FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000832

EX0000832: Raw Auto Box 79 mm	
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Addition of black spray paint and red and beige ink on the container closure system Increasing/Decreasing the quantity of existing tobacco additives: • Decreasing the quantity of (b) (4) on the container closure system • Increasing the quantity of (b) (4) in the (b) (4)
Attributes of Exemption Request	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Other
Package Quantity	1 per box
Package Type	Box
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.12.16 15:43:59 -05'00'

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: 2019.12.17 06:40:57 -05'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000832: Raw Auto Box 79 mm	
Product Name	Zen Automatic Roll Box 79 mm
Package Quantity	1 per box
Package Type	Box
Characterizing Flavor	None

The applicant manufactures the original tobacco product and claims that it is grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 5, 2019, FDA received an Exemption Request from BBK Tobacco & Foods LLP dba HBI International. FDA issued an Acceptance letter for the Exemption Request on November 12, 2019. On November 22, 2019, the Office of Compliance and Enforcement (OCE) conducted a teleconference to request the applicant provide additional information to identify where the original tobacco product was shipped. On November 26, 2019, FDA received amendment, EX0000890, in response to the request from OCE.

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:

- Addition of black spray paint and red and beige ink on the container closure system
- Decreasing the quantity of (b) (4) on the container closure system
- Increasing the quantity of (b) (4) in the (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Nikole Ayala-Agosto on November 12, 2019. The review concludes that this Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

OCE completed a review to determine whether the applicant established that the original tobacco product is a grandfathered product (i.e., was commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE review dated December 16,

2019, concludes that the original tobacco product is a grandfathered product. Therefore, the original product is eligible for modification under the Exemption Request pathway.[1]

4. SCIENTIFIC REVIEW

Scientific review was conducted solely by the TPL as the proposed modifications to the rolling machine (accessory) are not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of tobacco rolling paper when used with the new tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on December 4, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 9, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 9, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of black spray paint and red/beige ink on the container closure system
- Decreasing the quantity of (b) (4) on the container closure system
- Increasing the quantity of (b) (4) in the (b) (4)

These modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 900(1) of the FD&C Act defines '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 have concluded that the increase in the existing additive of (b) (4) on the (b) (4) is an increase in the quantity of an existing tobacco additive. Based on information submitted by the applicant, there is an additional modification of a change in the container closure system by adding black spray paint and red and beige ink on the container closure system and decreasing the quantity of (b) (4) on the container closure system. I, as TPL, find that the container closure system in the original and new tobacco products meet the definition of 'additive' because they are substances used in the packaging of the tobacco products. In addition, I find that these modifications are minor because they do not affect the characteristics of the consumable portion of the tobacco product. 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. The increase in the existing additive of (b) (4) on the (b) (4) is not expected to materially affect any other characteristics (e.g., materials, ingredients, design, composition, heating source, or other features) of the tobacco product as the (b) (4) are not combusted, volatilized, or otherwise

[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.

released during regular cigarette rolling. As TPL, I also find that the change in container closure system are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, that an exemption for these modifications are 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 a modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product is a grandfathered product (i.e., was commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007).

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 EX0000832 as identified on the cover page of this review.