



January 19, 2022

**SUBSTANTIALLY EQUIVALENT**

John Middleton Co.  
Attention: Ms. Rebecca A. Rivas, R.A.C., Sr. Director, Regulatory Submissions  
Altria Client Services LLC  
601 East Jackson Street  
Richmond, VA 23219

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Rebecca Rivas:

We completed our review of your SE Reports<sup>1</sup> and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

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<sup>1</sup> Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

If you have any questions, please contact Jill Grosperre, Regulatory Health Project Manager, at (301) 796-1714 or [Jill.Grosperre@fda.hhs.gov](mailto:Jill.Grosperre@fda.hhs.gov).

Sincerely,

Digitally signed by Todd L. Cecil -S

Date: 2022.01.19 08:10:20 -05'00'

Todd L. Cecil, Ph.D.  
Deputy Director  
Office of Science  
Center for Tobacco Products

**Enclosures:**

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Health Information Summary

**Appendix A<sup>2,3,4,5,6</sup>****New and Corresponding Predicate Tobacco Products Subject of This Letter**

<b>Common Attributes of SE Reports</b>		
Submission date	May 6, 2020 <sup>3</sup> ; June 30, 2020 <sup>4</sup>	
Receipt date	May 6, 2020 <sup>3</sup> ; June 30, 2020 <sup>4</sup>	
Product manufacturer	John Middleton Co.	
Product category	Cigars	
Product subcategory	Unfiltered, Sheet-Wrapped <sup>5</sup> and Filtered, Sheet-Wrapped <sup>6</sup>	
<b>Attributes</b>	<b>New Product</b>	<b>Predicate Product</b>
<b>STN</b>	<b>SE0016588</b>	<b>GF1602193</b>
Product name	Black & Mild <sup>®</sup> Red Label	Prince Albert Soft Cherry Vanilla
Eligibility status	Not applicable	Grandfathered
Package type	Film <sup>7</sup>	Film <sup>7</sup>
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	Cherry Vanilla
Length	126.9 mm	126.9 mm
Diameter	9.57 mm	9.62 mm
Tip	Plastic	Plastic
<b>STN</b>	<b>SE0016589</b>	<b>GF1602172</b>
Product name	Black & Mild <sup>®</sup> Red Label FT	Black & Mild FT
Eligibility status	Not applicable	Grandfathered
Package type	Film <sup>7</sup>	Film <sup>7</sup>
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	110 mm	110 mm
Diameter	8.9 mm	8.9 mm
Ventilation	None	None
<b>STN</b>	<b>SE0016590</b>	<b>GF1602193</b>
Product name	Black & Mild <sup>®</sup> Red Label Wood Tip	Prince Albert Soft Cherry Vanilla
Eligibility status	Not applicable	Grandfathered
Package type	Film <sup>7</sup>	Film <sup>7</sup>
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	Cherry Vanilla
Length	126.9 mm	126.9 mm
Diameter	9.57 mm	9.62 mm
Tip	Wood	Plastic

<sup>2</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<sup>3</sup> SE0016588-SE0016590.

<sup>4</sup> SE0016754-SE0016755.

<sup>5</sup> SE0016588, SE0016590, SE0016754, and SE0016755.

<sup>6</sup> SE0016589.

<sup>7</sup> Cello is defined as clear film. The applicant considers cello and film to be synonymous when identifying cigar product packaging. Based on information provided in the SE Report, there is no change in the packaging between the new and predicate products, and for this submission, cello and film are synonymous.

<b>STN</b>	<b>SE0016754</b>	<b>GF1602166</b>
Product name	Black & Mild® Casino	Black & Mild
Eligibility status	Not applicable	Grandfathered
Package type	Film <sup>7</sup>	Film <sup>7</sup>
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	126.9 mm	126.9 mm
Diameter	9.57 mm	9.62 mm
Tip	Plastic	Plastic
<b>STN</b>	<b>SE0016755</b>	<b>GF1602166</b>
Product name	Black & Mild® Casino Wood Tip	Black & Mild
Eligibility status	Not applicable	Grandfathered
Package type	Film <sup>7</sup>	Film <sup>7</sup>
Package quantity	1 cigar	1 cigar
Characterizing flavor	None	None
Length	126.9 mm	126.9 mm
Diameter	9.57 mm	9.62 mm
Tip	Wood	Plastic

## **Appendix B**

### Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.