FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000244

EX0000244: Black & Mild	
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0 %
Characterizing Flavor	None
Tip	Plastic Tip
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of (b) (4) from the tobacco filler • Addition of (b) (4) to the tobacco filler • Deletion of (b) (4) from the cigar wrapper and cigar binder • Addition of (b) (4) to the cigar wrapper and cigar binder
Attributes of Exemption Requests	
Applicant	John Middleton Co.
Product Category	Cigar
Product Sub-Category	Unfiltered Sheet-Wrapped
Package Quantity	One cigar
Package Type	Polypropylene (clear plastic) wrap
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.09.04 12:21:54 -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: 2018.09.04 14:10:00 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000244: Black & Mild	
Product Name	Black & Mild
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0%
Characterizing Flavor	None
Tip	Plastic Tip

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Request (EX0000244) on July 11, 2018. FDA issued an Acknowledgement letter on July 17, 2018. On July 23, 2018, an email was sent to the applicant requesting clarifying information from the Office of Compliance and Enforcement. In response, the applicant submitted an amendment (EX0000250) to the Exemption Request, received on July 23, 2018. On August 3, 2018, FDA sent an email to the applicant requesting clarification on the product sub-category and ventilation for both the grandfathered and new tobacco product. On August 6, 2018, FDA received an amendment (EX0000261) containing the requested information on sub-category and ventilation information.

1.3. SCOPE OF MEMO

This memo 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:

- Deletion of (b) (4) from the tobacco filler
- Addition of (b) (4) to the tobacco filler
- Deletion of (b) (4) from the cigar wrapper and cigar binder
- Addition of (b) (4) to the cigar wrapper and cigar binder

2. REGULATORY REVIEW

A regulatory review was completed by Keyur Patel on July 17, 2018. This review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (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 on August 22, 2018, concludes that the original tobacco product is a grandfathered product. Therefore, the original product is eligible for modifications under the Exemption Request pathway.[1]

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on September 4, 2018.

The review states that the new tobacco product has been modified by adding and deleting tobacco additives. (b) (4), and (b) (4) are used in the manufacturing of the original tobacco product and 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 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. The review concludes that the deletion of (b) (4) µg) from the tobacco filler and addition of (b) (4) µg) to the tobacco filler is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. Furthermore, the deletion of (b) (4) mg) from the cigar wrapper and binder and addition of (b) (4) mg) to the cigar wrapper and binder is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. These modifications represent small quantity changes and do not result in a net weight change of the tobacco product, therefore, these changes would be a minor modification of an additive.

[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.

Thus, the review concludes that these modifications are minor modifications of a tobacco 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 Kimberly Benson, Ph.D. on August 27, 2018. The FONSI was supported by an environmental assessment prepared by FDA on August 27, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of (b) (4) from the tobacco filler
- Addition of (b) (4) to the tobacco filler
- Deletion of (b) (4) from the cigar wrapper and cigar binder
- Addition of (b) (4) to the cigar wrapper and cigar binder

I concur with the conclusion of the scientific review that, based upon the information available at this time, 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 changes represent deletion of two tobacco additives ((b) (4) and (b) (4)), and the addition of two tobacco additives ((b) (4)). The deletion of (b) (4) μg) from the tobacco filler and addition of (b) (4) μg) to the tobacco filler is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. Furthermore, the deletion of (b) (4) mg) from the cigar wrapper and binder and addition of (b) (4) mg) to the cigar wrapper and binder is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. This is because there is complete removal of (b) (4), a substance associated with severe obstructive lung disease, bronchiolitis obliterans and decreased lung function, from the new tobacco product. The addition of (b) (4) is to replace (b) (4) and not expected to affect the characteristics of the product. Also, based on the smoke data submitted by the applicant, the deletion of (b) (4) and the addition of (b) (4) does not significantly affect the smoke chemistry of the modified 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. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, 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 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 modifications through the Exemption Request pathway because it is 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 EX0000244 as identified on the cover page of this review.