ANNUAL REPORT

FDA STNs	Tobacco Product Names
PM0000424 - MR0000059	*Marlboro* Amber *HeatSticks*
PM0000425 - MR0000060	*Marlboro* Green Menthol *HeatSticks*
PM0000426 - MR0000061	*Marlboro* Blue Menthol *HeatSticks*
PM0000479 - MR0000133	*IQOS* System Holder and Charger
PM0000634 - MR0000192[1]	*IQOS* 3 System Holder and Charger
PM0004691.PD1	*Marlboro* Amber *HeatSticks*
PM0004337.PD1	*Marlboro* Sienna *HeatSticks*
PM0004337.PD2[2]	*Marlboro* Bronze *HeatSticks*
EX0002940.PD1[3]	*Marlboro* Amber *HeatSticks*
EX0002940.PD3	*Marlboro* Green Menthol *HeatSticks*
EX0002940.PD5	*Marlboro* Blue Menthol *HeatSticks*
EX0003036.PD1	*Marlboro* Bronze *HeatSticks*
EX0003036.PD3	*Marlboro* Sienna *HeatSticks*
Tobacco Product Category	HTP
Tobacco Product Sub-category	Open HTP and HTP consumable
Applicant	Philip Morris Products S.A. (PMP S.A.)
Date of Report	April 28, 2024
Reporting Period	March 1, 2023, to February 29, 2024

1 Exposure Modification Orders for the *IQOS* device and three variants (PM0000424, PM0000425, PM0000426, PM0000479 and PM0000634) of Marlboro *HeatSticks* require that manufacturing information be submitted together with Annual Report for PMTAs.

2 *Marlboro* Amber *HeatSticks* (PM0004691.PD1), *Marlboro* Sienna *HeatSticks* (PM0004337.PD1), *Marlboro* Bronze *HeatSticks* (PM0004337.PD2) as authorized by the January 26, 2023, Marketing Granted Order (MGO).

3 *Marlboro* Green *HeatSticks* (EX0002940.PD3), *Marlboro* Blue *HeatSticks* (EX0002940.PD5), *Marlboro* Bronze *HeatSticks* (EX0003036.PD1), *Marlboro* Sienna *HeatSticks* (EX0003036.PD3), *Marlboro* Amber *HeatSticks* (EX0002940.PD1) as authorized by the January 19, 2024, Exemption Request Order (EX Order). These products were not commercialized during the reportable data period. There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to discuss in this Annual Report.

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FOREWORD

This Annual Report covers the period from March 1, 2023, through to February 29, 2024 (the "Reporting Period"). As mentioned in the 2023 Annual Report, *IQOS* devices and *HeatSticks* have not been commercialized in the United States since November 2021, as a consequence of the Cease-and-Desist Order (CDO) issued on September 29, 2021, by the United States International Trade Commission (ITC). This prohibited the importation of, and the marketing, sale and distribution of *IQOS* devices and *HeatSticks* in the United States.[4] As a result of the CDO, Altria stopped marketing and selling all *IQOS* devices and *HeatSticks* by November 28, 2021, at all third-party retail stores, at all Altria-owned stores, and on the *IQOS*.com website. Therefore, by the end of November 2021, *IQOS* devices and *HeatSticks* were not available for purchase in the U.S. market.[5]

As a result of this cessation of marketing and sales, this Annual Report will not show sales data. This cessation of sales also has a corresponding impact on data on product purchasers, as there have been no U.S. product purchasers since November 28, 2021.

As per our correspondence with FDA on January 14, 2022,[6] this CDO impacted plans for Post-Market Surveillance and Studies (PMSS). Specifically, there was a cessation of marketing and sales since November 28, 2021, so consumers have been unable to purchase the products in the United States. Therefore, this annual report will not show sales data. In addition, the cessation of marketing and advertising impacted data on advertising impressions, dollar amounts and flighting of paid media plans, and other advertising and marketing metrics that are required as part of this annual report. Except where otherwise noted, a lack of data for a given marketing channel or time period is not a reflection of an error in the report, but rather an accurate reflection of the impact of the CDO.

[4] Certain Tobacco Heating Articles and Components Thereof, 337-TA-1199 U.S. International Trade Commission (September 29, 2021).

[5] PMP S.A.'s parent company, Philip Morris International Management (PMI), entered into an agreement with Altria Client Services LLC (ALCS) in December 2013, which granted ALCS an exclusive license to sell *IQOS* products in the United States.

[6] Adjustment to the PMSS Plan for MR0000059 - MR000061 and MR0000133, January 14, 2022

1 EXECUTIVE SUMMARY

On April 30, 2019, the U.S. Food and Drug Administration (FDA) issued a Marketing Granted Order (MGO) authorizing the marketing of the *IQOS* device with three variants of *Marlboro HeatSticks*,[7] after determining that such marketing was appropriate for the protection of public health (APPH) and that the other statutory requirements were met. The following year, on December 7, 2020, FDA issued MGOs for the *IQOS* 3.0 device. Then, on January 26, 2023, FDA issued MGOs for the *Marlboro* Sienna *HeatSticks, Marlboro* Bronze *HeatSticks* and modified *Marlboro* Amber *HeatSticks*.[8] On January 19, 2024, the FDA issued Exempt orders[9] to all five *Marlboro HeatSticks* products with an MGO.

Altria Client Services LLC (ALCS) were licensed to distribute and sell these products in the United States. However, as announced publicly in late 2022,[10] Altria's license to market *IQOS* devices and *HeatSticks* in the United States is terminating as of April 30, 2024.

The MGOs established restrictions and post market requirements, such as regularly reporting to FDA certain product and marketing information. Detailed discussion concerning respective reporting obligations, as specified in Appendix B and C to the MGOs, is provided later in this report (Sections 1 – 18 with corresponding Annexes). Please refer to Tables 1 - 4 below for additional authorization information on the products in scope.

Table 1: Exempt Orders Issued on January 19, 2024

Exempt Product	STN
Marlboro Green Menthol *HeatSticks*	EX0002940.PD3
Marlboro Blue Menthol *HeatSticks*	EX0002940.PD5
Marlboro Bronze *HeatSticks*	EX0003036.PD1
Marlboro Sienna *HeatSticks*	EX0003036.PD3
Marlboro Amber *HeatSticks*	EX0002940.PD1

[7] *Marlboro* Amber *HeatSticks* were formerly *Marlboro HeatSticks*
Marlboro Green Menthol *HeatSticks* were formerly *Marlboro* Smooth Menthol *HeatSticks*
Marlboro Blue Menthol *HeatSticks* were formerly *Marlboro* Fresh Menthol *HeatSticks*

[8] We refer to the April 30, 2019, Marketing Order, the December 7, 2020, Marketing Granted Order and January 26, 2023, Marketing Granted Orders collectively as the Marketing Orders, MOs, or MO.

[9] We refer to the January 19, 2024, Exemption Request Order(s) as the exemption order(s), exemption request order(s) or EXR(s).

[10] See "Philip Morris International Reaches Agreement with Altria Group, Inc. to End the Companies' Commercial Relationship Covering IQOS in the U.S. as of April 30, 2024," available at https://www.pmi.com/investor-relations/press-releases-and-events/press-releases-overview/press-release-details/?newsId=25656 (Oct. 20, 2022).

Table 2: Modified Risk Granted Orders issued on July 7, 2020

Modified Risk Granted Order	STN
Marlboro Amber *HeatSticks*	PM0000424/MR0000059
Marlboro Green Menthol *HeatSticks*	PM0000425/MR0000060
Marlboro Blue Menthol *HeatSticks*	PM0000426/MR0000061
IQOS Device	PM0000479/MR0000133
IQOS 3 Device	PM0000634/MR0000192

Table 3: Premarket Tobacco Product Marketing Orders

Marketing Granted Order	STN	Authorization Date
Marlboro Amber *HeatSticks*	PM0004691.PD1	01/26/2023
Marlboro Sienna *HeatSticks*	PM0004337.PD1	01/26/2023
Marlboro Bronze *HeatSticks*	PM0004337.PD2	01/26/2023
IQOS 3 Device	PM0000634	12/07/2020
Marlboro HeatSticks[11]	PM0000424	04/30/2019
Marlboro Smooth Menthol *HeatSticks*	PM0000425	04/30/2019
Marlboro Fresh Menthol *HeatSticks*	PM0000426	04/30/2019
IQOS Device	PM0000479	04/30/2019

The evidence supplied with this Annual Report confirms that the marketing of the authorized tobacco products continues to be APPH because:

- PMP S.A.-sponsored studies, as well as findings reported in publications by PMP S.A. and independent researchers not previously reported to the FDA show that *IQOS* products are reaching their intended audience, adult cigarette smokers. Moreover, studies show that *IQOS* use is low among non-users (never or former) of tobacco products, including youth
- There were no serious and unexpected adverse experiences (SAEs) reported by consumers in the United States during this reporting period. The analysis of all reported adverse experiences (AEs) for the tobacco products confirms that there were no

11 The updated names for all three *HeatSticks* was submitted with 30-day notification dated July 31, 2020. *Marlboro HeatSticks* (PM0000424/MR0000059), *Marlboro* Smooth Menthol *HeatSticks* (PM0000425/MR0000060), and *Marlboro* Fresh Menthol *HeatSticks* (PM0000426/MR0000061) are now *Marlboro* Amber *HeatSticks*. *Marlboro* Green Menthol *HeatSticks*, and *Marlboro* Blue Menthol *HeatSticks,* respectively.

changes to risk information related to the products including the nature of AEs and their frequency

- There are no new concerns related to health effects, product quality, human factors or product misuse
- There has been no sale or distribution of the IQOS devices or *HeatSticks* in the United States during the Reporting Period so there is no marketing material to discuss.

Considering the above, we conclude that the grounds for the marketing authorization for the *IQOS* device (PM0000479/MR0000133), *IQOS* 3.0 device (PM0000634/MR0000192) and *Marlboro HeatSticks* (PM0000424/MR0000059, PM0000426/MR0000061, PM0004691.PD1, PM0004337.PD1-PD2, EX0002940.PD3, EX0002940.PD5, EX0003036.PD1, EX0003036.PD3, EX0002940.PD1) have not changed. The risks and benefits to the population, including users and nonusers of the tobacco products, have not changed, and therefore the marketing of those products remains APPH.

2 SUMMARY OF SCIENTIFIC STUDIES AND PUBLICATIONS

The Summary of Scientific Studies and Publications provides an overview of PMP S.A.-affiliated scientific studies that are either completed or ongoing as well as significant findings from scientific publications by PMP S.A. or other tobacco and nicotine-containing product manufacturers, and independent researchers. Detailed materials about these studies and publications are found in Annex 1 and Annex 2.

2.1 Summary of on-going and completed studies

A status report of ongoing and completed scientific studies performed by PMP S.A. and not previously submitted to the Agency is provided in Annex 1. This includes completed scientific studies that are reported as ongoing in this current annual report (March 1, 2023, to February 29, 2024).

Information related to consumer evaluation research studies conducted to determine the effectiveness of labeling, advertising, marketing and/or promotional materials are discussed in Section 14 below.

2.2 Significant findings from publications not previously reported

Significant findings from scientific publications are presented by scientific area in Annex 2-1 for the period from March 1, 2023, to February 29, 2024.

We sell modified versions of the *IQOS* device and additional variants of *HeatSticks* in markets outside of the United States. The publications discussed in Annex 2-1 may be related to versions of the *IQOS* device and *HeatSticks* other than the *Authorized Products*[12], but we believe it is important to provide this information because those other versions are designed to

[12] *Authorized Products* are products that have received MGOs or Exempt Orders.

have the same principles of operation and performance as the *Authorized Products*. Therefore, throughout the Annex 2-1, we reference publications that are related to all *IQOS* products.

The publications included in our literature summary in Annex 2-1 encompass various scientific fields including:

- Aerosol chemistry and physics, including data on product properties related to non-combustion, emissions of harmful and potentially harmful constituent (HPHCs), non-targeted analysis of the emissions from the product, indoor air quality and secondhand exposure
- Standard and systems toxicology including *in vitro* toxicology testing, *in vivo* inhalation studies, and animal models of disease
- Clinical studies on exposure reduction to HPHCs, effect on biomarkers of potential harm (BoPHs) and early markers of disease risk
- Observational studies on trends related to the potential impact of the product on health care utilization due to smoking-associated diseases
- Both perception/behavioral and post-market studies, primarily outside the United States to assess the impact of *IQOS* product use trajectories, impact on former and never smokers, impact on cessation, product acceptability and the impact of marketing approaches.

The complete list of publications containing the findings is available in Annex 2-2.

3 ADVERSE EXPERIENCES (AES) REPORTED TO PMP S.A.

A summary of global AEs reported to us is presented in the Safety Update Report (SUR) provided as Annex 3 of this report. The SUR, which has the same format and data collection procedure as previous SURs submitted to FDA, provides a comprehensive and critical analysis of the safety profile of all *IQOS* devices and *HeatSticks* variants sold worldwide. The data presented in the SUR cover the period from January 1, 2023, to December 31, 2023, as well as the cumulative period from November 4, 2014 (when the first ever market launched) through to December 31, 2023. The SUR also includes an appendix that is specific to reported AEs in the United States.

Although the products were not commercialized in the United States, a total of 23 non-serious AEs potentially associated with use of the *Authorized Products* were reported. These AEs were received from unsolicited sources during the reporting period.

The AEs reported more than once in the United States include: *No adverse event* (n=3), *Accidental exposure to product* (n=2), *Throat irritation* (n=2), *Accidental exposure to product by child* (n=2), and *Nicotine dependence* (n=2).

Table 4: Adverse Events that were reported more than once in the United States during the reporting period

MedDRA PT	Interval Non-Serious	Interval Serious	Interval Total
No Adverse Event	3	0	3
Accidental Exposure to Product	2	0	2
Throat Irritation	2	0	2
Accidental Exposure to Product by Child	2	0	2
Nicotine Dependence	2	0	2

Most of the spontaneous reports received by us during the Reporting Period were not medically confirmed, as they were received from consumers and not from healthcare professionals, which results in limited data provided in each case. We perform follow-up attempts if the reporter has provided consent to be contacted back, and only in countries where specific local laws governing the collection of personal data permit such activities. Nevertheless, for most of the reports received, information regarding the AEs and their circumstances was limited.

No SAEs were reported by U.S. consumers during the Reporting Period. Since distribution of the *Authorized Products* began, a total of 245 non-serious AEs were received from unsolicited sources in the United States. Cumulatively, no SAEs were received from the United States. Overall, the analysis of the data from the U.S. market did not reveal any new or increased risks in consumers who switched from cigarettes to the *Authorized Products*. The AEs reported by U.S. consumers are consistent with those reported outside the U.S.

The evaluation of the latest information identified during the Reporting Period and the cumulative analysis did not show any changes in the safety profile of *IQOS* products. We will continue to collect and evaluate all new safety information to track the safety of *IQOS* products and their impact on public health.

4 SALES AND DISTRIBUTION

Sales and distribution of the *Authorized Products* is addressed in the quarterly reports dated: July 28, 2023, October 30, 2023, and January 30, 2023. In addition to, and concurrent with the submission of this Annual Report, a quarterly report dated April 30, 2024, is being submitted.

5 DATA ON PRODUCT PURCHASERS

Data on product purchasers were included in the quarterly reports dated: July 28, 2023, October 30, 2023, and January 30, 2024. In addition, concurrent with the submission of this Annual Report, a quarterly report dated April 30, 2024, is being submitted.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data on product purchasers to discuss in this Annual Report.

6 SUMMARY OF IMPLEMENTED POLICIES AND PROCEDURES REGARDING VERIFICATION OF THE AGE AND IDENTITY OF PURCHASERS

In previous Annual Reports, we provided a "summary of the implementation and effectiveness of [our] policies and procedures regarding verification of the age and identity of purchasers of the products" as part of our report on commercial activities for *IQOS* products.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to summarize.

7 SUMMARY OF IMPLEMENTED POLICIES AND PROCEDURES REGARDING RESTRICTIONS ON YOUTH ACCESS TO THE PRODUCTS

In earlier Annual Report, we have provided a "summary of the implementation and effectiveness of [our] policies and procedures regarding restrictions on youth access to the products" as part of a summary of our commercial activities for *IQOS* products.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to summarize.

8 CHANGES TO THE MANUFACTURING, FACILITIES OR CONTROLS

8.1 Changes to the manufacturing, facilities, and controls for the reporting period

As described in the original PMTAs/MRTPAs, we use a Change Management Process (CMP) to ensure that all proposed changes are assessed for their potential impact on product performance, safety, and quality before implementation.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no change in manufacturing, facilities, or controls to report.

8.2 List of changes previously included in PS0000119

Related to the previous FDA request[13], we are providing more details about the (b) (4) identified in the respective correspondence: (b) (4)

We conclude that (b) (4) does not produce a new tobacco product. We notified FDA about this change in the 2021 Annual Report (PS0000119). (b) (4)

[13] TC0009076 dated February 28, 2023, from Office of Science and Meeting denied letter and PS0000119 Letter dated June 24, 2022, from Office of Compliance and Enforcement

(b) (4) nd does not change any actual steps during the manufacturing process.

Similarly, (b) (4) does not change the product's performance, composition, constituents, or characteristics and, therefore, does not render the products as new tobacco products under section 910 of the FD&C Act. (b) (4) and do not affect product moisture, organoleptic properties, or product stability.

9 MANUFACTURING DEVIATIONS

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no manufacturing deviation to report.

10 SUMMARY OF STABILITY MONITORING AND TESTING

The 24-month stability data were provided in 2021 Annual Report and showed that no changes were observed that could cause potential health risks for consumers.

No further stability monitoring and testing of authorized *HeatSticks* was performed during the Reporting Period. Two studies were initiated in March 2023 and are described in the ongoing studies of Annex 10.

11 LABELING CHANGES

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is nothing to report in Annex 11 to this Annual Report.

12 ADVERTISING NOT PREVIOUSLY SUBMITTED

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is nothing to report in Annex 12 to this Annual Report.

13 CONSUMER RESEARCH STUDIES CONDUCTED IN THE FORMATION OF NEW LABELING, ADVERTISING, MARKETING, AND/OR PROMOTIONAL MATERIALS

Altria conducted consumer research studies during this Reporting Period that were not initially classified as formative or evaluative when conducted. Most of the studies, however, include elements that could be reasonably viewed as formative and evaluative based on the definitions provided in the MGOs. Therefore, rather than attempt to categorize summaries of the research studies by placement into a particular annex, we have provided a summary of all consumer research studies that are responsive to the MGOs in Annex 14.

14 CONSUMER EVALUATION RESEARCH STUDIES CONDUCTED TO DETERMINE THE EFFECTIVENESS OF LABELING, ADVERTISING, MARKETING AND/OR PROMOTIONAL MATERIALS

A summary of all consumer evaluation research studies conducted – whether by us, on our behalf, or at our direction – among any audiences, to determine the effectiveness of labeling, advertising, marketing and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, is included in Annex 14 of this Annual Report. Findings of these studies and copies of the stimuli used in testing are also included in Annex 14 of this Annual Report.

A total of 7 studies were conducted during the Reporting Period. These studies were split into 2 projects and were mainly conducted online among U.S. adults aged 21 years of age or older who had either smoked cigarettes or cigars or used any nicotine containing alternatives to cigarettes (such as electronic cigarettes, nicotine pouches, moist snuff, snus, chewing tobacco) in the past 7 days. The goal of these studies was to gauge understanding of and improve upon *IQOS* product communication and to ascertain *IQOS*'s current brand equity. Summaries of these studies are provided in Annex 14 of this report.

15 CREATION AND DISSEMINATION OF THE PRODUCTS' LABELING, ADVERTISING, AND/OR PROMOTIONAL MATERIALS

A summary of the creation and dissemination of the *Authorized Products'* labeling, advertising, marketing, and/or promotional materials, including a list and description of all entities involved and their activities, is required in Annex 15 of this Annual Report. We have previously provided such a summary, as well as a list of the entities involved and a description of their involvement for prior reporting periods.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to summarize.

16 DESCRIPTION OF THE IMPLEMENTATION OF ALL ADVERTISING AND MARKETING PLANS

A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans, is required in Annex 16 of this Annual Report.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to summarize.

17 ANALYSIS OF THE ACTUAL DELIVERY OF ADVERTISING IMPRESSIONS

An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics was included in the quarterly reports submitted on July 28, 2023, October 30, 2023, and January 30, 2024. In addition, and concurrent with the submission of this Annual Report, we are submitting a quarterly report dated April 30, 2024. These quarterly reports contain an analysis of the actual delivery of advertising impressions and are referenced in Annex 17 of this Annual Report.

18 SUMMARY OF MEDIA TRACKING AND OPTIMIZATION

A summary of media tracking and optimization, by channel, by product, and by audience demographics is referenced in the quarterly reports submitted on July 28, 2023, October 30, 2023, and January 30, 2024. In addition, and concurrent with the submission of this Annual Report, a quarterly report dated April 30, 2024, that contains summary information is being submitted.

There has been no sale or distribution of the *IQOS* devices or *HeatSticks* in the United States during the Reporting Period, so there is no new data to summarize.