

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
STNs	EX0003223.PD1, EX0003223.PD3, EX0003224.PD1, EX0003225.PD1
Common Attributes	
Submission date	May 7, 2024
Receipt date	May 7, 2024
Applicant	John Middleton Co.
Product manufacturer	John Middleton Co.
Product category	Cigars
Product subcategory	Unfiltered, Sheet-Wrapped ²
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Social Science evaluation of design of Cigarette Tipping Papers (May 16, 2017).
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Youbang Liu -S
Date: 2025.01.28 14:47:46 -05'00'

Youbang Liu, Ph.D.
Chemistry Team Supervisor
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2025.01.31 10:20:58 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

¹ Product details, amendments, and dates provided in the Appendix. STN means submission tracking number including product static identification number (PD) if applicable. EX means exemption (request) from substantial equivalence.

² EX0003225.PD1 is determined a filtered product.

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

The applicant submitted information for the new and original products listed in detail in Appendix A.

1.2. REGULATORY ACTIVITY

On May 7, 2024, FDA received 4 EX Requests from John Middleton Co. FDA completed an acceptance review on June 3, 2024, and issued an acceptance letter to the applicant on June 4, 2024.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1	
Discipline	Reviewer(s)	Review Date
Chemistry	Ruth Ganunis	12/17/2024
Environmental Science	John Teem	11/8/2024

2. COMPLIANCE REVIEW

The original products in EX0003223.PD1, EX0003223.PD3, EX0003224.PD1, EX0003225.PD1 were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA.

Therefore, the original products are eligible for modification under the Exemption Request pathway.³

3. TOBACCO ADDITIVE MODIFICATION

The applicant identifies that the modifications of the original products compared to the corresponding new products are the result of:

- deleting an additive (plastic tip) in EX0003223.PD1, EX0003223.PD3
- adding an additive (alternate plastic tip 1) in EX0003223.PD1
- adding an additive (alternate plastic tip 2) in EX0003223.PD3
- deleting an additive (wood tip) in EX0003224.PD1
- adding an additive (alternate wood tip) in EX0003224.PD1
- deleting an additive (lip release) in EX0003225.PD1
- adding an additive (alternate lip release) in EX0003225.PD1

³ Any 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

The review finds these modified ingredients (see Section 3) 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 products. The review concludes that the collective modifications are minor modifications of a 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 Luis Valerio, Ph.D. on December 17, 2024. The FONSI was supported by an environmental assessment prepared by FDA on December 16, 2024.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these collective modifications (see Section 3) are a minor modification of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. 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 products to be marketed would be appropriate for the protection of the public health.

In all EX Requests, the following ingredient modifications are observed:

- 1) Replacing plastic tip with alternate plastic tips
 - Plastic Tip 1 (EX0003223.PD1) and Plastic Tip 2 (EX0003223.PD3)
 - All the compositional changes in the plastic tips are in the colorants
 - All ingredients used in the tips of the new products are approved for use in, or in contact with foods and CFR citations are provided
 - Colors of new and original tips are not provided, however, impact on consumer behavior due to tip color likely to be minimal
 - Cigar plastic tips are unburned materials that do not combust, volatilize, or otherwise release during normal consumption. Therefore, the modifications are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents, and hence from a chemistry perspective, the above modifications are considered minor.
- 2) Replacing wood tip with an alternate wood tip
 - EX0003224.PD1
 - All the compositional changes in the wood tips are in the sweeteners ((b) (4) mg/cigar) applied to the wood tip
 - ((b) (4) mg/cigar, ↑ 100%) and ((b) (4) mg/cigar, ↑ 100%)
 - The sweeteners are permitted for use in food and CFR citations are provided
 - The sweeteners used on the tip of the new product are below their respective acceptable daily intake (ADI)
 - Currently, there is a lack of specific scientific evidence to demonstrate that adding sweetener to the cigar tip would increase cigar initiation and/or enhance cigar appeal
 - Cigar wood tips are unburned materials that do not combust, volatilize, or otherwise release during normal consumption. Therefore, the modifications are not expected to

significantly alter the smoke chemistry or consumer exposure to chemical constituents, and hence from a chemistry perspective, the above modifications are considered minor.

3) Replacing lip release with an alternate lip release

- EX0003225.PD1
- Addition of (b) (4) mg/cigar of (b) (4) sweetener in the lip release of the new product that is absent in the original product
- (b) (4) is permitted for use in food and CFR citations are provided
- (b) (4) used on the tip of the new product is below its ADI
- Currently, there is a lack of specific scientific evidence to demonstrate that adding sweetener to the cigar tip would increase cigar initiation and/or enhance cigar appeal
- Lip release is unburned materials that do not combust, volatilize, or otherwise release during normal consumption. Therefore, the modifications are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents, and hence from a chemistry perspective, the above modifications are considered minor.

In addition, In the Confidential EAs for EX0003223.PD1, EX0003223.PD3, and EX0003224.PD1, the applicant states “The binder and wrapper are leaf tobacco or tobacco-based (b) (4).” Other than these occurrences, the EX requests for these products consistently describe the binder and wrapper as tobacco-based (b) (4), which is consistent with the original product information in SE0016588 and SE0016590. Therefore, while the Confidential EAs for EX0003223.PD1, EX0003223.PD3, and EX0003224.PD1 indicate that the binder and wrapper are leaf tobacco or tobacco-based (b) (4), the binder and wrapper of the products were determined to be tobacco-based (b) (4).

In EX0003225.PD1 Table 2.1. Product Identifying Information, the applicant identified the Tobacco Product Sub-Category as “Unfiltered, Sheet-Wrapped Cigar” while the Tip is described as “Filter”, and “Filter Tip” is included in the product name in the same table. Other than this single occurrence in Table 2.1, the information in the body of the EX request clearly indicates that the tip is filtered, which is consistent with the original product information in SE0016589. It is concluded that the single mention of unfiltered in Table 2.1 is an administrative or typographical error as elsewhere the product is consistently described as filtered cigar.

Thus, the applicant has demonstrated that the collective product modifications are a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act, and as TPL, I have concluded that the applicant has shown that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, SE Reports are not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health. Lastly, I find 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 products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are previously found SE and in compliance with the FD&C Act by FDA.

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

An exempt order should be issued for the new products, as identified on the cover page of this review.

7. DEFICIENCIES

None.

8. APPENDICES

8.1. Appendix A. NEW AND ORIGINAL CORRESPONDING PRODUCTS

Common Attributes ^{4,5,6,7,8}	
Submit date	May 7, 2024
Receipt date	May 7, 2024
Applicant	John Middleton Co.
Product manufacturer	John Middleton Co.
Product category	Cigars
Product subcategory	Unfiltered, Sheet-Wrapped ²

⁴ We interpret package type to mean container closure system and product quantity to mean quantity within the container closure system, unless otherwise identified.

⁵ Product name is brand/sub-brand or other commercial name used in commercial distribution.

⁶ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

⁷ Attributes in Appendix A may display converted values.

⁸ Nicotine source was not provided by the applicant; however, the application for this product was received prior to April 14, 2022, or is modifying an original product that was marketed prior to April 14, 2022. As such, nicotine source is classified as tobacco.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0003223.PD1	SE0016588
Product name	Black & Mild Red Label	Black & Mild Red Label
Eligibility status	Not applicable (N/A)	Previously Found SE
Marketing authorization date	N/A	January 19, 2022
Abbreviated report date	N/A	N/A
Package type	Film	Film
Product quantity	1 Cigars	1 Cigars
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length	126.90 millimeters (mm)	126.90 mm
Diameter	9.57 mm	9.57 mm
Tip	Plastic	Plastic
Additional property	Plastic Tip 1; Ventilation: None; Heating Source: Combusted	Ventilation: None; Heating Source: Combusted
Product modifications	Addition/Deletion of tobacco additives: • Deletion of plastic tip • Addition of alternate plastic tip using different colorants (Plastic Tip 1)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0003223.PD3	SE0016588
Product name	Black & Mild Red Label	Black & Mild Red Label
Eligibility status	N/A	Previously Found SE
Marketing authorization date	N/A	January 19, 2022
Abbreviated report date	N/A	N/A
Package type	Film	Film
Product quantity	1 Cigars	1 Cigars
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length	126.90 mm	126.90 mm
Diameter	9.57 mm	9.57 mm
Tip	Plastic	Plastic
Additional property	Plastic Tip 2; Ventilation: None; Heating Source: Combusted	Ventilation: None; Heating Source: Combusted
Product modifications	Addition/Deletion of tobacco additives: • Deletion of plastic tip • Addition of alternate plastic tip using different colorants (Plastic Tip 2)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0003224.PD1	SE0016590
Product name	Black & Mild Red Label Wood Tip	Black & Mild Red Label Wood Tip
Eligibility status	N/A	Previously Found SE
Marketing authorization date	N/A	January 19, 2022
Abbreviated report date	N/A	N/A
Package type	Film	Film
Product quantity	1 Cigars	1 Cigars
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length	126.90 mm	126.90 mm
Diameter	9.57 mm	9.57 mm
Tip	Wood	Wood
Additional property	Ventilation: None; Heating Source: Combusted	Ventilation: None; Heating Source: Combusted
Product modifications	Addition/Deletion of tobacco additives: • Deletion of wood tip • Addition of alternate wood tip	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0003225.PD1	SE0016589
Product name	Black & Mild Red Label Filter Tip	Black & Mild Red Label Filter Tip
Eligibility status	N/A	Previously Found SE
Marketing authorization date	N/A	January 19, 2022
Abbreviated report date	N/A	N/A
Package type	Film	Film
Product quantity	1 Cigars	1 Cigars
Characterizing flavor (CF)	Tobacco	Tobacco
Nicotine source	Tobacco	Tobacco
Length	110.0 mm	110.0 mm
Diameter	8.90 mm	8.90 mm
Tip	Filter	Filter
Additional property	Ventilation: None; Heating Source: Combusted	Ventilation: None; Heating Source: Combusted
Product modifications	Addition/Deletion of tobacco additives: • Deletion of lip release on filter tip • Addition of alternate lip release that contains sweetener	