FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:
Exemption Request EX0000297 – EX0000300

EX0000297: Gold & Mild	
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0 %
Characterizing Flavor	None
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 binder • Addition of (b) (4) to the cigar wrapper and binder
EX0000298: Gold & Mild	
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0 %
Characterizing Flavor	None
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 binder • Addition of (b) (4) to the cigar wrapper and binder
EX0000299: Black & Mild Select	
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0 %
Characterizing Flavor	None
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 binder • Addition of (b) (4) to the cigar wrapper and binder
EX0000300: Black & Mild Select	
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0 %
Characterizing Flavor	None
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 binder • Addition of (b) (4) to the cigar wrapper and binder

Common Attributes of Exemption Request	
Applicant	John Middleton Co.
Product Category	Cigar
Product Sub-Category	Unfiltered Sheet-Wrapped
Tip	Plastic Tip
Package Quantity	Five cigars: EX0000297 and EX0000299 One cigar: EX0000298 and EX0000300
Package Type	Box: EX0000297 and EX0000299 Polypropylene (clear plastic) wrap: EX0000298 and EX0000300
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Jeannie H. Jeong-im -S 2018.12.28 07:58:50 -05'00'

For 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)

Deirdre L. Kittner -S Digitally signed by Deirdre L. Kittner -S
Date: 2018.12.28 11:24:40 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND 4

1.1. ORIGINAL TOBACCO PRODUCT 4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 5
1.3. SCOPE OF REVIEW 5
1.4. TOBACCO ADDITIVE MODIFICATION 5

2. REGULATORY REVIEW 5

3. COMPLIANCE REVIEW 5

4. SCIENTIFIC REVIEW 6

5. ENVIRONMENTAL DECISION 6

6. CONCLUSION AND RECOMMENDATION 6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000297: Gold & Mild	
Product Name	Gold & Mild
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0%
Characterizing Flavor	None
Tip	Plastic Tip
EX0000298: Gold & Mild	
Product Name	Gold & 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
EX0000299: Black & Mild Select	
Product Name	Black & Mild Mild
Package Type	Box
Package Quantity	Five cigars
Length	126.9 mm
Diameter	9.62 mm
Ventilation	0%
Characterizing Flavor	None
Tip	Plastic Tip
EX0000300: Black & Mild Select	
Product Name	Black & Mild 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 these Exemption Requests (EX0000297-EX0000300) on November 2, 2018. FDA issued Acknowledgement letters on November 14, 2018. On December 4, 2018, FDA received four unsolicited amendments (EX0000320, EX0000321, EX0000324, and EX0000327), correlating to each submission (EX0000321 amends EX0000297, EX0000320 amends EX0000298, EX0000327 amends EX0000299, and EX0000324 amends EX0000300), containing information on an additional manufacturing facility.

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
- Addition of (b) (4) to the cigar wrapper and cigar binder

2. REGULATORY REVIEW

Regulatory reviews were completed by Shireen Fotelargias on November 14, 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., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated December 2, 2018 for EX0000297 and EX0000298, and December 7, 2018 for EX0000299 and EX0000300, concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.[1]

[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.

4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Coraggio on December 13, 2018.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. (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) 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 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 December 12, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 21, 2018. The FONSI was supported by an environmental assessment prepared by FDA on December 21, 2018.

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
- 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 [redacted] and the addition of two tobacco additives [redacted]. The deletion of [redacted] µg) from the tobacco filler and addition of [redacted] 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 [redacted] mg) from the cigar wrapper and binder and addition of [redacted] 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 [redacted] a substance associated with severe obstructive lung disease, bronchiolitis obliterans and decreased lung function, from the new tobacco product. The addition of [redacted] is to replace [redacted] and not expected to affect the characteristics of the product. Also, based on the smoke data submitted by the applicant, the deletion of [redacted] and the addition of [redacted] 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 Requests 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 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., 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 products exempt and made a finding of no significant impact.

Exempt order letters should be issued for the new tobacco products in EX0000297 – EX0000300 as identified on the cover page of this review.