

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000333 – EX0000336**

EX0000333: Black & Mild® Shorts	
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	88.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	None
Products Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b)(4) from the tobacco filler</li> <li>• Addition of (b)(4) to the tobacco filler</li> <li>• Deletion of (b)(4) from the cigar wrapper and cigar binder</li> <li>• Addition of (b)(4) to the cigar wrapper and cigar binder</li> </ul>
EX0000334: Black & Mild® FT – 5 Pack	
Package Type	Box
Package Quantity	Five cigars
Length	110 mm
Diameter	8.9 mm
Ventilation	0%
Characterizing Flavor	None
Products Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b)(4) from the tobacco filler</li> <li>• Addition of (b)(4) to the tobacco filler</li> <li>• Deletion of (b)(4) from the cigar wrapper</li> <li>• Addition of (b)(4) to the cigar wrapper</li> </ul>
EX0000335: Black & Mild® Cream	
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cream
Products Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b)(4) from the tobacco filler</li> <li>• Addition of (b)(4) to the tobacco filler</li> <li>• Deletion of (b)(4) from the cigar wrapper and cigar binder</li> <li>• Addition of (b)(4) to the cigar wrapper and cigar binder</li> </ul>

EX0000336: Black & Mild® Cream	
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cream
Products Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b)(4) from the tobacco filler</li> <li>• Addition of (b)(4) to the tobacco filler</li> <li>• Deletion of (b)(4) from the cigar wrapper and cigar binder</li> <li>• Addition of (b)(4) to the cigar wrapper and cigar binder</li> </ul>
Common Attributes of Exemption Requests	
Applicant	John Middleton Co.
Product Category	Cigar
Product Sub-Category	Unfiltered, Sheet-Wrapped: EX0000333, EX0000335, and EX0000336 Filtered, Sheet-Wrapped: EX0000334
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Matthew J. Walters -S  
 2019.02.06 11:47:14 -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: 2019.02.06 12:07:04 -05'00'

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 products:

**Table 1. Original Tobacco Product**

<b>EX0000333: Black &amp; Mild® Shorts</b>	
<b>Product Name</b>	Black & Mild Fast Break Cigar
<b>Package Type</b>	Polypropylene (clear plastic) wrap
<b>Package Quantity</b>	One cigar
<b>Length</b>	88.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip
<b>Characterizing Flavor</b>	None
<b>EX0000334: Black &amp; Mild® FT – 5 Pack</b>	
<b>Product Name</b>	Black & Mild FT – 5 Pack
<b>Package Type</b>	Box
<b>Package Quantity</b>	Five cigars
<b>Length</b>	110 mm
<b>Diameter</b>	8.9 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>EX0000335: Black &amp; Mild® Cream</b>	
<b>Product Name</b>	Black & Mild Cream
<b>Package Type</b>	Box
<b>Package Quantity</b>	Five cigars
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip
<b>Characterizing Flavor</b>	Cream
<b>EX0000336: Black &amp; Mild® Cream</b>	
<b>Product Name</b>	Black & Mild Cream
<b>Package Type</b>	Polypropylene (clear plastic) wrap
<b>Package Quantity</b>	One cigar
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip
<b>Characterizing Flavor</b>	Cream

The applicant manufactures the original tobacco products and claims they are grandfathered for EX0000333, EX0000335, and EX0000336. Additionally, for EX0000334 the original tobacco product was previously found substantially equivalent by FDA under SE0014 625.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Requests (EX0000333-EX0000336) on December 14, 2018. FDA issued Acknowledgement letters on December 19, 2018.

## 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

## 1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- 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 for EX0000333, EX0000335, and EX0000336
- Addition of (b)(4) to the cigar wrapper and cigar binder for EX0000333, EX0000335, and EX0000336
- Deletion of (b)(4) from the cigar wrapper for EX0000334
- Addition of (b)(4) to the cigar wrapper for EX0000334

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Nicholas Hasbrouck on December 19, 2018. These reviews conclude that the Exemption Requests are 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 products for EX0000333, EX0000335, and EX0000336 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated on January 14, 2019, concludes that the original tobacco products are grandfathered products. The original tobacco product in EX0000334 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0014625. Therefore, the original products are eligible for modifications under the Exemption Request pathway.<sup>1</sup>

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<sup>1</sup> 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.

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on January 25, 2019.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. (b)(4) and (b)(4) are used in the manufacturing of the original tobacco products 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) from the tobacco filler and addition of (b)(4) 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 (b)(4) for all EX Requests and cigar binder (b)(4) for EX0000333, EX0000335, and EX0000336 and addition of (b)(4) to the cigar wrapper (b)(4) for all EX Requests and cigar binder (b)(4) for EX0000333, EX0000335, and EX0000336 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 Mehran Niazi on January 4, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 5, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 5, 2019.

#### 6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the original tobacco products:

- 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 for EX0000333, EX0000335, and EX0000336
- Addition of (b)(4) to the cigar wrapper and cigar binder for EX0000333, EX0000335, and EX0000336
- Deletion of (b)(4) from the cigar wrapper for EX0000334
- Addition of (b)(4) to the cigar wrapper for EX0000334

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 two tobacco additives (b)(4), and the addition of two tobacco additives (b)(4). The deletion of (b)(4) from the tobacco filler and addition of (b)(4) 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 products. Furthermore, the deletion of (b) (4) from the cigar wrapper (b)(4) for all EX Requests and cigar binder (b)(4) for EX0000333, EX0000335, and EX0000336 and addition of (b)(4) to the cigar wrapper (b)(4) for all EX Requests and cigar binder (b)(4) for EX0000333, EX0000335, and EX0000336 is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. 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 products. The addition of (b)(4) is to replace (b)(4) and not expected to affect the characteristics of the products. 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 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. Lastly, FDA finds, based on the information contained in the Exemption Requests 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products for are eligible for modifications through the Exemption Request pathway because they are legally marketed in the United States. The original products for EX0000333, EX0000335, and EX0000336 are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The original product for EX0000334 was previously found SE and in compliance with the FD&C Act by FDA under SE0014625.

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

Exempt order letters should be issued for the new tobacco products in EX0000333 – EX0000336 as identified on the cover page of this review.