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Module 4: Labeling, Advertising

4.2 Marketing Plans

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1. INTRODUCTION

The marketing plan for the *IQOS* 3 System is (b) (4); and the planned (b) (4) in the marketing of *IQOS* 3 is consistent with what was described, and has been submitted and authorized, (b) (4)

This section, therefore, is cross-referenced to the amendments (b) (4) and to the supplemental PMTA for the *IQOS* 3 System. We also cross-reference to post-authorization submissions made pursuant to the Marketing Orders for the *IQOS* 2.4 System and the *IQOS* 3 System. This includes 30-Day Notifications of labeling, advertising, marketing and promotional material that, as of, July 27, 2020, included materials and plans for use of (b) (4) in conjunction with marketing of the *IQOS* 2.4 System.

As with the *IQOS* 2.4 System, Altria Client Services LLC (ALCS)[1] and an ALCS affiliate are licensed to distribute and sell the *IQOS* 3 System (*IQOS*) in the United States. The ALCS affiliate that distributes and sells the product in the U.S. is Philip Morris USA Inc. (PM USA).

When commercializing the *IQOS* 2.4 System and the *IQOS* 3 System, PM USA conforms with the requirements and marketing restrictions included in the Marketing Order[2] and Marketing Granted Order[3], respectively, for those products.

2. MARKETING PLAN OVERVIEW

Upon issuance by FDA of a Modified Risk Granted Order (MRGO), under Section 911(g)(2), PM USA intends to continue to use the current marketing plan for the *IQOS* 3 System, (b) (4) when appropriate given the context and marketing channel.

The target audience for such marketing will continue to be adult smokers 21+. PM USA remains 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.

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[1] Altria Client Services LLC (ALCS) is a wholly-owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

[2] Marketing Order, April 30, 2019, PM0000424-PM0000426, PM0000479

[3] Marketing Granted Order, December 7, 2020, PM0000634

(b) (4)

(b) (4) and the need for adult consumer support.

3. CROSS-REFERENCED DOCUMENTS

The marketing plan for the *IQOS* 3 System (b) (4),

(b) (4)

(b) (4) we cross-reference amendments to the PMTA for the *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 *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 Order for the *IQOS* 2.4 System 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 in the following 30-Day notifications submitted to FDA:

- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, June 7, 2019 (Appendix A4-2-1-iqos-30day-notification-2019-06-07),
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, July 27, 2020 (Appendix A4-2-1-iqos-30day-notification-2020-07-27).
- 30-Day Notification for PM0000424 - PM0000426 and PM0000479, October 30, 2020 (Appendix A4-2-2-iqos-30day-notification-2020-10-30).

The first 30-Day notification referenced above was provided as part of the supplemental PMTA for the *IQOS* 3 System and therefore is cross-referenced in the context of this supplemental MRTPA. The second and third 30-Day notifications referenced above were not submitted as part of our supplemental PMTA for the *IQOS* 3 System, therefore for ease of reference those notifications are provided as part of this submission.

The amendments to the original PMTA and the 30-Day Notifications referenced above all set forth PM USA's marketing plan for the Authorized 2.4 *IQOS* System, including (b) (4)

(b) (4)

4. INFORMATION COLLECTED IN THE U.S. MARKET TO DATE

PM USA introduced the *IQOS* 2.4 System into the Atlanta, Georgia and Richmond, Virginia markets in September and November of 2019, respectively. In August 2020, the *IQOS* 2.4 System was introduced in the Charlotte, North Carolina market. Most recently, on March 8 of 2020, the *IQOS* 3 System was introduced in all three existing markets mentioned above. At the time of the submission of this supplemental MRTPA, there has been too short a period to report in-market sales for the *IQOS* 3 System. PM USA will continue to collect data on sales and distribution and product purchasers, the delivery of advertising impressions, and media tracking and optimization for both systems. The information which has been submitted to FDA since the *IQOS* 3 System sPMTA was submitted on March 30, 2020, regarding U.S. Market performance, was done through the following periodic reports:

- Periodic Report for PM0000424-PM0000426 and PM0000479, April 30, 2020 (Appendix A4-2-3-quarterly-reporting-30Apr2020), and
- Periodic Report for PM0000424-PM0000426 and PM0000479, July 30, 2020 (Appendix A4-2-4-quarterly-reporting-30July2020), and
- Periodic Report for PM0000424-PM0000426 and PM0000479, October 30, 2020 (Appendix A4-2-5-quarterly-reporting-30Oct2020), and
- Amendment to Periodic Reports for PM0000424-PM0000426 and PM0000479[4], December 9, 2020 (Appendix A4-2-6-quarterly-report-amendment-9Dec2020), and
- Periodic Report for PM0000424-PM0000426 and PM0000479, January 29, 2021 (Appendix A4-2-7-quarterly-reporting-29Jan2021).

The periodic reports referenced above were not submitted as part of our supplemental PMTA for the *IQOS* 3 System, therefore for ease of reference those reports are provided as part of this sMRTPA.

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

- Annual Report for PM0000424-PM0000426 and PM0000479, April 30, 2020.

[4] Periodic Reports Amended: April 30, 2020 and July 30, 2020 for Reporting Periods: December 2019 – February 2020 and March – May 2020.

Although provided in more detail in the referenced Periodic Reports, the data shows that sales of the *IQOS* 2.4 System 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) f *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 System are expected to be generally consistent with the above.

5. CONCLUSION

The marketing plan for the *IQOS* 3 System utilizing the (b) (4), if authorized, will be (b) (4)

(b) (4)