

February 14, 2019

EXEMPT

John Middleton Co.
ATTENTION: Rebecca A. Rivas, Senior Director, Regulatory Submissions
Altria Client Services LLC
2325 Bells Road
Richmond, VA 23234

FDA Submission Tracking Number (STN): MULTIPLE STNs, SEE APPENDIX A

Dear Ms. Rivas:

The Food and Drug Administration (FDA) completed review of your Requests for Exemption from Substantial Equivalence (EX REQs), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the tobacco products specified in Appendix A.

Based on our review of your EX REQs, we find the new tobacco products specified in Appendix A are exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market the new tobacco products that are the subject of these EX REQs, the following must be met:

- 1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
- 2. Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix B for FDA's recommended format for the submission of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA "approved" the new tobacco products specified in Appendix A; therefore, you may not promote or in any way represent the modified tobacco products specified in Appendix A, or their labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. This order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the new tobacco products specified in Appendix A, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)¹ using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>). Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutcontact/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Nicholas Hasbrouck, Regulatory Health Project Manager, at (240) 402-5413 or nicholas.hasbrouck@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.02.14 11:57:54 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures – Appendix A: List of New Tobacco Products Subject of This Letter
Appendix B: FDA's Recommended Format of the Submission of an Abbreviated Report

¹ The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

Appendix A

List of new tobacco products that FDA has found exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent

Common Attributes of Exemption Requests	
Date of Submission:	December 19, 2018
Date of Receipt:	December 19, 2018
Product Manufacturer:	John Middleton Co.
Product Category:	Cigars
Product Sub-Category:	Unfiltered, Sheet-Wrapped Cigar
New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000343
Product Name:²	Middleton's Cherry Blend
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Cherry
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic tip
Modifications:	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of diacetyl from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder
Original Tobacco Product Specific Attributes	
Product Name:²	Middleton's Cherry Blend
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Cherry
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

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

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000344
Product Name:²	Black & Mild® Wine
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Wine
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip
Modification:	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of diacetyl and potassium sorbate from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder <p>Increasing/Decreasing the quantity of existing additives:</p> <ul style="list-style-type: none"> • Increase of licorice extract (1.0 mg/cigar) in the tobacco filler
Original Tobacco Product Specific Attributes	
Product Name:²	Black & Mild Wine
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Wine
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000345
Product Name:²	Black & Mild® Wine
Package Type:	Cello (polypropylene plastic wrap)
Package Quantity:	1 Cigar
Characterizing Flavor:	Wine
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic tip
Modification:	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of diacetyl and potassium sorbate from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder <p>Increasing/Decreasing the quantity of existing additives:</p> <ul style="list-style-type: none"> • Increase of licorice extract (1.0 mg/cigar) in the tobacco filler
Original Tobacco Product Specific Attributes	
Product Name:²	Black & Mild Wine
Package Type:	Polypropylene (clear plastic) wrap
Package Quantity:	1 Cigar
Characterizing Flavor:	Wine
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000346
Product Name:²	Middleton's Cherry Blend
Package Type:	Cello (polypropylene plastic wrap)
Package Quantity:	1 Cigar
Characterizing Flavor:	Cherry
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic tip
Modification:	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of diacetyl from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder
Original Tobacco Product Specific Attributes	
Product Name:²	Middleton's Cherry Blend
Package Type:	Polypropylene (clear plastic) wrap
Package Quantity:	1 Cigar
Characterizing Flavor:	Cherry
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000347
Product Name:²	Prince Albert Soft Cherry Vanilla
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Cherry Vanilla
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic tip
Modification:	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of diacetyl from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder
Original Tobacco Product Specific Attributes	
Product Name:²	Prince Albert Soft Cherry Vanilla
Package Type:	Box
Package Quantity:	5 Cigars
Characterizing Flavor:	Cherry Vanilla
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000348
Product Name:²	Prince Albert Soft Cherry Vanilla
Package Type:	Polypropylene (clear plastic) wrap
Package Quantity:	1 Cigar
Characterizing Flavor:	Cherry Vanilla
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic tip
Modification:	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of diacetyl from the tobacco filler • Addition of water to the tobacco filler • Deletion of potassium sorbate from the cigar wrapper and cigar binder • Addition of sodium benzoate to the cigar wrapper and cigar binder
Original Tobacco Product Specific Attributes	
Product Name:²	Prince Albert Soft Cherry Vanilla
Package Type:	Polypropylene (clear plastic) wrap
Package Quantity:	1 Cigar
Characterizing Flavor:	Cherry
Eligibility Status:	Grandfathered
Length:	126.9 mm
Diameter:	9.62 mm
Tip:	Plastic Tip

Appendix B
FDA's Recommended Format of the Submission of an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe
Vice President
Mock-Up Tobacco Company

OFFICE OF SCIENCE—HISTORY AND CONCURRENCE PAGE

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Document History

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Document History:	<i>Each reviewer is to include their name and date of review of this document:</i> Nick Hasbrouck: 2/11/19, 2/12/19, 2/14/19 Marvin Mitchell: 2/12/19 Lana Rossiter: 2/14/19

Issues (check all that apply):	Describe issue(s):
<input type="checkbox"/> Amendment(s)	
<input type="checkbox"/> POC Change	
<input type="checkbox"/> Policy	
<input type="checkbox"/> Predicate	
<input type="checkbox"/> Transfer of Ownership	
<input type="checkbox"/> Other	

Final Clearance

Position	Name and date of final clearance
RHPM	CONCUR <i>By Nicholas Hasbrouck at 11:31 am, Feb 14, 2019</i>
RHPM CHIEF	CONCUR <i>By Lana.Rossiter at 11:34 am, Feb 14, 2019</i>

END OF HISTORY AND CONCURRENCE PAGE