



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

June 03, 2020

SUBSTANTIALLY EQUIVALENT

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

FDA Submission Tracking Number (STN): SE0015224, see Appendix A

Dear Ms. Rivas:

We completed our review of your SE Report¹ and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A and is 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 product subject of this letter.

Our finding does not mean we “approved” the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product 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 product 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 product specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Travelle Mason, M.P.H., Regulatory Health Project Manager, at (240) 402-7805 or Travelle.Mason@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2020.06.03 16:59:26 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

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

Appendix B – Health Information Summary

Appendix A
New and Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
Date of Submission:	May 8, 2019	
Date of Receipt:	May 8, 2019	
Product Manufacturer:	John Middleton Co.	
Product Category:	Cigars	
Product Sub-Category:	Unfiltered, Sheet-Wrapped Cigar	
	New Tobacco Product	Predicate Tobacco Product
	SE0015224: Black & Mild® Estate Blend ²	GF1602168: Black and Mild Wine ²
Package Type:	Cello ³	Cello ³
Package Quantity:	1 Cigar	1 Cigar
Eligibility Status:	N/A	Grandfathered
Length:	126.9 mm	126.9 mm
Diameter:	9.57 mm	9.62 mm
Tip:	Plastic Tip	Plastic Tip
Characterizing Flavor:	None ⁴	Wine ⁵

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

³ The applicant defines "cello" as a clear wrap. In this case, cello is composed of polypropylene plastic wrap.

⁴ The applicant uses the term (b) (4)

[REDACTED]

[REDACTED]

In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

⁵ The applicant uses the term (b) (4)

[REDACTED]

[REDACTED]

In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

Appendix B

Health Information Summary

Your SE Report did not provide a summary of any health information related to the new tobacco product, required by section 910(a)(4) of the FD&C Act; however, your SE Report 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 Report 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 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].”

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.