TABLE OF CONTENTS

INTRODUCTION TO PMI'S CONFIDENTIALITY DESIGNATIONS 2

A. PMI's Approach to the Categorical Designation of Confidential Information in its Application 3

B. Designation Information 13

TABLE OF TABLES

TABLE 1 REDACTION AND DISCLOSURE TABLE 4

Confidentiality Statement

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.

INTRODUCTION TO PMI'S CONFIDENTIALITY DESIGNATIONS

This document provides a description of the information within PMI's modified risk tobacco product application (the Application) that PMI considers trade secret or confidential commercial information and that is exempt from public disclosure. This section is intended to help FDA in redacting the trade secrets and confidential commercial information from the Application before FDA discloses the Application publicly.

PMI has included in this section a Redaction and Disclosure Table, which identifies the categories of information within PMI's Application that meet the definitions of trade secret or confidential commercial information and that should be redacted, along with examples of such categories of information. The Table also lists, in instances where there may be uncertainty, categories of information that may be disclosed publicly. Among the grounds for such disclosure are (1) that PMI itself has already disclosed the information publicly, and (2) that PMI now consents to the information being released publicly.

PMI has additionally submitted, in a folder entitled "MRTPA Redacted Selections," copies of redacted portions of the Application (the Redacted Application Selections) to give FDA further exemplary guidance regarding the kinds of information that PMI considers confidential and exempt from disclosure throughout the Application, particularly where the confidential nature of the information may not be obvious to those outside PMI and/or where the confidential information is particularly sensitive for PMI. More specifically, PMI has included the following portions of the Application in the Redacted Application Selections: (1) all narrative summaries of each module in the Application (the Narratives); (2) the Appendices to Module 3; (3) the Appendices to Module 5; (4) two confidential documents among the reference documents in Module 9; and (5) this Confidentiality Designation, which itself contains confidential information.

Some of the documents composing the above-identified portions of the Redacted Application Selection do not include any redactions and may be fully disclosed. To make clear which documents are fully disclosable and which ones contain redactions, we have adopted the following naming convention. The file names for documents that are fully disclosable contain the suffix, "DISCLOSABLE," set off with a hyphen. Those documents that contain one or more redactions contain the suffix, "REDACTED," set off with a hyphen. As indicated in the Redaction and Disclosure Table, some of the file names contain confidential information, such as confidential chemical constituents or ingredients, and confidential vendor or supplier names. PMI requests that FDA replaces the file name with a substitute title for the publicly-disclosed document.

We believe that the combination of the categorical designations in the Redaction and Disclosure Table and the specific redactions in the Redacted Application Selections is the most efficient and effective way to convey PMI's views on redactions that are necessary throughout the Application.

Confidentiality Statement

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.

A. PMI's Approach to the Categorical Designation of Confidential Information in its Application

Based on statutory provisions, case law, regulations, and FDA Guidance documents and policies, PMI has created the following table to identify the categories of information within PMI's Application that meet the definitions of trade secret or confidential commercial information and that should be redacted.

For ease in discerning between disclosable and non-disclosable information, we have used the following color coding:

Green	**Disclose**
Red	**Redact**

This coloring appears only in the third and fourth columns in the table. The coloring of the first and second columns alternates between white and gray simply to make it easy to see where one Module begins and the next one ends. We have organized the table according to the Modules in which the listed category of information most commonly appears. We are **NOT** indicating that the listed Module is the only one in which that category of information appears. It is very important that wherever the categories of protected information appear in the Application, that FDA redact them from the publicly disclosed version of the Application.

We have used the following abbreviations in the table:

- Ad Comm Guidance: Guidance for Industry Advisory Committee Meetings — *Preparation and Public Availability of Information Given to Advisory Committee Members* (Aug. 2008)
- EA Guidance: Guidance for Industry: *Environmental Assessment of Human Drug and Biologics Applications* (July 1998)
- QA: Quality Assurance

Confidentiality Statement

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.

TABLE 1 REDACTION AND DISCLOSURE TABLE

(b) (4)

[redacted]

Confidentiality Statement

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.

(b) (4)



Confidentiality Statement

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.

(b) (4)

[redacted]

[1] (b) (4)
[redacted].

Confidentiality Statement

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.

(b) (4)

Confidentiality Statement

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.

(b) (4)



Confidentiality Statement

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.

(b) (4)

Confidentiality Statement

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.

(b) (4)



Confidentiality Statement

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.

(b) (4)

Confidentiality Statement

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.

(b) (4)

Confidentiality Statement

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.

B. Designation Information

For the reasons above, PMI hereby designates as exempt from public disclosure under exemption 4 of the Freedom of Information Act (FOIA) all the categories of information identified above as trade secrets and confidential commercial information. We welcome the opportunity to discuss with FDA any questions about the categories of information designated as confidential in this document or any concerns about the proposed redactions. In the event that any information that has been identified or designated as confidential by PMI is considered non-confidential by FDA, we respectfully request that FDA provide predisclosure notice to PMP S.A. pursuant to the procedures set forth in 21 C.F.R. §201.61(d) and (e).

Confidentiality Statement

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.