Module 1: General Information

1.4 Samples of New Tobacco Products

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1. SAMPLES OF *IQOS* 3 SYSTEM 2

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1. SAMPLES OF *IQOS* 3 SYSTEM

Section 910(b)(1)(E) of the FD&C Act requires that PMTA contains samples of the tobacco product. However, the Proposed PMTA Rule[1] states that applicants should submit samples only after a PMTA has been accepted for review, if these are requested by the Agency "[*a*]*fter FDA accepts a submission, FDA will determine whether it will require product samples and, if so, issue instructions on how and where to submit the samples, and the number of samples that are required*."

PMP S.A. hereby confirms that samples of the *IQOS* 3 System, the tobacco product in scope of this supplemental PMTA, will be provided after FDA accepts the application for review, and upon receipt of a request to provide samples.

[1] 84 Fed. Reg. 50,580 (September 25, 2019) "*Premarket Tobacco Product Applications and Recordkeeping Requirements*"

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