Module 8: Postmarket Information

8.1 Periodic Reports

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1. PERIODIC REPORT

In the proposed rule on Premarket Tobacco Applications and Recordkeeping Requirements ("Proposed PMTA Rule")[1], FDA provides a process for submitting supplemental PMTAs, such as this one. The Proposed PMTA Rule prescribes the format and content of a supplemental PMTA and requires that if an applicant has submitted post-market reports for the original product those reports must be submitted by cross-reference in the supplemental PMTA. This section addresses that requirement.

The Marketing Order (MO) for the Authorized *IQOS* System requires submission of post-market or periodic reports on a quarterly and annual basis (MO for PM0000424-PM0000426 and PM0000479, April 30, 2019, Appendix B, Section IV). The postmarket periodic reports will help the FDA to determine whether continued marketing of the tobacco products for which the MO was issued is appropriate for the protection of public health and/or there are or may be other grounds for withdrawing or temporarily suspending the marketing authorization order.

1.1. Quarterly Reports

The MO requires the submission of periodic reports to the FDA on a quarterly basis, beginning three months from the date of the order.

The MO requires quarterly submissions that include i) a summary of the U.S. sales and distribution of the tobacco products, ii) data on product purchasers, iii) an analysis of the actual delivery of advertising impressions, and iv) a summary of media tracking and optimization.

Items i) and ii) must be provided for a period of two years. There is no limit on the length of time for which items iii) and iv) must be submitted.

Altria Client Services LLC (ALCS)[2], on behalf of Philip Morris USA Inc. (PM USA)[3] submits reports required by the MO.[4]

From the date of issuance of the MO, the following quarterly reports were submitted to FDA:

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[1] 84 Fed. Reg. 50,566 (September 25, 2019) "*Premarket Tobacco Product Applications and Recordkeeping Requirements*"

[2] ALCS and its affiliates, including PM USA, entered into an agreement with Philip Morris International Management S.A. (PMI), by which they are licensed to sell the authorized products in the United States after the marketing authorization.

[3] PM USA is a wholly owned subsidiary of Altria Group, Inc. (Altria). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. PM USA distributes and sells the authorized products in the United States.

[4] ALCS submits these reports pursuant to a Letter of Authorization (LoA) from PMP S.A.

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Table 1: Overview of Quarterly Reports submitted to the FDA since the issuance of the MO

Submission date	Reporting Period
July 30, 2019	May 2019
October 30, 2019	June – August 2019
January 30, 2020	September – November 2019

These quarterly reports are incorporated to this Application by cross-reference.

The next quarterly report will be provided to FDA on April 30, 2020, and will cover the reference period of December 2019 – February 2020.

1.2. Annual Reports

The MO also requires the submission of reports to the FDA on an annual basis, beginning twelve months from the date of the order.

The first Annual Report will be provided to FDA on April 30, 2020, and will cover the reference period of May 2019 – February 2020.

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