

December 07, 2018

**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):** EX0000282

Dear Ms. Rivas:

The Food and Drug Administration (FDA) has completed review of your Request for Exemption from Substantial Equivalence (EX REQ), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco product:

|  |   |
|--|---|
| <b>Tobacco Product Manufacturer:</b>     | John Middleton Co.  |
| <b>Tobacco Product Name:<sup>1</sup></b> | Black and Mild  |
| <b>Tobacco Product Category:</b>         | Cigars  |
| <b>Tobacco Product Sub-Category:</b>     | Unfiltered, Sheet-Wrapped Cigar   |
| <b>Package Type:</b>                     | Box   |
| <b>Package Quantity:</b>                 | 5 Pack  |
| <b>Characterizing Flavor:</b>            | None  |
| <b>Diameter:</b>                         | 9.62 mm   |
| <b>Length:</b>                           | 126.9 mm  |
| <b>Tip:</b>                              | Plastic   |
| <b>Modification:</b>                     | 1) removal of (b)(4) (CAS number (b)(4)) and replacement with an equal amount of (b)(4) in the tobacco filler; and 2) removal of (b)(4) (CAS number (b)(4)) and replacement with an equal amount of (b)(4) (CAS number (b)(4)) in the cigar wrapper and binder. |

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

**To market the new tobacco product that is the subject of this EX REQ, 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.

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution.

See Appendix A 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 product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its 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 product specified above, 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 product specified above complies 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](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto: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>)<sup>2</sup> 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/aboutctp/contactus/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.

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<sup>2</sup> The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, you may contact Shireen Fotelargias, MS, Regulatory Health Project Manager, at (240) 402 - 0435 or [Shireen.Fotelargias@fda.hhs.gov](mailto:Shireen.Fotelargias@fda.hhs.gov).

Sincerely,

Matthew R.  
Holman -S

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Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Appendix A

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