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Module 4: Labeling, Advertising

4.1 Labeling

Upon renewal by FDA of the Modified Risk Granted Orders – Exposure Modification, the labeling for the *IQOS* products (*i.e.*, *IQOS* 2.4 System Holder and Charger, *IQOS* 3.0 System Holder and Charger, with three variants of *HeatSticks*) will remain as authorized.

Therefore, Section 4 Labeling of the MRTPA and PMTA for the Authorized *IQOS* 2.4 System Holder and Charger (PM0000479 and MR0000133), *HeatSticks* (PM0000424-PM0000426 and MR0000059-MR0000061) and Section 4.1 Labeling of the supplemental MRTPA and PMTA for the *IQOS* 3.0 System (PM0000634 and MR0000192) are cross-referenced in the context of this renewal application.

Confidentiality Statement

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