FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000804

EX0000804: Raw Auto Box 70 mm	
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Addition of (b) (4) on the container closure system Increasing/Decreasing the quantity of existing tobacco additives: • Increasing the quantity of (b) (4) on the container closure system • Increasing the quantity of (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	Cardboard Box
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.11.25 12:10:18 -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: 2019.11.25 12:36:45 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000804: Raw Auto Box 70 mm	
Product Name	Zen Automatic Box 70 mm
Package Quantity	1 per box
Package Type	Cardboard 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 October 7, 2019, FDA received an Exemption Request from BBK Tobacco & Foods LLP dba HBI International. FDA issued the applicant an Acceptance letter for the Exemption Request on October 24, 2019. On October 23, 2019, the Office of Compliance and Enforcement (OCE) conducted a telecon to request the applicant provide additional information to identify where the predicate product was shipped. On October 28, 2019, FDA received amendment, EX0000824, in response to a 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 (b) (4) on the container closure system
- Increasing the quantity of (b) (4) on the container closure system
- Increasing the quantity of (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Crystal Caesar on October 24, 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 November 17,

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

A scientific review was completed by Jason Hsieh on November 18, 2019.

The review states that the new tobacco product has been modified by increasing the quantity of an existing additive. (b) (4) is used in the manufacturing of the original tobacco product and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes that the increase in the existing additive of (b) (4) is a minor modification. The increase in the existing additive of (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 (b) (4) are not combusted, volatilized, or otherwise released during regular cigarette rolling.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on November 22, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 22, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 21, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) on the container closure system
- Increasing the quantity of (b) (4) on the container closure system
- Increasing the quantity of (b) (4)

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 '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 the increase in the existing additive of (b) (4) is an increase/decrease in quantity of an existing tobacco additive. Based on information submitted by the applicant, there is an additional modification of a change in container closure by adding (b) (4) on the container closure system and increasing the quantity of (b) (4) on the container

[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.

closure system. I, as TPL, find that the container closure systems 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 this modification is minor because this modification does not affect the characteristics of the consumable portion of the tobacco products. 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 products to be marketed would be appropriate for protection of the public health. The increase in the existing additive of [redacted] 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 [redacted] are not combusted, volatilized, or otherwise released during regular cigarette rolling. As TPL, I also find that the change in container closure system is 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 EX0000804 as identified on the cover page of this review.