

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0002089.PD1-EX0002091.PD1, EX0002143.PD1, EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1
Common Attributes	
Submission date	June 28, 2021, July 8, 2021, and July 14, 2021
Receipt date	June 28, 2021, July 8, 2021, and July 14, 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 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: 2022.09.20 17:20:27 -04'00'

Tricia L. Johnson, M.A.
 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: 2022.09.21 14:52:08 -04'00'

Todd L. Cecil, Ph.D.
 Acting 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 appendix for products.

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	6/2/2022
Environmental Science	Susana AddoNtim	5/31/2022

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 June 11, 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 EX0002089.PD1
- deleting an additive (b)(4) in EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1
- deleting an additive (b)(4) in EX0002089.PD1-EX0002091.PD1, and EX0002143.PD1
- deleting an additive (b)(4) in all the EX Requests
- adding an additive (b)(4) in EX0002089.PD1-EX0002091.PD1, and EX0002143.PD1
- increasing the quantity of an existing additive (b)(4) in EX0002144.PD1, EX0002146.PD1, and EX0002147.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 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 June 3, 2022. The FONSI was supported by an environmental assessment prepared by FDA on June 1, 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) (EX0002089.PD1) (b)(4) (EX0002089.PD1-EX0002091.PD1, and EX0002143.PD1), (b)(4) (EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1), and (b)(4) (all EX Requests) from the cigar wrapper in the corresponding new products, adding an additive, (b)(4) (EX0002089.PD1-EX0002091.PD1, and EX0002143.PD1) to the cigar wrapper in corresponding new products, and increasing the quantity of an existing additive, (b)(4) (EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1), to the wrapper in the corresponding new products. The design parameters (i.e., diameter, length, weight) are identical

between all the new and corresponding original products. The applicant states that the adhesives, (b)(4) are applied to the (b)(4) of the cigar, during the (b)(4). After cutting the cigar cap, prior to lighting the cigar, only a trace amount of the adhesives remains. (b)(4) (b)(4) g/cigar) is an (b)(4) consisting primarily of (b)(4) (4.8 – 6.0% w/v), which represents 0.44% of the total cigar weight in the original product in EX0002089.PD1. (b)(4) mg/cigar) is used as a processing aid and preservative in the cigar wrapper, which accounts for (b)(4)% of the total cigar weight in the original products in EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1. The complex additive, (b)(4) g/cigar), consists of a (b)(4) (b)(4) (b)(4) is a (b)(4)-based adhesive, consisting of (b)(4) and (b)(4). (b)(4) is a low toxicity (b)(4) adhesive, consisting of (b)(4), and used as a (b)(4) (b)(4) in (b)(4). In modifying the new products in EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1, the applicant deleted (b)(4) g/cigar) from the cigar wrapper in the new products, while increasing the quantity of (b)(4) (↑250% (b)(4) g/cigar) in the new products compared to the corresponding original products (b)(4) g/cigar). Collectively, (b)(4) quantities are similar between the new and original product in EX0002090.PD1 (↑1.89%, (b)(4) g/cigar). However, these additives decreased in the new products in EX0002089.PD1 (↓13%, (b)(4) g/cigar), EX0002091.PD1 (↓13%, (b)(4) g/cigar), and EX0002143.PD1 (↓27%, (b)(4) g/cigar), compared to the corresponding original products. Because the design parameters (i.e., diameter, length, weight) are identical between all the new and corresponding original products in EX0002089.PD1-EX0002091.PD1, EX0002143.PD1, EX0002144.PD1, EX0002146.PD1, and EX0002147.PD1, the changes are relatively small, compared to the total cigar weight. Furthermore, the modifications are not expected to result in any measurable difference in mainstream smoke yields in the new products compared to the corresponding original 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 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^{a,b}

Common Attributes		
Submission date	June 28, 2021, July 8, 2021, and July 14, 2021	
Receipt date	June 28, 2021, July 8, 2021, and July 14, 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	EX0002089.PD1	GF1805269
Product name	Blender's Gold Dominican Maduro Churchill	Blender's Gold Dominican Maduro Churchill
Eligibility status	Not Applicable (N/A)	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 50 (1/64 in)	Ring Gauge: 50 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) • (b)(4) 	

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

^b Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification.

<https://www.congress.gov/bill/117th-congress/house-bill/2471>

^c 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	EX0002090.PD1	GF1804183
Product name	Altadis 28 x 4 7/8 Parejo	Romeo y Julieta 1875 Julietas
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	123.95 mm	123.95 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 28 (1/64 in)	Ring Gauge: 28 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	
STN	EX0002091.PD1	GF1806025
Product name	Altadis 36 x 6 ¹ / ₂ Parejo	Blenders Gold Dominican Panetella
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	165.1 mm	165.1 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 36 (1/64 in)	Ring Gauge: 36 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	

Attributes	New Product	Original Product
STN	EX0002143.PD1	GF1806024
Product name	Altadis 43 x 6 ¹ / ₁₆ Parejo	Blenders Gold Dominican Lonsdale
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cellophane	Cellophane
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	153.92 mm	153.92 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 43 (1/64 in)	Ring Gauge: 43 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) • (b)(4) 	
STN	EX0002144.PD1	GF1804186
Product name	Altadis 36 x 7 Parejo	Romeo y Julieta Reserva Real Porto Real
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Cedar-lined aluminum Tube	Cedar-lined aluminum Tube
Package quantity	1 Cigar	1 Cigar
Characterizing flavor	None	None
Length	177.8 mm	177.8 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 36 (1/64 in)	Ring Gauge: 36 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (b)(4) 	

Attributes	New Product	Original Product
STN	EX0002146.PD1	GF1702857
Product name	Altadis 42 x 5 ⁵ / ₈ Parejo	Montecristo No. 10
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Box	Box
Package quantity	25 Cigars	25 Cigars
Characterizing flavor	None	None
Length	143 mm	143 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 42 (1/64 in)	Ring Gauge: 42 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (b)(4) 	
Attributes	New Product	Original Product
STN	EX0002147.PD1	GF1702858
Product name	Altadis 38 x 6 ⁷ / ₈ Parejo	Montecristo No. 20
Eligibility status	N/A	Grandfathered
Marketing authorization date	N/A	N/A
Abbreviated report date	N/A	N/A
Package type	Box	Box
Package quantity	25 Cigars	25 Cigars
Characterizing flavor	None	None
Length	174.75 mm	174.75 mm
Diameter ^c	Not Provided	Not Provided
Wrapper material	(b)(4) tobacco	(b)(4) tobacco
Nicotine Source:	Tobacco	Tobacco
Additional Property	Ring Gauge: 38 (1/64 in)	Ring Gauge: 38 (1/64 in)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • (b)(4) • (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • (b)(4) 	