Module 3: Product Description

3.1.5 Restrictions on Sale, Distribution, Advertising or Promotion

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.

The *IQOS* 3 System will be marketed under the same restrictions on sale, distribution, advertising and promotion that are currently applicable to the Authorized *IQOS* System in the U.S. Altria affiliate. Restrictions on sale, distribution, advertising and promotion were described in amendments to the original PMTA, which are cross-referenced in Module 4 of this application, and were provided by Philip Morris USA ("PM USA"), which is licensed to sell the Authorized *IQOS* System and the IQOS 3 System in the U.S., in certain 30-day notifications submitted to FDA pursuant to the Marketing Order for the Authorized *IQOS* System.[1]

In addition, FDA has imposed restrictions on the sale, distribution, advertising and promotion of the Authorized *IQOS* System in the Marketing Order for that product that we believe will be similarly mandated for the *IQOS* 3 System and with which PM USA will comply.

[1] The relevant 30-day notifications are provided in appendices to Module 4 of this application: 30-Day Notification for PM0000424 – PM0000426 and PM0000479, June 7, 2019 (Appendix A4-2.1_IQOS_30_Day_Notification_07062019) and 30-Day Notification for PM0000424 – PM0000426 and PM0000479, August 22, 2019 (Appendix A4-2.2_IQOS_30_Day_Notification_22082019)

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