DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

June 16, 2015

SUBSTANTIALLY EQUIVALENT

Altria Client Services Inc.
Attention: CRT 3rd Fl.
Rebecca Rivas, Senior Manager Regulatory Affairs
2325 Bells Road
Richmond, VA 23234

FDA Submission Tracking Number (STN): SE0009417

Dear Ms. Rivas:

The Food and Drug Administration (FDA) completed review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	Philip Morris USA Inc.
Tobacco Product Name[1]:	Basic Menthol Silver Pack Box
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 Cigarettes Per Pack
Characterizing Flavor:	Menthol
Length:	83 mm
Diameter:	7.9 mm
Filter Ventilation:	43%
Additional Property:	Cigarette Paper 2

[1] Brand/sub-brand or other commercial name used in commercial distribution

Based on our review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following tobacco product, which was commercially marketed in the United States as of February 15, 2007:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Philip Morris USA Inc.
Tobacco Product Name[2]:	Basic Menthol Ultra Lights Box
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 Cigarettes Per Pack
Characterizing Flavor:	Menthol
Length:	83 mm
Diameter:	7.9 mm
Filter Ventilation:	43%
Additional Property:	None

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 specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. No later than 30 days from date of letter, we will make your summary available to the public.

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

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA "approved" the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or it's labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

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

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

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, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

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

We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Stephanie Durkin, M.S., Regulatory Health Project Manager, at (301) 796 - 0370.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.06.16 15:58:45 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director, Office of Science
Center for Tobacco Products