



November 16, 2017

Dr. Benjamin Apelberg, Ph.D.
Director, Division of Population Health Science
Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

**Re: RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for
MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061
- Additional information**

Dear Dr. Apelberg,

In reference to our September 8, 2017 response to the above-mentioned FDA Advice/Information Request, we hereby provide additional information related to our responses to the following questions:

- Question 9: A3.3-11 Stability Final Results (12 months) – Menthol 2
[\[A3.3-11 Final-Stab-Report-Menthol-2\]](#)
- Question 10: Letter of Authorization to cross-reference Celerion MF0000264
[\[1.7 LoA-MF0000264\]](#)
- Question 21: Corrigendum
[\[Q21-Corrigendum\]](#)

In addition, we are providing an updated Appendix A3.3-8 ‘Stability Final Results (12 months) – Menthol 1’ [\[A3.3-8 Final-Stab-Report-Menthol-1\]](#), which was submitted on September 8, 2017 in response to the above-mentioned FDA Advice/Information Request. The correction is due to the CAPA-RRP-NEU-2017-237 that was initiated to align results reported in the study with Out of Trend (OOT) investigation done at T4 time point. The detailed description and the justification of the updates are included in the section ‘Revision history for stability report’ of the document. The correction has no impact on the conclusions of the stability study.



PHILIP MORRIS
PRODUCTS S.A.

This response/amendment contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in this amendment.

We remain available for any further information that is required.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.

Jeffrey Walker, M.D.
US Agent for PMP S.A.
CEO, Teton Regulatory Sciences

Enclosures