

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0002078.PD1, EX0002078.PD3, EX0002078.PD5
Common Attributes	
Submission date	June 18, 2021
Receipt date	June 18, 2021
Applicant	ITG Brands, LLC
Product manufacturer	ITG Brands, LLC
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	<ul style="list-style-type: none"> Internal Memorandum: (b) (4) Internal Memorandum (b) (4) 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 Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeffrey R. Ammann -S
Date: 2022.07.06 16:00:15 -04'00'

Jeffrey R. Ammann, Ph.D.
Chemistry Team Supervisor
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Todd L. Cecil -S
Date: 2022.07.07 09:01:45 -04'00'

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 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	
	Reviewers	Review Date
Regulatory	Kenna Randall	7/20/2021
Chemistry	Norman Fraley	6/10/2022
Environmental Science	Yasmin Termeh-Zonoozi	6/8/2022

2. COMPLIANCE REVIEW

The original products in EX0002078.PD1, EX0002078.PD3, and EX0002078.PD5 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 (fire standard compliant (FSC) cigarette paper (b) (4)) in all the EX Requests
- adding an additive (FSC cigarette paper (b) (4)) 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 July 6, 2022. The FONSI was supported by an environmental assessment prepared by FDA on July 6, 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. In all EX Requests, the applicant proposes to delete FSC cigarette paper manufactured by (b) (4) and add a different FSC cigarette paper (b) (4) purchased from (b) (4). There is a (b) (4) mg/cigarette increase in the total quantity of carbohydrate-containing ingredients (e.g., (b) (4)”) in the new products compared to their corresponding original products in all EX Requests. These increases correspond to 0.07%³ of the weight of the tobacco rod, which is a negligible amount.⁴ Therefore, the changes in the levels in carbohydrate-containing ingredients are considered minor. The overall (b) (4) content of the new products is lower than their corresponding original products in all EX Requests. There is a decrease of (b) (4) mg/cigarette of (b) (4) and an increase of (b) (4) /cigarette of (b) (4) in the new products compared to their corresponding original products in all EX Requests. Since there is an overall decrease in (b) (4) concentration of 0.01-0.02% of the weight of the tobacco rod in the new products, the changes in the levels of (b) (4) are considered minor. 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, 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 products exempt and made a finding of no significant impact.

³ The weights of the tobacco rods in the new and original products in EX0002078.PD1, EX0002078.PD3, and EX0002078.PD5 are 756.6 mg, 701.8 mg, and 882.1 mg, respectively.

⁴ Internal Memorandum: Review of Saccharides as Tobacco Ingredients: Effects on Smoke Chemistry, July 17, 2017.

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 products⁵

Common Attributes		
Submission date	June 18, 2021	
Receipt date	June 18, 2021	
Applicant	ITG Brands, LLC	
Product manufacturer	ITG Brands, LLC	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Product	Original Product
STN	EX0002078.PD1	EX0000446
Product name	Kool Box	Kool Box
Eligibility status	Not Applicable (N/A)	Previously Found EX
Marketing authorization date	N/A	3/29/2019
Abbreviated report date	N/A	4/17/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 millimeters (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 complex ingredient, FSC cigarette paper (b) (4) Addition of complex ingredient, FSC cigarette paper (b) (4) 	
Attributes	New Product	Original Product
STN	EX0002078.PD3	EX0000445
Product name	Kool Blue Box	Kool Blue Box
Eligibility status	N/A	Previously Found EX
Marketing authorization date	N/A	3/29/2019
Abbreviated report date	N/A	4/17/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.79 mm	7.79 mm

⁵ Brand/sub-brand or other commercial name used in commercial distribution.

Length	83 mm	83 mm
Ventilation	29%	29%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of complex ingredient, FSC cigarette paper (b) (4) • Addition of complex ingredient, FSC cigarette paper (b) (4) 	
Attributes	New Product	Original Product
STN	EX0002078.PD5	EX0000443
Product name	Kool 100s Box	Kool 100s Box
Eligibility status	N/A	Previously Found EX
Marketing authorization date	N/A	3/29/2019
Abbreviated report date	N/A	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 complex ingredient, FSC cigarette paper (b) (4) • Addition of complex ingredient, FSC cigarette paper (b) (4) 	