Module 1: General Information

1.3 Letters of Authorization

TABLE OF CONTENTS

1. LETTERS OF AUTHORIZATION..... 2

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International.

1. LETTERS OF AUTHORIZATION

Certain proprietary information and data applicable to this Application has been provided by means of the Tobacco Product Master File (TPMF). An overview of TPMFs and respective Letters of Authorization (LoAs) applicable to this Application is provided below.

1) TPMF (b) (4) from Enthalpy Analytical

The MF0000276 contains information regarding test methods used for analysis of Droplet Size Distribution (DSD) of the aerosol.

The LoA authorizing the Center for Tobacco Products (CTP) of the U.S. Food and Drug Administration (FDA) to reference the Enthalpy Analytical TPMF FDA STN: (b) (4) in support of submissions and filings submitted by Philip Morris Products S.A. (PMP S.A.) and to review the information in (b) (4) when considering this supplemental PMTA, is provided as part of the submission (Appendix A1-3-1-LoA-enthalpy-analytical).

2) TPMF (b) (4) from Labstat International ULC

The (b) (4) containing information regarding test methods used for analysis of Harmful and Potentially Harmful Constituents (HPHCs) in the aerosol (PMI-58 and FDA 18 + 6).

The LoA provided with the original PMTA remains valid.

3) TPMF (b) (4) from Celerion Inc.

The (b) (4) containing information regarding test methods used for analysis of biomarkers of exposure to HPHCs during PMI's clinical studies.

The LoA provided with the original PMTA remains valid.

4) TPMF (b) (4) from PMP S.A.

The (b) (4) containing information regarding the composition of the authorized *HeatSticks*.

The LoA provided with the original PMTA remains valid.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International.