



PHILIP MORRIS
PRODUCTS S.A.

May 16, 2018

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

Submitted via ESG

Re: Amendment to MR0000059-MR0000061 - Additional information

Dear Sir or Madam,

We are hereby providing, in amendment to the above-mentioned applications, the recently finalized Safety Update Report (SUR). This SUR summarizes relevant safety data received by Philip Morris International (PMI) within the period from January 01, 2017 to December 31, 2017. The safety data lock point (DLP) is December 31, 2017. The report has been prepared according to the International Conference of Harmonisation (ICH) guideline E2C (R2) and provides a comprehensive and critical analysis of new safety information on THS.

This 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,

Małgorzata 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 : [Appendix A](#)



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May 16, 2018: Amendment to MR0000059-61

Appendix A:

| Attachments |
|--|
| [Filename] |
| Safety Update Report: Electrically Heated Tobacco Product (EHTP) and Tobacco Heating Device (THD), as part of the Tobacco Heating System (THS) |
| [PMI_SURV_2018_SUR01] |