FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000424

EX0000424: RAW SW Cut Corners	
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Product Modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decreasing the quantity of (b)(4) [redacted] and cationic starch
Attributes of Exemption Request	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Package Type	Booklet
Package Quantity	50 sheets
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.03.25 15:49:50 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.03.26 07:02:01 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Products

EX0000424: RAW SW Cut Corners	
Product Name	RAW Single Wide[1]
Package Type	Booklet
Package Quantity	50 sheets
Length	37 mm
Width	70 mm
Characterizing Flavor	None

The applicant manufactures the original tobacco product. The original tobacco product was previously found substantially equivalent by FDA under SE0002393.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 24, 2019, FDA received an Exemption Request (EX0000424) from BBK Tobacco & Foods LLP dba HBI International. On January 30, 2019, FDA issued an Acknowledgement letter to the applicant.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Decreasing the quantity of (b)(4) [redacted] and cationic starch

2. REGULATORY REVIEW

A regulatory review was completed by Kaylene Charles on January 30, 2019. The review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000424 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0002393.

[1] The original product's name was RAW SW SW at the time of the SE order on October 3, 2017.

4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on March 21, 2019.

The review states that the new tobacco product has been modified by decreasing the quantities of the existing additives of (b)(4) and cationic starch from the rolling paper. These substances are used in the manufacturing of the original tobacco product and are additives because the intended use may reasonably be expected to result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. This modification is the result of decreasing the existing additives of (b)(4) and cationic starch due to the removal of two semi-circular sections of the corners from one side of the rolling paper. This modification is to allow customers to easily identify which side of the rolling paper has the gum line. These modifications are not expected to influence HPHC yields of the new product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Mehran Niazi on February 19, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 25, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 25, 2019.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modification compared to the original tobacco product:

- Decreasing the quantity of (b)(4) and cationic starch

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines an "additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I concur with the scientific review that (b)(4) and cationic starch are decreasing quantities of existing additives from the rolling paper. 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 product to be marketed would be appropriate for protection of the public health. This modification is the result of decreasing the existing additives of (b)(4) and cationic starch due to the removal of two semi-circular sections of the corners from one side of the rolling paper. This modification is to allow customers to easily identify which side of the rolling paper has the gum line. These modifications are not expected to influence HPHC yields of the new product. Therefore, FDA finds, based on the information

contained in the Exemption Request and CTP's scientific understanding, that an exemption for these modifications is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product was previously found SE and in compliance with the FD&C Act by FDA under SE00002393.

FDA has examined the environmental effects of finding the new tobacco product exempt and made a finding of no significant impact.

An exempt order letter should be issued for the new tobacco product in EX0000424 as identified on the cover page of this review.