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# Module 4: Labeling, Advertising

## 4.2 Marketing Plans

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## 1. INTRODUCTION

Due to the decision of the U.S. International Trade Commission (ITC) which resulted in the mandatory withdrawal of *IQOS* and *HeatSticks* from the U.S. market as of November 28, 2021<sup>1</sup>, the products are not on the U.S. market for now. The ITC issued its Final Determination (FD), Limited Exclusion Order (LEO), and Cease and Desist Orders (CDO) after concluding that two patents of an affiliate of R.J. Reynolds Tobacco Company (RJR) are violated by PMI and not invalid. The CDO prohibits Altria Client Services (ALCS)<sup>2</sup> and PM USA<sup>3</sup> from, among other things, importing, selling, marketing, advertising, distributing, or transferring imported *IQOS* Products (including their components).

This section, therefore, is cross-referenced to the initial MRTPA for the Authorized *IQOS* 2.4 System Holder and Changer (MR0000133), *HeatSticks* (MR0000059 - MR0000061) and the *IQOS* 3.0 System Holder and Changer (MR0000192). We also cross-reference to post-authorization submissions made pursuant to the Marketing Orders for the Authorized *IQOS* products. This includes 30-Day Notifications of labeling, advertising, marketing, and promotional material, that included materials and plans for use of (b) (4) in conjunction with marketing of the Authorized *IQOS* products.

*IQOS* and *HeatSticks* will be marketed in the United States by Triaga Inc., a U.S. affiliate of PMP S.A. When commercializing the *IQOS* products, Triaga Inc. conforms with the requirements and marketing restrictions included in the Marketing Order<sup>4</sup> and Marketing Granted Order<sup>5</sup>, respectively, for those products.

## 2. MARKETING PLAN OVERVIEW

Upon renewal by FDA of the Modified Risk Granted Orders (MRGO), under Section 911(g)(2) of the FD&C Act, PMP S.A. intends to continue to use the current marketing plan. Any new labeling, advertising, marketing, and promotional materials, that include materials and plans

<sup>1</sup> Investigation No. 337-TA-1199, *In the Matter of Certain Tobacco Heating Articles and Components Thereof*.

<sup>2</sup> PMP S.A., formerly Philip Morris International Management S.A., has entered into a distribution agreement with Altria Client Services LLC (ALCS) by which ALCS and an ALCS affiliate will be licensed to distribute and sell the candidate product in the United States, upon issuance of the requested marketing order. ALCS is a wholly-owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

<sup>3</sup> PM USA is not part of Philip Morris International group of companies.

<sup>4</sup> Marketing Order, April 30, 2019, PM0000424-PM0000426, PM0000479

<sup>5</sup> Marketing Granted Order, December 7, 2020, PM0000634

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for use of the reduced exposure claim in conjunction with marketing of the authorized *IQOS* products will continue to be reported to FDA through 30-Day Notifications.

The target audience for such marketing will continue to be adult smokers 21+. We remain focused on providing adult consumers a high level of education and guidance. Marketing will continue to be grounded in the (b) (4) and Good Conversion Principles, and current marketing restrictions will remain in place.

### 3. CROSS-REFERENCED DOCUMENTS

Upon renewal, the marketing plan (b) (4). Because of this consistency in the planned use of the authorized claim, we cross-reference amendments to the PMTA for the Authorized *IQOS* 2.4 System that provide more detail about the marketing plans. PMP S.A. and PM USA communicated details about the marketing plan for the Authorized *IQOS* 2.4 System, including age verification processes, in response to FDA's request for additional information during the review of the original PMTA. The amendments are contained in the following documents:

- Response to August 20, 2018, Advice/Information Request for PM0000424-PM0000426 and PM0000479, dated September 5, 2018, and
- Response to March 19, 2019, Advice/Information Request for PM0000424-PM0000426 and PM0000479, dated March 25, 2019

Also, in response to the requirement in the Marketing Orders for the Authorized *IQOS* products that all "labeling, advertising, marketing, and/or promotional materials" be provided to FDA "at least 30 days prior to the initial publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials," PM USA provided additional information about its marketing plans, including marketing plans which use the authorized claim, for the *IQOS* 2.4 System and *IQOS* 3.0 System in the following 30-Day notifications submitted to FDA:

- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, June 7, 2019
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, August 23, 2019
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, January 15, 2020
- 30-Day Notification for PM0000424 -PM0000426 and PM0000479, February 14, 2020
- 30-Day Notification for PM0000424 -PM0000426 and PM0000479, March 30, 2020
- 30-Day Notification for PM0000424 -PM0000426 and PM0000479, October 30, 2020

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The amendments to the original PMTA and the 30-Day Notifications referenced above all set forth marketing plan for the authorized *IQOS* products, including (b) (4)

As of November 29, 2021, in compliance with the International Trade Commission's Cease and Desist Order, PM USA stopped sales, marketing and distribution of all authorized *IQOS* device versions as well as *HeatSticks* variants. (b) (4)

The information summarized above was provided in greater detail in several periodic reports ranging from October 30, 2019, to April 28, 2023, including<sup>6</sup>:

- Periodic Report for PM0000424-PM0000426 and PM0000479, October 30, 2019
- Periodic Report for PM0000424-PM0000426 and PM0000479, January 30, 2020
- Periodic Report for PM0000424-PM0000426 and PM0000479, April 30, 2020
- Periodic Report for PM0000424-PM0000426 and PM0000479, July 30, 2020
- Periodic Report for PM0000424-PM0000426 and PM0000479, October 30, 2020
- Amendment to Periodic Reports for PM0000424-PM0000426 and PM0000479<sup>7</sup>, December 9, 2020
- Periodic Report for PM0000424-PM0000426 and PM0000479, January 29, 2021
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634, April 30, 2021
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634, July 30, 2021
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634, October 29, 2021
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634, January 28, 2022

<sup>6</sup> Periodic Report of October 30, 2019, and January 30, 2020, were previously included in sPMTA for the Authorized *IQOS* 3.0 System and therefore are not provided as part of this sPMTA for the modified product.

<sup>7</sup> Periodic Reports Amended: April 30, 2020, and July 30, 2020 for Reporting Periods: December 2019 – February 2020 and March – May 2020.

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- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634, April 29, 2022
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634 July 29, 2022
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634 October 28, 2022
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634 January 30, 2023
- Periodic Report for PM0000424-PM0000426, PM0000479 and PM0000634 April 28, 2023

Although it is too large to submit as appendix, we also refer to the following annual reports:

- Annual Report for PM0000424-PM0000426 and PM0000479, April 30, 2020
- Annual Report for PM0000424-PM0000426 and PM0000479, April 30, 2021
- Annual Report for PM0000424-PM0000426 and PM0000479, April 30, 2022
- Annual Report for PM0000424-PM0000426 and PM0000479, April 28, 2023

Although provided in more detail in the referenced Periodic Reports, the data shows that sales of the authorized *IQOS* products are consistent with PM USA's measured introduction to limited markets and the high level of adult consumer education and guidance provided. In addition, (b) (4) of *IQOS* purchasers who provided their age with purchase are over age (b) (4), and none were reported to be under age 21. This age data is consistent with PM USA's practice of restricting owned-retail store entry and purchase, face-to-face engagement, and e-commerce purchase to adults verified as age 21+. In addition, where tracking is available, advertising impressions have been delivered predominately (b) (4). These results are consistent with implementation of PM USA's age restriction and verification practices, and immediate corrective actions in the event such practices are not applied properly. The data on sales and distribution and product purchasers, delivery of advertising impressions, and media tracking and optimization for the *IQOS* 3.0 System are consistent with the above.

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