintage Capo Grande
Eligibility status	Not applicable	Grandfathered
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	190.5 mm	190.5 mm
Diameter	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) Increasing/Decreasing the quantity of existing tobacco additives: - Increasing the quantity of (b) (4)	

Appendix B. Amendments

None