

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0002339.PD1, EX0002339.PD3, EX0002339.PD5, EX0002339.PD7, EX0002339.PD9, and EX0002339.PD11
Common Attributes	
Submission date	September 10, 2021
Receipt date	September 10, 2021
Applicant	ITG Brands LLC
Product manufacturer	ITG Brands LLC
Product category	Cigarette
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
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: 2022.08.30 14:36:26 -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: 2022.08.30 14:42:16 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
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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 corresponding 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	
	Reviewer(s)	Review Date
Regulatory	Kenna Randall	9/20/2021
Chemistry	Therese Ku	8/5/2022
Environmental science	Yasmin Termeh-Zonoozi	8/4/2022

2. COMPLIANCE REVIEW

The original products in all EX Requests were determined to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence by FDA. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and at least 90 days have elapsed since receipt of the Abbreviated Reports by FDA.

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 (FSC cigarette paper) in all the EX Requests
- adding an additive (alternative FSC cigarette paper) 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 FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on August 11, 2022. The FONSI was supported by an environmental assessment prepared by FDA on August 11, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that this modification (see Section 3) is 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.

In all EX Requests, the applicant proposes modifying all the original products by deleting a FSC cigarette paper (b) (4) from the cigarette in the original products and adding an alternative FSC cigarette paper (b) (4) to the cigarette in the corresponding new products, which are both manufactured by (b) (4). The FSC cigarette paper ingredients (b) (4) – (b) (4) mg/cigarette) in the new and corresponding original products are composed of cellulose fibers, filler, combustion modifiers, binder, banding materials and processing aids. Although some of the new and corresponding original products contain similar cigarette design parameters (i.e., cigarette weight, filter ventilation, cigarette draw resistance (pressure drop open)), the following design parameter differences between all the new and corresponding original products include:

(b) (4)

The container closure system between the new and corresponding original products are identical, consisting of a foil inner liner, inner frame, box, film overlap, and carton.

As a result of deleting the FSC cigarette paper in the original products and adding an alternative FSC cigarette paper in the corresponding new products, the total FSC cigarette paper ingredient quantity increased by (b) (4) mg/cigarette) in the new products compared to the corresponding original products. This change may be contributed to the following single ingredient quantity differences between the new and corresponding original products: (b) (4)

(b) (4)

mg/cigarette); but not in the corresponding original products. Similarly, the following single ingredients are present in the original products: (b) (4)

(b) (4) but not in the corresponding new products. The carbohydrate containing ingredients (e.g., (b) (4)) increased by (b) (4) mg/cigarette) in the new products compared to the corresponding original products. (b) (4)

However, the carbohydrate ingredients represent (b) (4) % of the total cigarette weight in the new products (b) (4) mg/cigarette).

Combustion modifier ingredients, (b) (4), increased by (b) (4) % ((b) (4) mg/cigarette) and decreased by (b) (4) mg/cigarette), respectively, in the new products compared to the corresponding original products. (b) (4)

(b) (4) alter the burn rate. However, the combustion modifier ingredient quantities represent (b) (4) % of the total cigarette weight in the new products. Furthermore, differences in base paper basis weight, banded paper basis weight, base paper porosity, band spacing, and cigarette draw resistance (pressure drop open) between the new and the corresponding original products may affect mainstream smoke yields, such as tar, nicotine, and carbon monoxide (TNCO).

The applicant provided tar, nicotine, and carbon monoxide (TNCO) data and puff count in all the new and corresponding original products, under ISO and Health Canadian Intense (HCI) smoking regimens. The mainstream smoke data were evaluated, using a two one-sided t-test (TOST) analysis was used to determine the average mean difference in the TNCO yields between the new and corresponding predicate products. TNCO yields were identical and similar between the new and corresponding predicate products, but the new and corresponding original products in some instances, TNCO yields decreased by 6-13% (0.07-2.0 mg/cigarette) in the new products compared to the corresponding original products. Therefore, the FSC cigarette paper ingredients in the new products compared to the corresponding original products did not significantly alter the tobacco smoke chemistry.

The proposed modification to the original products in EX0002339.PD1, EX0002339-PD3, EX0002339-PD5, EX0002339-PD7, EX0002339-PD9, and EX0002339-PD11 is a minor modification in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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 previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports.

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	September 10, 2021	
Receipt date	September 10, 2021	
Applicant	ITG Brands LLC	
Product manufacturer	ITG Brands LLC	
Product category	Cigarette	
Product subcategory	Combusted, Filtered	
Attributes ^a	New Product	Original Product
STN	EX0002339.PD1	EX0000286
Product Name	Winston Red Box	Winston Red Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	83 mm	83 mm
Portion Length	83 mm	83 mm
Ventilation	17%	17%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019
Abbreviated report	Not Applicable	AS0000092
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC Paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of Fire Standard Compliant ("FSC") cigarette paper (b) (4) ; (b) (4) mg/cigarette) • Addition of alternative FSC cigarette paper (b) (4) ; (b) (4) mg/cigarette)	
STN	EX0002339.PD3	EX0000285
Product Name	Winston Red 100's Box	Winston Red 100's Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	98 mm	98 mm
Portion Length	98 mm	98 mm
Ventilation	17%	17%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019

Abbreviated report	Not Applicable	AS0000091
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of FSC cigarette paper ((b) (4) ; (b) (4) mg/cigarette) • Addition of alternative FSC cigarette paper ((b) (4) ; (b) (4) mg/cigarette)	
STN	EX0002339.PD5	EX0000284
Product Name	Winston Gold Box	Winston Gold Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	83 mm	83 mm
Portion Length	83 mm	83 mm
Ventilation	32%	32%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019
Abbreviated report	Not Applicable	AS0000090
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of FSC cigarette paper ((b) (4) ; (b) (4) mg/cigarette) • Addition of alternative FSC cigarette paper ((b) (4) ; (b) (4) mg/cigarette)	
STN	EX0002339.PD7	EX0000283
Product Name	Winston Gold 100's Box	Winston Gold 100's Box
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	98 mm	98 mm
Portion Length	98 mm	98 mm
Ventilation	28%	28%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019
Abbreviated report	Not Applicable	AS0000089
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of FSC cigarette paper ((b) (4) ; (b) (4) mg/cigarette)	

	• Addition of alternative FSC cigarette paper (b) (4); (b) (4) mg/cigarette)	
STN	EX0002339.PD9	EX0000288
Product Name	Winston White Box	Winston White Box
Package Type	Box	Box
Package Quantity	20 Count	20 Count
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	83 mm	83 mm
Portion Length	83 mm	83 mm
Ventilation	54%	54%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019
Abbreviated report	Not Applicable	AS0000094
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of FSC cigarette paper (b) (4); (b) (4) mg/cigarette) • Addition of alternative FSC cigarette paper (b) (4); (b) (4) mg/cigarette)	
STN	EX0002339.PD11	EX0000287
Product Name	Winston White 100's Box	Winston White 100's Box
Package Type	Box	Box
Package Quantity	20 Count	20 Count
Characterizing Flavor	None	None
Diameter	7.79 mm	7.79 mm
Product Length	98 mm	98 mm
Portion Length	98 mm	98 mm
Ventilation	60%	60%
Eligibility status	Not Applicable	Previously found exempt
Marketing authorization date	Not Applicable	February 8, 2019
Abbreviated report	Not Applicable	AS0000093
Abbreviated report date	Not Applicable	February 27, 2019
Additional Property	Alternative FSC paper	FSC paper
Product Modifications	Addition/Deletion of existing tobacco additives: • Deletion of FSC cigarette paper (b) (4); (b) (4) mg/cigarette) • Addition of alternative FSC cigarette paper (b) (4); (b) (4) mg/cigarette)	