

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000343 – EX0000348**

EX0000343: Middleton's Cherry Blend	
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry
Products 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) (b)(4) from the cigar wrapper and cigar binder • Addition of (b) (4) to the cigar wrapper and cigar binder
EX0000344: Black & Mild® Wine	
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Wine
Products Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of (b) (4) (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 <p>Increasing/Decreasing the quantity of existing additives:</p> <ul style="list-style-type: none"> • Increase of (b) (4) (cigar) in the tobacco filler

EX0000345: Black & Mild® Wine	
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Wine
Products 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 <p>Increasing/Decreasing the quantity of existing additives:</p> <ul style="list-style-type: none"> • Increase of (b) (4) (cigar) in the tobacco filler
EX0000346: Middleton's Cherry Blend	
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry
Products 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
EX0000347: Prince Albert Soft Cherry Vanilla	
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry Vanilla
Products 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) 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

EX0000348: Prince Albert Soft Cherry Vanilla	
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry Vanilla
Products Modifications	Addition/Deletion of tobacco additives: <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
Common Attributes of Exemption Requests	
Applicant	John Middleton Co.
Product Category	Cigar
Product Sub-Category	Unfiltered Sheet-Wrapped
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Matthew J. Walters -S
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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: 2019.02.08 08:49:29 -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 products:

Table 1. Original Tobacco Products

EX0000343: Middleton's Cherry Blend	
Product Name	Middleton's Cherry Blend
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry
EX0000344: Black & Mild® Wine	
Product Name	Black & Mild Wine
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Wine
EX0000345: Black & Mild® Wine	
Product Name	Black & Mild Wine
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Wine
Tip	Plastic Tip
EX0000346: Middleton's Cherry Blend	
Product Name	Middleton's Cherry Blend
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry

EX0000347: Prince Albert Soft Cherry Vanilla	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry Vanilla
EX0000348: Prince Albert Soft Cherry Vanilla	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Polypropylene (clear plastic) wrap
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
Characterizing Flavor	Cherry Vanilla

The applicant manufactures the original tobacco products and claims they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Requests (EX0000343-EX0000348) on December 19, 2018. FDA issued acknowledgement letters on December 21, 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
- Deletion of (b) (4)(b) (4) from the tobacco filler for EX0000344 and EX0000345 only
- Addition of (b)(4) to the tobacco filler
- Deletion of (b) (4)(b) (4) from the cigar wrapper and cigar binder
- Addition of (b) (4)(b) (4) to the cigar wrapper and cigar binder
- Increase of (b) (4)(b) (4) /cigar) for EX0000344 and EX0000345 only

2. REGULATORY REVIEW

Regulatory reviews were completed by Nicholas Hasbrouck on December 21, 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 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 16, 2019, concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on January 30, 2019. The review states that the new tobacco products have been modified by adding and deleting tobacco additives. (b) (4) and (b) (4)(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 products. 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) (b) (4) from the tobacco filler and addition of (b) (4)(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)(b) (4) from the cigar wrapper ((b) (4) mg) and binder ((b) (4) mg) and addition of (b) (4) (b) (4) to the cigar wrapper ((b) (4) mg) and binder ((b) (4) mg) is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Additionally, for EX0000344 and EX0000345, the applicant deleted (b) (4)(b) (4)(b) (4) /cigar) from the tobacco filler and increased an existing additive in the cigar

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.

filler – (b) (4) – by (b) (4)/cig. The applicant provided a study that demonstrated that a change in this additive in cigars at this quantity is not expected to influence HPHC yields. Therefore, these modifications represent small quantity changes and do not result in a net weight change of the tobacco products 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 Ronald Edwards on January 28, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 7, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 7, 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
- Deletion of (b)(4) from the tobacco filler for EX0000344 and EX0000345 only
- 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
- Increase of (b)(4)/cigar) for EX0000344 and EX0000345 only

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 deletion of two tobacco additives (b) (4)(b) (4)(b) (4)(b) (4) the addition of two tobacco additives (b) (4)(b) (4)(b) (4) and the increase of an existing additive² (b) (4)(b) (4). The deletion of (b) (4)(b) (4) from the tobacco filler and addition of (b) (4)(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)(b) (4) from the cigar wrapper (b) (4) mg) and binder (b) (4) and addition of sodium benzoate to the cigar wrapper (b) (4) and binder (b) (4) 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,

² For EX0000344 and EX0000345 only

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 tobacco products. Also, based on the smoke data submitted by the applicant, the deletion of (b) (4)(b) (4) and the addition of (b) (4)(b) (4) do not significantly affect the smoke chemistry of the modified products. Additionally, for EX0000344 and EX0000345, the applicant deleted (b) (4)(b) (4) (b) (4)/cigar) from the tobacco filler and increased an existing additive in the cigar filler – (b) (4) (b) (4) – by (b) (4) cig. The applicant provided a study that demonstrated that a change in this additive in cigars at this quantity is not expected to influence HPHC yields. 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 the 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 are eligible for modifications through the Exemption Request pathway because they are legally marketed in the United States. The original products are grandfathered products (i.e., were 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 products exempt and made a finding of no significant impact.

Exempt order letters should be issued for the new tobacco products in EX0000343 – EX0000348 as identified on the cover page of this review.