

**Technical Project Lead (TPL) Review:
Exemption Request EX0000453**

EX0000453: Black & Mild® Shorts	
Package Type	Box
Package Quantity	Five cigars
Length	88.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • 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 Request	
Applicant	John Middleton Co.
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped
Recommendation	
Issue Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.04.04 17:32:02 -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: 2019.04.04 18:11:55 -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 Product

EX0000453: Black & Mild® Shorts	
Product Name	Black & Mild® Shorts
Package Type	Box
Package Quantity	Five cigars
Length	88.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	None

The applicant manufactures the original tobacco product. The original tobacco product was previously found substantially equivalent by FDA under SE0014918.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 13, 2019, FDA received Exemption Request EX0000453 from Altria Client Services LLC on behalf of John Middleton Co. On February 14, 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:

- Deletion of (b) (4) from the tobacco filler
- Addition of (b) 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 Nicholas Hasbrouck on February 14, 2019. This review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000453 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0014918. Therefore, the original product is eligible for modifications under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Tianrong Cheng on March 11, 2019.

The review states that the new tobacco product has been modified by adding and deleting tobacco additives. (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) (1.44 µg) from the tobacco filler and addition of (b) (4) (1.44 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) from the cigar wrapper (0.458 mg) and cigar binder (0.365 mg) and addition of (b) (4) to the cigar wrapper (0.458 mg) and cigar binder (0.365 mg) 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. 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

An environmental review was completed by William Brenner on March 18, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 4, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 4, 2019.

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.

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 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 the deletion of (b) (4) tobacco additives (b) (4), and the addition of two tobacco additives (water and sodium benzoate). The deletion of (b) (4) (1.44 µg) from the tobacco filler and addition of (b) (4) 1.44 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) from the cigar wrapper (0.458 mg) and cigar binder (0.365 mg) and addition of (b) (4) to the cigar wrapper (0.458 mg) and cigar binder (0.365 mg) 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) do 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 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 modifications through the Exemption Request pathway because it is legally marketed in the United States. The original product was previously found SE and in compliance with the FD&C Act by FDA under SE0014918.

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

An Exempt order letter should be issued for the new tobacco product in EX0000453 as identified on the cover page of this review.