

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001327-PD1, EX0001327-PD3, EX0001327-PD5, EX0001327-PD7, EX0001327-PD9, EX0001327-PD11, EX0001327-PD13, and EX0001327-PD15
Common Attributes	
Submission date	November 12, 2020
Receipt date	November 12, 2020
Applicant	ITG Brands, LLC
Product manufacturer	ITG Brands, LLC
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2021.01.27 08:52:17 -05'00'

Jeannie Jeong-Im, Ph.D.
Branch Chief, Chemistry Branch III
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.01.27 08:55:01 -05'00'

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

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

The applicant submitted information for the new and original tobacco products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendix for tobacco products.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewer(s)	Review Date
regulatory	Megan Nguyen	11/18/2020
chemistry	Robert Gahl	12/17/2020
environmental science	Sang Ki Park	12/10/2020

2. COMPLIANCE REVIEW

The original tobacco products in EX0001327-PD1, EX0001327-PD3, EX0001327-PD5, EX0001327-PD7, EX0001327-PD9, EX0001327-PD11, EX0001327-PD13, and EX0001327-PD15 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 tobacco products are eligible for modification under the Exemption Request pathway.¹

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modification of the original tobacco products compared to the corresponding new tobacco products is the result of:

- deleting an additive (Fire Standard Compliant (FSC) cigarette paper (b)(4), manufactured by (b)(4) in all the EX Requests
- adding an additive (FSC cigarette paper, (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 tobacco products. The review concludes that the

¹ Any tobacco 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.

modifications are minor modifications of a tobacco 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 December 21, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 21, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications of a tobacco 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 tobacco products to be marketed would be appropriate for the protection of the public health. The applicant intends to delete the original FSC cigarette paper and add an alternate FSC cigarette paper. There are minor differences (< (b) mg/cigarette) in the levels of (b)(4) (b)(4)), (b)(4) (b)(4) and other ingredients less than (b)(4) mg/cigarette in the FSC cigarette paper between the new and corresponding original tobacco products. However, these differences are not expected to have a significant impact on the product performance or measurable effect on tobacco smoke. The applicant provided tar, nicotine, carbon monoxide (TNCO), and puff data under both ISO and CI smoking regimens. Although HPHCs and TNCO are not needed to evaluate the modifications in these Exemptions Requests, FDA evaluated the submitted information and found that the TNCO and puff count data did not raise concerns. Sufficient information about the methods and validation reports was provided. The mainstream smoke yields of TNCO and puff count in the new tobacco products were analytically equivalent by TOST² analyses to the corresponding original tobacco products in all EX Requests. 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 tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are previously found Exempt by FDA, reports 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 tobacco products exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco products in EX0001327-PD1, EX0001327-PD3, EX0001327-PD5, EX0001327-PD7, EX0001327-PD9, EX0001327-PD11, EX0001327-PD13, and EX0001327-PD15, as identified on the cover page of this review.

² Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.

7. APPENDIX

Appendix A. New and original tobacco products

Common Attributes		
Submission date	November 12, 2020	
Receipt date	November 12, 2020	
Applicant	ITG Brands, LLC	
Product manufacturer	ITG Brands, LLC	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001327-PD1	EX0000816
Product name	Winston Blue Box	Winston Blue Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	11/22/2019
Abbreviated report date	Not Applicable	12/17/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 Millimeters (mm)	83 mm
Diameter	7.79 mm	7.79 mm
Ventilation	25%	25%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4); target: (b)(4) Milligrams (mg)/cigarette • Addition of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette 	

EX0001327-PD1, EX0001327-PD3, EX0001327-PD5, EX0001327-PD7, EX0001327-PD9, EX0001327-PD11, EX0001327-PD13, and EX0001327-PD15

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001327-PD3	EX0000817
Product name	Winston Full Flavor 100's Box	Winston Full Flavor 100's Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	11/22/2019
Abbreviated report date	Not Applicable	12/17/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.79 mm	7.79 mm
Ventilation	14%	14%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) 	
STN	EX0001327-PD5	EX0000283
Product name	Winston Gold 100's Box	Winston Gold 100's Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not Applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.79 mm	7.79 mm
Ventilation	28%	28%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001327-PD7	EX0000284
Product name	Winston Gold Box	Winston Gold Box
Eligibility status	Not applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not Applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.79 mm	7.79 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4); target (b)(4) mg/cigarette) 	
STN	EX0001327-PD9	EX0000285
Product name	Winston Red 100's Box	Winston Red 100's Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not Applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98mm
Diameter	7.79 mm	7.79 mm
Ventilation	17%	17%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4); target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4); target (b)(4) mg/cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001327-PD11	EX0000286
Product name	Winston Red Box	Winston Red Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83mm
Diameter	7.79 mm	7.79 mm
Ventilation	17%	17%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) [REDACTED]; [609AR]; (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4) [REDACTED] mg/cigarette) 	
STN	EX0001327-PD13	EX0000287
Product name	Winston White 100's Box	Winston White 100's Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not Applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98mm
Diameter	7.79 mm	7.79 mm
Ventilation	60%	60%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) [REDACTED]; [609AR]; (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4) [REDACTED] mg/cigarette) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001327-PD15	EX0000288
Product name	Winston White Box	Winston White Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	02/08/2019
Abbreviated report date	Not Applicable	03/01/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.79 mm	7.79 mm
Ventilation	54%	54%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b)(4) ; (b)(4) ; target: (b)(4) mg/cigarette) • Addition of FSC cigarette paper (b)(4) ; (b)(4) ; target: (b)(4) mg/cigarette) 	