FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review[1]	
STNs	EX0001834.PD1 - EX0001835.PD1
Common Attributes	
Submission date	April 2, 2021
Receipt date	April 2, 2021
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International
Product category	Roll-Your-Own Tobacco Products
Product subcategory	Rolling Paper
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
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: 2022.08.01 11:41:26 -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: 2022.08.01 11:48:27 -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

	Cycle 1		Cycle 2	
Discipline	**Reviewer(s)**	**Review Date**	**Reviewer(s)**	**Review Date**
Regulatory	Taylor Worsley	5/5/2021	Jessica Scudder	4/26/2022
Chemistry	Jason Hsieh	8/18/2021	Not assigned	N/A
Environmental science	Chad Baisden	8/26/2021	Chad Baisden	4/20/2022

2. COMPLIANCE REVIEW

The original products in EX0001834.PD1 and EX0001835.PD1 were determined to be substantially equivalent 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.[1]

3. TOBACCO ADDITIVE MODIFICATION

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

- decreasing the quantity of an existing additive ((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

[1] 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.

otherwise affecting the characteristics of the products. The review concludes that the modification is a minor modification 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 April 21, 2022. The FONSI was supported by an environmental assessment prepared by FDA on April 21, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that the 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 ingredient is an "additive" 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 (b) (4) ((b) (4) mg/g paper [EX0001834.PD1] and (b) (4) mg/g paper [EX0001835.PD1]) decrease in the weight of the (b) (4) compared to the corresponding original products. The new and original products have identical target physical parameters, including paper length ((b) (4) [EX0001834-PD1 only], (b) (4) [EX0001835-PD1 only]), paper width (b) (4)), air permeability (watermarked) (b) (4) and width of (b) (4)), except for paper basis weight. The paper basis weight is (b) (4) lower (b) (4)) in the new products of EX0001834.PD1 and EX0001835.PD1 compared to the corresponding original products. Since the air permeability of the new products has the same air permeability compared to the corresponding original products, the lower paper basis weight is not a concern from a chemistry perspective. Lastly, I find that an exemption for this modification is 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 previously found Substantially Equivalent by FDA.

7. APPENDICES

Appendix A. New and original products

Common Attributes		
Submission date	April 2, 2021	
Receipt date	April 2, 2021	
Applicant	BBK Tobacco & Foods dba HBI International	
Product manufacturer	BBK Tobacco & Foods dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Rolling Paper	
Attributes	**New Product**	**Original Product**
STN	**EX0001834.PD1**	**SE0015544**
Product name	RAW BLACK ORGANIC HEMP 1¼[2]	RAWBLACK 1¼
Eligibility status	Not Applicable (N/A)	Previously found SE
Marketing authorization date	N/A	7/23/2020
Package type	Booklet	Booklet
Package quantity	50 Papers	50 Papers
Characterizing flavor	None	None
Length	76 millimeters (mm)	76 mm
Width	44 mm	44 mm
Additional property	Off-white, "RAW" watermark	Off-white, "RAW" watermark
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decrease in the quantity of (b) (4)	
Attributes	**New Product**	**Original Product**
STN	**EX0001835.PD1**	**SE0015423**
Product name	RAW BLACK ORGANIC HEMP King Size Slim[2]	RAWBLACK KING SIZE SLIM
Eligibility status	N/A	Previously found SE
Marketing authorization date	N/A	2/3/2020
Package type	Booklet	Booklet
Package quantity	32 Papers	32 Papers
Characterizing flavor	None	None
Length	108 mm	108 mm
Width	44 mm	44 mm
Additional property	Off-white, "RAW" watermark	Off-white, "RAW" watermark
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decrease in the quantity of (b) (4)	

[2] Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
September 20, 2021	September 20, 2021	EX0002426	All	Yes	Response to September 15, 2021, Deficiency Letter