

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001504-PD1, EX0001504-PD3, EX0001504-PD5
Common Attributes	
Submission date	February 1, 2021
Receipt date	February 1, 2021
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	<ul style="list-style-type: none"> Internal Memorandum: Equivalence Testing for SE Evaluations (February 24, 2017) Internal Memorandum: Addendum to February 24, 2017, Equivalence Testing for SE Evaluations Memo (April 16, 2019)
Recommendation	
Issue an Exempt (EX) order for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeffrey R. Ammann -S
Date: 2021.07.27 13:08:46 -04'00'

Jeffrey R. Ammann, Ph.D.
Chemistry Team Lead
DPS

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.07.27 13:13:48 -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

	Cycle 1	
Discipline	Reviewer(s)	Review Date
regulatory	Megan Nguyen	2/10/2021
chemistry	Jason Hsieh	7/6/2021
environmental science	Chad Baisden	7/1/2021

2. COMPLIANCE REVIEW

The original products in EX0001504-PD1, EX0001504-PD3, and EX0001504-PD5 were determined to be exempt from substantially equivalence (EX) and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA. Therefore, the original products are 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 Fire Standard Compliant (FSC) cigarette paper (b) (4) all EX Requests
- Adding FSC cigarette paper (b) (4) in all 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 G. Valerio, Jr., Ph.D. on July 8, 2021. The FONSI was supported by an environmental assessment prepared by FDA on July 9, 2021.

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. In all new products, there is an overall 4% (b) (4) mg/cig decrease in (b) (4) (b) (4) a 13% (b) (4) mg/cig increase in (b) (4) (b) (4) (b) (4) (b) (4) and 48-50% (b) (4) mg/cig decrease in (b) (4) CA; (b) (4) compared to the corresponding original products. Moreover, the total cigarette weight of the new products is increasing by 0.37% (4 mg/cig) in EX0001504-PD1, increasing by 0.44% (1 mg/cig) in EX0001504-PD3, and decreasing by 0.11% (1 mg/cig) in EX0001504-PD5; this minimal change is not anticipated to have a measurable change or impact smoke chemistry significantly. In all EX Requests, the cigarette paper of the original products contains (b) (4) mg/cig of (b) (4) (b) (4) (b) (4) and (b) (4) mg/cig of (b) (4) (CAS# (b) (4) and (b) (4)); these (b) (4) are replaced by (b) (4) mg/cig of (b) (4) and (b) (4) mg/cig of (b) (4) (b) (4) ((b) (4)) in the new products, resulting in a net decrease of (b) (4) mg/cig in the (b) (4) ingredient content. Although the (b) (4) ingredient content is different in the new products of all EX Requests, (b) (4) molecular weight of (b) (4) g/mol¹ and (b) (4)

¹National Center for Biotechnology Information. PubChem Compound Summary for CID (b) (4) [https://pubchem.ncbi.nlm.nih.gov/compound/\(b\)\(4\)](https://pubchem.ncbi.nlm.nih.gov/compound/(b)(4)) Accessed Dec 3 2020.

(b) (4) molecular weight of (b) (4) g/mol)² share the same function (burn modifier) as the (b) (4) molecular weight (b) (4) g/mol)³ and (b) (4) molecular weight (b) (4) g/mol)⁴ in the corresponding original products; the molecular weight differences between these ingredients is primarily driven by the amounts of (b) (4) and (b) (4). Therefore, from a chemistry perspective, the proposed modifications of all ingredients listed above are considered minor modifications, collectively. 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 were previously found Exempt 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.

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	February 1, 2021
Receipt date	February 1, 2021
Applicant	ITG Brands, LLC
Product manufacturer	ITG Brands, LLC
Product category	Cigarettes
Product subcategory	Combusted, Filtered

Attributes	New Product	Original Product
STN	EX0001504-PD1	EX0000443
Product name	Kool 100s Box	Kool 100s Box

² National Center for Biotechnology Information. PubChem Compound Summary for CID (b) (4) (b) (4) [\(b\) \(4\) https://pubchem.ncbi.nlm.nih.gov/compound/\(b\)\(4\)](https://pubchem.ncbi.nlm.nih.gov/compound/(b)(4)) Accessed Dec. 3, 2020.

³ National Center for Biotechnology Information. PubChem Compound Summary for CI (b) (4) [\(b\) \(4\) https://pubchem.ncbi.nlm.nih.gov/compound/\(b\)\(4\)](https://pubchem.ncbi.nlm.nih.gov/compound/(b)(4)) Accessed Dec. 3, 2020.

⁴ (b) (4) Product Data Sheet: Chemical Book. Accessed Dec. 3, 2020 [https://www.chemicalbook.com/ProductChemicalProperties/\(b\)\(4\).htm](https://www.chemicalbook.com/ProductChemicalProperties/(b)(4).htm)

Eligibility status	Not applicable	Previously found EX
Marketing authorization date	Not applicable	3/29/2019
Abbreviated report date	Not applicable	4/17/2019
Package type	Box	Box
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Length	97 mm	97 mm
Ventilation	23%	23%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of Fire Standard Compliant (FSC) cigarette paper [(b)(4)] Addition of FSC cigarette paper [(b)(4)] 	
Attributes	New Product	Original Product
STN	EX0001504-PD3	EX0000445
Product name	Kool Blue Box	Kool Blue Box
Eligibility status	Not applicable	Previously found EX
Marketing authorization date	Not applicable	3/29/2019
Abbreviated report date	Not applicable	4/17/2019
Package type	Box	Box
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	29%	29%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of FSC cigarette paper [(b)(4)] Addition of FSC cigarette paper 	

Attributes	New Product	Original Product
STN	EX0001504-PD5	EX0000446
Product name	Kool 100s Box	Kool 100s Box
Eligibility status	Not applicable	Previously found EX

Marketing authorization date	Not applicable	3/29/2019
Abbreviated report date	Not applicable	4/17/2019
Package type	Box	Box
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm
Length	83 mm	83 mm
Ventilation	10%	10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none">• Deletion of FSC cigarette paper (b)(4)• Addition of FSC cigarette paper	