

Temporary Compliance Waiver Notice

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1.3 – Letters of Authorization	Version 1.0

Module 1: General Information

1.3 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 (b) (4)

The (b) (4) contains information regarding test methods used for analysis of Droplet Size Distribution (DSD) of the aerosol.

The LoA provided with the supplemental PMTA for PM0000634 remains valid.

(2) TPMF (b) (4) from (b) (4)

The (b) (4) contains 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 MRTPA for MR0000133 remains valid.

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

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

The LoA provided with the original MRTPA for MR0000133 remains valid.

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

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

The LoA provided with the original MRTPA for MR0000133 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.
