

Technical Project Lead (TPL) Review of Exemption Requests

| New Products Subject of this Review | |
|--|---------------------------------|
| Submission tracking numbers (STNs) | EX0001545.PD1, EX0001545.PD3 |
| Common Attributes | |
| Submission date | February 11, 2021 |
| Receipt date | February 11, 2021 |
| Applicant | ITG Cigars, LLC |
| Product manufacturer | ITG Cigars, LLC |
| Product category | Cigars |
| Product subcategory | Unfiltered, Sheet-Wrapped Cigar |
| Cross-Referenced Submissions | |
| All EX Requests | None |
| Supporting FDA Memoranda Relied Upon in this Review | |
| All EX Requests | None |
| Recommendation | |
| Issue an Exempt (EX) order for the new tobacco product subject of this review. | |

Technical Project Lead (TPL):

Digitally signed by Jeffrey R. Ammann -S
Date: 2022.04.21 15:00:17 -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: 2022.05.05 08:06:06 -04'00'

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

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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

| Discipline | Cycle 1 | | Cycle 2 | |
|-----------------------|--------------|-------------|--------------|-------------|
| | Reviewer(s) | Review Date | Reviewer(s) | Review Date |
| regulatory | Megan Nguyen | 2/19/2021 | Not Reviewed | N/A |
| chemistry | Jason Hsieh | 7/23/2021 | Not Reviewed | N/A |
| environmental science | Chad Baisden | 7/7/2021 | Chad Baisden | 3/15/2022 |

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 March 26, 2022 concludes that the evidence submitted by the applicant is adequate to demonstrate original-products are grandfathered products.

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 the cigar binder) in all the EX Requests
- deleting an additive (cigar tip reinforcing tape (b) (4) in all the EX Requests
- deleting an additive (cigar tip reinforcing tape adhesive (b) (4)) in all the EX Requests
- adding an additive (b) (4) in the cigar binder) in all the EX Requests
- adding an additive (cigar tip adhesive (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 March 17, 2022. The FONSI was supported by an environmental assessment prepared by FDA on March 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 products subject of this review, the applicant proposed the deletion of an adhesive ((b) (4)) in the cigar binder and addition of an adhesive ((b) (4)) in the cigar binder. The applicant also proposed to modify how the wood tip is affixed to the cigar by deletion of the tip reinforcement tape ((b) (4)) and associated adhesive ((b) (4)), with the addition of a tip adhesive ((b) (4)). The quantities of adhesive in the binders of the new products are lower than in the corresponding original products, and the ((b) (4)) represents 2% of the total cigar binder ingredient, which is minor. Modification of the wood tips of the new products involve non-combusted components of the cigar and is not anticipated to have a measurable change or impact on harmful and potentially harmful constituents (HPHCs) in smoke yields. Therefore, the addition and deletion of adhesives (and deletion of tip reinforcement tape) in the new products of both EX Reports are minor modifications and should not materially affect other characteristics (materials, ingredients, design, composition, or other features) of the new 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

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.

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).

7. APPENDICES

Appendix A. New and original products

| Common Attributes | | |
|-----------------------|---|---------------------------------|
| Submission date | February 11, 2021 | |
| Receipt date | February 11, 2021 | |
| Applicant | ITG Cigars Inc. | |
| Product manufacturer | ITG Cigars Inc. | |
| Product category | Cigars | |
| Product subcategory | Unfiltered, Sheet-Wrapped Cigar | |
| Attributes | New Product | Original Product |
| STN | EX0001545.PD1 | GF1702882 |
| Product name | HAV-A-TAMPA Jewels Original Cigars 5pk (NW) | Havatampa Jewels Reg 5pk |
| Eligibility status | Not applicable | Grandfathered |
| Package type | OPP film-wrapped | OPP film-wrapped |
| Package quantity | 1 Cigar | 1 Cigar |
| Characterizing flavor | None | None |
| Diameter | 11.51 mm | 11.51 mm |
| Length | 123.8 mm | 123.8 mm |
| Tip | Wood tip | Wood tip |
| Additional Property | Ventilation: 0%, Wrapper: Sheet | Ventilation: 0%, Wrapper: Sheet |
| Product modifications | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cigar binder, (b) (4) • Addition of (b) (4) • Deletion of tip reinforcement tape ("TRT") and associated TRT adhesive • Addition of tip adhesive, (b) (4) | |
| Attributes | New Product | Original Product |
| STN | EX0001545.PD3 | GF1702886 |
| Product name | HAV-A-TAMPA Jewels Sweet Cigars 5pk (NW) | Havatampa Jewels Swt 5pk |
| Eligibility status | Not applicable | Grandfathered |
| Package type | OPP film-wrapped | OPP film-wrapped |
| Package quantity | 1 Cigar | 1 Cigar |
| Characterizing flavor | None | None |
| Diameter | 11.51 mm | 11.51 mm |
| Length | 123.8 mm | 123.8 mm |
| Tip | Wood tip | Wood tip |
| Additional Property | Ventilation: 0%, Wrapper: Sheet | Ventilation: 0%, Wrapper: Sheet |
| Product modifications | Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cigar binder, (b) (4) • Addition of (b) (4) • Deletion of tip reinforcement tape ("TRT") and associated TRT adhesive • Addition of tip adhesive, (b) (4) | |

Appendix B. Amendments

| Submission Date | Receipt Date | Amendment | Applications being amended | Reviewed | Brief Description |
|------------------------|---------------------|------------------|-----------------------------------|-----------------|---|
| September 16, 2021 | September 16, 2021 | EX0002403 | All | Yes | Response to August 18, 2021 Deficiency Letter |