FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Request

New Product Subject of this Review[1]	
STN	EX0002035.PD1
Common Attributes	
Submission date	June 4, 2021
Receipt date	June 4, 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	
EX0002035.PD1	None
Supporting FDA Memoranda Relied Upon in this Review	
EX0002035.PD1	None
Recommendation	
Issue an Exempt (EX) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Tricia L. Johnson -S
Date: 2022.11.14 12:52:37 -05'00'

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: 2022.11.14 13:16:52 -05'00'

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 product and amendment.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

	Cycle 1		Cycle 2	
Discipline	**Reviewer(s)**	**Review Date**	**Reviewer(s)**	**Review Date**
Regulatory	Michael Jokoh	10/27/2021	Not Applicable (N/A)	N/A
Chemistry	Kyle Ferguson	5/11/2022	N/A	N/A
Environmental science	Corey DeBoom	5/16/2022	Corey DeBoom	10/5/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original product is a pre-existing[2] product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated September 29, 2022, concludes that the evidence submitted by the applicant is adequate to demonstrate original product is a pre-existing product. Therefore, the original product is eligible for modification under the Exemption Request pathway.[3]

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive ((b) (4)) in EX0002035.PD1
- deleting an additive ((b) (4)) in EX0002035.PD1
- increasing the quantity of an existing additive ((b) (4)) in EX0002035.PD1

[2] FDA updated the term "grandfathered tobacco product" (GF) to "pre-existing tobacco product" (PTP). This update will not affect review of pending submissions and STNs will not change retroactively. You may continue to use the STN (GF or PX) assigned in the FDA Acceptance letter confirming receipt of your submission. Refer to FDA's website for more information on the GF to PTP update.

[3] 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 product. 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 October 5, 2022. The FONSI was supported by an environmental assessment prepared by FDA on October 5, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications 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 product to be marketed would be appropriate for the protection of the public health.

The applicant proposed modifying the original product by deleting additives, (b) (4) , and increasing the quantity of an existing additive, (b) (4) , to the wrapper in the new product in EX0002035.PD1. The design parameters (i.e., diameter, length, weight) are identical between the new and original products.

The applicant states that (b) (4) is used as a (b) (4) (b) (4) , (b) (4) the new product. (b) (4) has previously been used as a preservative against both bacteria (*Escherichia coli*)[1] and fungi (*Candida albicans*)[2] and is comprised of (b) (4) mg/cigar) of the total cigar weight. Therefore, the removal of (b) (4)) from the wrapper in the new product is not expected to have a measurable impact on the cigar mainstream smoke yields in the new product compared to the original product. Additionally, the applicant proposed modifying the original product by deleting (b) (4) (b) (4) g/cigar) and increasing the quantity of (b) (4) ((b) (4) g/cigar) to the wrapper in the new product. Furthermore, (b) (4) and (b) (4) are adhesives, (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 product compared to the original product. Collectively, the proposed modifications to the original product in EX0002035.PD1 are minor modifications in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Lastly, I find that

(b) (4)

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 product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product is a pre-existing product, i.e., were commercially marketed in the United States as of February 15, 2007.

FDA has examined the environmental effects of finding the new product exempt and made a finding of no significant impact.

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

7. APPENDICES

Appendix A. New and original products

Common Attributes		
Submission date	June 4, 2021	
Receipt date	June 4, 2021	
Applicant	Tabacalera de Garcia S.A.S.	
Product manufacturer	Tabacalera de Garcia S.A.S.	
Product category	Cigar	
Product subcategory	Unfiltered, Leaf-Wrapped	
Attributes	**New Product**	**Original Product**
STN	EX0002035.PD1	GF1804219
Product name	Altadis 38 x 6 1/2 Parejo[3]	Romeo y Julieta 1875 Lancero
Eligibility status	Not applicable	Pre-existing
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	Tobacco	Tobacco
Nicotine Source	Tobacco	Tobacco
Length	165.1 Millimeter (mm)	165.1 mm
Diameter (Ring Gauge 1/64 in)	38	38
Wrapper material	Whole leaf tobacco	Whole leaf tobacco
Additional Property[4]	Bundle 5	Bundle 5
Product modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) [redacted] mg/cigar) • Deletion of (b) (4) [redacted] g/cigar) Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4) [redacted] g/cigar)	

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

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
September 2, 2022	September 2, 2022	EX0002832	EX0002035.PD1	Yes	Response to August 12, 2022, Deficiency letter