DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

December 01, 2015

RESCISSION OF SUBSTANTIALLY EQUIVALENT ORDER

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): SE0009413

Dear Ms. Rivas:

This letter is in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report) for L&M Blue Pack Box (SE0009413), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

On June 16, 2015, you received a determination that your new tobacco product was substantially equivalent to a tobacco product which was commercially marketed in the United States as of February 15, 2007. On June 24, 2015 you contacted FDA to notify us about errors in this SE Report regarding inaccurate ingredient information in your reconstituted tobacco sheet ingredients due to miscalculations in ingredient quantities. On July 2, 2015 you provided the revised ingredients and calculations. After review of the July 2, 2015 submission, FDA determined that the corrected inaccuracies constitute a change in the new and predicate product characteristics, thus creating distinctly different predicate and new products from those on which the June 16, 2015 order is based. An SE determination compares the characteristics of the new and predicate tobacco products and evaluates whether any differences in characteristics causes the new tobacco product to raise different questions of public health. Therefore, because your June 16, 2015 SE order was based upon incorrect information about the characteristics of the new and predicate tobacco products, the order is no longer valid and FDA is rescinding the order.

Accordingly, this letter rescinds your June 16, 2015, SE order letter for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	Philip Morris USA Inc.
Tobacco Product Name[1]:	L&M Blue Pack Box
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 Cigarettes Per Pack
Characterizing Flavor:	None
Length:	83 mm
Diameter:	7.9 mm
Filter Ventilation:	18%
Additional Property:	Cigarette Paper 2

With the rescission of the SE determination for the tobacco product listed above, unless you seek and are granted future premarket authorization, you cannot distribute, import, sell, market, or promote this product in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA. Additionally the tobacco product is not eligible to serve as a predicate tobacco product in a future SE application[2].

This is a class of actions that ordinarily would be categorically excluded. There are no extraordinary circumstances that exist which requires preparation of an environmental assessment or an environmental impact statement (see 21 CFR 25.35(c)).

We understand that you are no longer pursuing this SE Report, and, therefore, with this letter, we are administratively closing your application. You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii) of the FD&C Act, (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).

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

[2] If you submit a new SE report for the product and it is subsequently found substantially equivalent to a predicate tobacco product, this new tobacco product will be eligible to serve as a predicate tobacco product.

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or mailed 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, Lead Regulatory Health Project Manager, at (301) 796 - 0370.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.12.01 13:48:38 -05'00'

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