

Altria
Altria Client Services

**Rebecca Rivas**
**Sr. Director**
**Regulatory Affairs**

October 30, 2019

*Via CTP Portal*

Ms. Lillian Ortega
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement
Center for Tobacco Product
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

**Re: Periodic Report for PM0000424 - PM0000426 and PM0000479**
**Date of Report: October 30, 2019**
**Reporting Period: June – August, 2019[1]**

Dear Ms. Ortega:

Pursuant to the letter of authorization from Philip Morris Products S.A. dated October 23, 2019, Altria Client Services LLC ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA")[2] submits this periodic report related to Philip Morris Products S.A.'s ("PMPSA")[3] Marketing Order for PM0000424 – PM0000426 and PM0000479 (the "Marketing Order") to the Food and Drug Administration ("FDA"). The Authorized Products covered in this report are:

- Marlboro HeatSticks® - PM0000424
- Marlboro Smooth Menthol HeatSticks® - PM0000425
- Marlboro Fresh Menthol HeatSticks® - PM0000426
- IQOS® System Holder and Charger - PM0000479

[1] June – August 2019 is hereby defined as the "Reporting Period".
[2] 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. "We" and "our" are used throughout to refer to PM USA.
[3] Philip Morris Products S.A. (PMP S.A.) is the PMTA applicant for PM0000424- PM0000426 and PM0000479 (collectively, the "Authorized Products"), all of which were granted a Marketing Order by FDA on April 30, 2019. PMP S.A. 's parent company, Philip Morris International Management S.A. (PMI) has entered into an agreement with Altria Client Services LLC ("ALCS") by which ALCS and its affiliates, including Philip Morris USA ("PM USA"), are licensed to sell the Authorized Products in the United States after marketing authorization. The ALCS affiliate that will distribute and sell the Authorized Products in the United States is PM USA. Therefore, the details provided in these quarterly reports belong to PM USA.

Unless otherwise stated, all data provided is specific to the above-mentioned Reporting Period.

## I. Sales and Distribution

PM USA did not have any sales or distribution activity for the Authorized Products during the Reporting Period; therefore, there is no data to include in the current report.

## II. Data on Product Purchasers

PM USA did not collect any data on product purchasers during the Reporting Period; therefore, the current report contains no such data.

## III. Analysis of Delivery of Advertising Impressions

PM USA advertised through email, owned websites and print advertisements. PM USA plans to advertise using social media and digital advertisement channels in the future but did not do so during this Reporting Period. The table below shows the media channels, our data sources, and how PM USA defines an impression for reporting purposes.

| Media Type | Data Host | Impression |
|---|---|---|
| Targeted Digital Advertisements | (b) (4) | Ads served |
| Facebook Branded Page | | Posts, followers, shares, likes |
| Instagram Branded Page | | Posts, followers, shares, likes |
| Print | | Publications reach |
| Email | | Emails delivered |
| Owned Website | | Page views |

(b) (4) reports the results of media tracking for email and owned websites. Email impressions consist of emails sent. On PM USA's owned website, getIQOS.com, impressions consist of website page views. PM USA also advertised IQOS on another PM USA owned website, Marlboro.com, by placing a tile about IQOS on the home page for that site, viewable only in select geographies. For Marlboro.com, which has content about many products other than IQOS, impressions consist of website page views of the home page that included the IQOS tile. For email and owned websites, impressions do not represent unique individuals, as one person may have received emails and viewed multiple pages on the website, with each considered an "impression."

Emails are sent to consumers who are at least 21 years old, identified through PM USA's Adult Tobacco Consumer Database ("ATCD"), as described in the June 7th, 2019 advance notification of advertising.[4] The ATCD registration process uses (b) (4) to validate age and identity. Emails were sent from both getIQOS.com and Marlboro.com domains. Total emails sent during the Reporting Period were (b) (4) from getIQOS.com and (b) (4) from Marlboro.com, as shown in Figure 1 below.

[4] 30-Day Notification for PM0000424 -PM0000426 and PM0000479, June 7, 2019, Attachment A, pp. 6 and 9.

The PM USA owned website getIQOS.com requires consumers to affirm that they are legal age smokers in their state prior to gaining access to informational content regarding IQOS, including a product overview and a locator for IQOS-branded stores. To access brand messaging or purchase devices via the website, third-party electronic age and identity verification is required. PM USA's company-owned website Marlboro.com requires third party electronic age and identity verification for all portions of the website. Once consumers are age-verified as 21+ on these websites, PM USA is able to collect certain demographic information.

On the owned getIQOS.com website, page views were (b) (4) of which (b) (4) were age-affirmed web impressions accessing the information-only section of the website. While these visitors self-affirm that they are legal age smokers in their state, PM USA collects no other demographic information for those not completing the age-verification process. The remaining (b) (4) page views or impressions, reflected in Figure 1 below, were by verified consumers age 21+ who continued through the electronic age verification process to view marketing content.

On the owned Marlboro.com website, there were (b) (4) impressions of the home page that included the IQOS tile, as reflected in Figure 1 below.

Figures 2-3, below show additional demographic data collected as part of the age verification process. PM USA does not collect data on ethnicity or race.

**Figure 1 – Advertising Impressions by Advertising Channel**

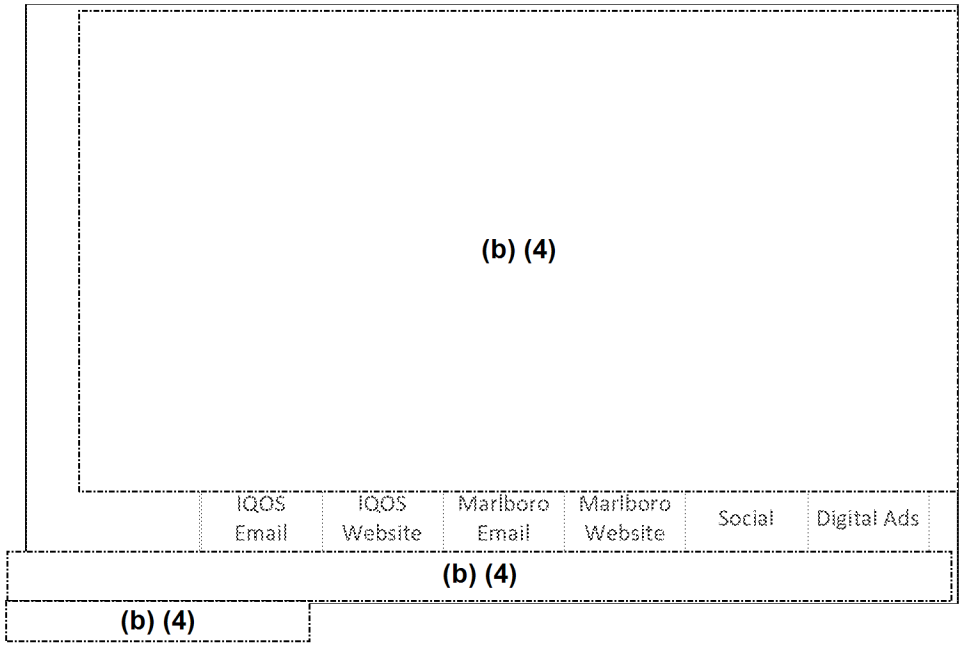



Figure 2 shows advertising impressions by gender for each channel in which PM USA advertised and for which PM USA has the ability to track advertising impressions of age-verified consumers.

**Figure 2 - Advertising Impressions by Gender and Advertising Channel**

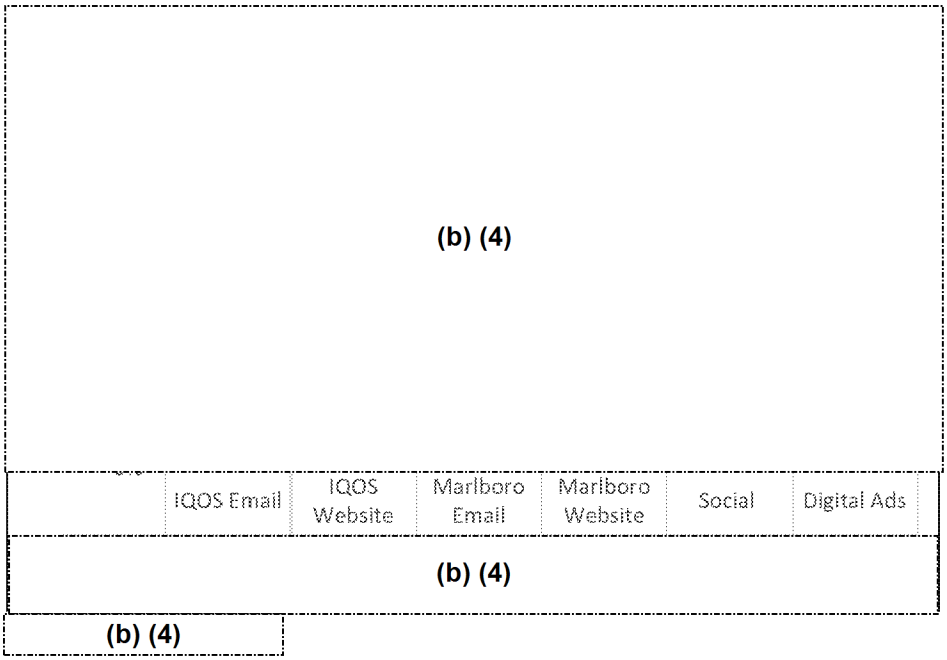
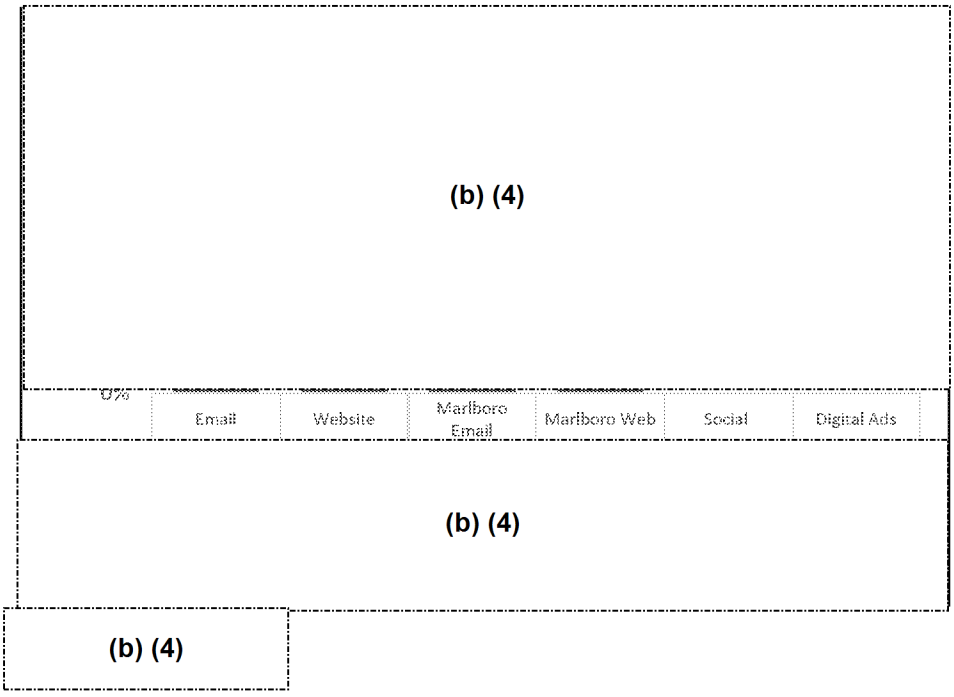



Figure 3 shows advertising impressions by age for each channel in which PM USA advertised and for which PM USA has the ability to track advertising impressions. Advertisements via email and the owned websites were served exclusively to persons at least age 21 (b)

(b) (4)

**Figure 3 – Advertising Impressions by Age and Advertising Channel**



Advertising impressions by state are included with this report as Attachment A, which includes impressions from PM USA's owned websites and emails delivered to consumers age-verified as 21+. PM USA's owned websites are available nationally, however the IQOS tile on the Marlboro.com site was only served in a limited geography.

Print advertising does not allow for post-launch delivery verification. However, PM USA only places print advertisements in adult publications with predominately adult readership. PM USA relies upon third-party data to determine if a publication is an 'adult publication,' defined by: at least 85% age 18+ readership, and less than 15% readership and fewer than 2 million total readers 17 years of age and under. (b) (4) (b) (4) (b) (4) Attachment B provides the data from these studies to show the readership demographics, including percentage of readership ages18+ and ages 12 to 17 for the print publications in which PM USA advertised the Authorized Products. The publications selected for print advertising exceed the requirements stated above.

## IV. Media Tracking and Optimization

This section provides details, by category, about the mechanisms used to monitor media delivery and to prevent delivery of advertising impressions to youth, ages 17 and under, during the Reporting Period.

*Print*

For print advertisements, (b) (4) (b) (4) manages IQOS print media buys based on (b) (4) which are standard in media planning. (b) (4) survey data provided annually to verify that advertisements are placed in adult publications with predominately adult readership. For information verifying this process for the Reporting Period, see Attachment B.

*Email*

Emails are only sent to consumers who are at least 21 years old, identified through PM USA's ATCD, as described in the June 7th, 2019 advance notification of advertising.[5] The ATCD registration process uses (b) (4) to validate age and identity. Additional information about our age verification process for email delivery can be found in the March 25, 2019 Response to FDA's March 19, 2019 Information Request for PM0000424-PM0000426.

*Owned Websites*

PM USA's owned getIQOS.com website requires consumers to affirm that they are legal age smokers in their state prior to gaining access to informational content regarding IQOS, including a product overview and a locator for IQOS-branded stores. To access brand messaging or purchase devices via the website, third-party electronic age and identity verification is required. PM USA's company-owned Marlboro.com website requires third party electronic age and identity verification for all portions of the website. In general, the electronic age and identity verification process has three main steps: (1) a consumer inputs data for age and identity; (2) the

[5] 30-Day Notification for PM0000424 -PM0000426 and PM0000479, June 7, 2019, Attachment A, pp. 6 and 9.

data is matched with third-party databases to confirm age; (3) the consumer answers questions to confirm identity. If age and identity cannot be confirmed through this process, access to this portion of the website is denied.

During the Reporting Period, PM USA's third party media partners and database managers did not record any youth impressions, as shown in Figure 3.

This report contains trade secret and confidential commercial information that PM USA considers to be proprietary and highly sensitive, and which is protected from disclosure under Federal Food, Drug, and Cosmetic Act § 301(j) and 906(c) (21 U.S.C. §§ 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. § 1905), the Freedom of Information Act (5 U.S.C. § 552), and FDA's implementing regulations, 21 C.F.R. Part 20. Accordingly, if FDA tentatively determines that any portion of this submission is disclosable to the public, FDA is required to provide PM USA with notice and an opportunity to object in accordance with 21 C.P.R.§§ 20.47 and 20.61. PM USA reserves all legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

Please address all correspondence related to this report to:

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Email (b) (6)
Phone: (b) (6)

Sincerely,

(b) (6)

CC: Jeff Walker
Malgorzata Wronowska

## ATTACHMENT A

**Advertising Impressions by State and Advertising Channel**

| State | IQOS Email | IQOS Website | Marlboro Email | Marlboro Website | Social Media | Digital Ads |
|---|---|---|---|---|---|---|
| Alabama | (b) (4) | | | | | |
| Alaska | | | | | | |
| Arizona | | | | | | |
| Arkansas | | | | | | |
| California | | | | | | |
| Colorado | | | | | | |
| Connecticut | | | | | | |
| Delaware | | | | | | |
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| Georgia | | | | | | |
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| Montana | | | | | | |
| Nebraska | | | | | | |
| Nevada | | | | | | |
| New Hampshire | | | | | | |
| New Jersey | | | | | | |
| New Mexico | | | | | | |
| New York | | | | | | |
| North Carolina | | | | | | |
| North Dakota | | | | | | |
| Ohio | | | | | | |
| Oklahoma | | | | | | |

| State | IQOS Email | IQOS Website | Marlboro Email | Marlboro Website | Social Media | Digital Ads |
|---|---|---|---|---|---|---|
| Oregon | (b) (4) | | | | | |
| Pennsylvania | | | | | | |
| Rhode Island | | | | | | |
| South Carolina | | | | | | |
| South Dakota | | | | | | |
| Tennessee | | | | | | |
| Texas | | | | | | |
| Utah | | | | | | |
| Vermont | | | | | | |
| Virginia | | | | | | |
| Washington | | | | | | |
| West Virginia | | | | | | |
| Wisconsin | | | | | | |
| Wyoming | | | | | | |
| District of Columbia | | | | | | |
| Other* | | | | | | |
| Totals | | | | | | |

*Other includes US Armed Forces Addresses and Marshall Islands

(b) (4)

## ATTACHMENT B

**Print Media Readership Statistics**

| Recommended Publications for IQOS for 2019 | 2018 Total Readership | 2018 Median Age | 2018 12+ MRI Study National Composition % age 18+ | 2018 12+ MRI Study National Composition % age 12-17 | 2018 Projected # of Readers age 18+(000s) | 2018 Projected # of Readers age 12-17 (000s) |
|---|---|---|---|---|---|---|
| *Men's Journal* | (b) (4) | | | | | |
| *Popular Science* | | | | | | |
| *Vogue* | | | | | | |
| *Wired* | | | | | | |

Source: *Men's Journal* (b) (4)

(b) (4)

Definitions:
Readership – Total estimated readers
A18+ - Readers age 18 or older
A12-17 – Readers ages 12 to 17