



Malgorzata Wronowska
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.
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Date: Oct 04, 2017

Re: Tobacco Product Master File - Letter of Authorization to reference
Submission Tracking Number (STN) MF0000264

Dear Ms. Wronowska:

Celerion Inc. provides this Letter of Authorization (LOA) to authorize Philip Morris Products S.A. to incorporate by reference information regarding Analytical Method Validation Reports contained in MF0000264 into any Modified Risk Tobacco Product Application / Premarket Tobacco Product Application for which these analytical methods have been used to analyze biomarkers of exposure to HPHCs during PMI clinical studies. We also authorize the FDA to review the information in MF0000264 when considering any MRTPA / PMTA filed by Philip Morris Products S.A.

The entire Tobacco Product Master File may be referenced.

Celerion confirms that, MF0000264 is current. Celerion will notify FDA through an amendment to MF0000264 of any addition, change, or deletion of information in the TPMF.

Celerion will also notify in writing Philip Morris Products S.A. that an addition, change, or deletion of information has been made to the TPMF.

Sincerely,

A handwritten signature in blue ink that reads "R H Farnen".

Raymond H. Farnen, Ph.D.
Vice President, Global Bioanalytical Services
Celerion

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cc: Food and Drug Administration
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