

Altria
Altria Client Services

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January 30, 2020

Submitted 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: January 30, 2020
Reporting Period: September – November, 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

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[1] September - November 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 distributes and sells the Authorized Products in the United States is PM USA. Therefore, the details provided in these quarterly reports belong to PM USA.

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The report that accompanies this letter contains confidential commercial information that PM USA considers to be proprietary and highly sensitive, and which is protected from disclosure under FDCA §§ 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 ("FOIA") (5 U.S.C. § 552), and FDA's implementing regulations, 21 C.F.R. Part 20. If FDA receives a request for these records and tentatively determines that any portion of the submission is disclosable, PM USA requests that FDA provide notice and an opportunity for PM USA to object to any disclosure in accordance with 21 C.F.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 submission to:

Ms. Rebecca Rivas
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Email: (b) (6)
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Sincerely

(b) (6)

CC: Jeff Walker
Marco Esposito

Attachments

Periodic Report for PM0000424 – PM0000426 and PM0000479
Reporting Period: September – November 2019

This report is in response to the requirement for periodic postmarket reporting set forth in the Marketing Order for PM0000424 – PM0000426 and PM0000479 (the "Authorized Products").[1] Pursuant to the Marketing Order, this report includes a summary of U.S. sales and distribution, data on product purchasers, an analysis of actual delivery of advertising impressions, and a summary of media tracking and optimization for the period September – November, 2019 (the "Reporting Period").

I. Introduction

Although PM USA has previously submitted two periodic reports, on July 30, 2019 and October 30, 2019, this report is the first one submitted since PM USA began selling the Authorized Products in the U.S. The information provided in this report, therefore, reflects a short period of in-market sales, initial geographies, and our first report of data collected regarding sales and purchasers.

PM USA introduced the IQOS® Tobacco Heating System and Heatsticks® in the Atlanta, Georgia market in PM USA-owned retail outlets on September 21, 2019. By the end of November, PM USA had expanded distribution of Marlboro HeatSticks® and Marlboro Smooth Menthol Heatsticks® to approximately (b) third-party retail outlets in the Atlanta area. On November 16, 2019, PM USA introduced the IQOS® Tobacco Heating System and Heatsticks® in the Richmond, Virginia market. This expansion included the IQOS® system holder and charger, Marlboro HeatSticks® and Marlboro Smooth Menthol HeatSticks®. Marlboro Fresh Menthol HeatSticks® were not distributed during the Reporting Period in either market.

II. Sales and Distribution

This report contains data regarding the Authorized Products' sales by volume, units and dollars as shown in Attachment 1 in Tables 1-1 and 1-2. Marlboro HeatSticks® are sold in third-party retail outlets and company-owned retail stores. The data source for Marlboro HeatStick® volume sold in third-party retail outlets is the STARS database, which covers all U.S. states. The STARS database consists of tobacco product shipments from wholesalers to retail and is reported by wholesalers through a wholesale trade program. Given that STARS data are reported weekly, the report ending date will not always correspond with the last date of the Reporting Period. Therefore, volume and dollar sales data in the current report represent the Reporting Period ending November 24, 2019.

(b) (4)	(b) (4)

Marlboro HeatStick® volume for each variant is reported in number of packs[2] by U.S. census region, major retail markets and channels.

[1] Marketing Order, April 30, 2019, Appendix B, Section IV., p. 9.
[2] A pack consists of 20 HeatSticks®.

(b) (4)

(b) (4) Dollar sales are reported by U.S. census region, major retail markets and channels. Sales taxes are excluded from sales reporting.

IQOS® system holders and chargers are sold through PM USA-owned retail outlets, IQOS® trained experts[3], and the IQOS® website. (b) (4) (b) (4) This information is broken out by U.S. census region, major retail markets and channels. Dollar sales are a combination of the sales volume and the retail price for devices.

Sales and purchaser data are net of returns and do not include devices that have been returned.

III. Data on Product Purchasers

PM USA collects data on product purchasers from three sources described below. For this Reporting Period, the only purchaser data collected was through registration upon purchase.

Registration
PM USA maintains a database of age-verified registered IQOS® users. Adult smokers have the opportunity to register through face-to-face engagements and through e-commerce transactions on the IQOS® website. The amount and types of information in the database depend on whether purchasers opt to register and whether they complete all fields in the registration process. Data about product purchasers is reported in Tables 2-1 through 2-4 in Attachment 2.

(b) (4)

Adult Tobacco Consumer Tracking Study
IQOS® has been added to the list of tobacco products in the ALCS Adult Tobacco Consumer Tracking Study ("ATCT"). (b) (4) (b) (4) The ATCT has been in continuous

[3] IQOS® trained experts are employees who conduct face-to-face interactions with adult smokers and IQOS® users. The IQOS® trained experts share their knowledge about the product by facilitating hands-on tutorials at third-party retail locations or consumer events.

operation since July 2013. (b) (4) (b) (4)

IV. Analysis of Delivery of Advertising Impressions

PM USA advertised through email, owned websites, print, branded social media pages, and digital paid advertisements during the Reporting Period.

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 having 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 3 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 during the Reporting Period. The publications selected for print advertising exceed the requirements stated above.

Email Impressions

(b) (4) reports the results of media tracking for email. Email impressions consist of emails delivered. Impressions do not represent unique individuals, as one person may have received multiple emails, 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 7, 2019 30-Day Notification of advertising.[5] The ATCD registration process uses LexisNexis to validate age and identity. Emails were sent from both getIQOS.com and Marlboro.com domains. Total emails delivered during the Reporting Period were (b) (4) from getIQOS.com and (b) (4) from Marlboro.com, as shown in Attachment 4, Figure 4-1.

Website Impressions

(b) (4) reports the results of media tracking for website impressions. Website impressions consist of

(b) (4)

[5] 30-Day Notification for PM0000424 -PM0000426 and PM0000479, June 7, 2019, Attachment 1, pp. 6 and 9.

page views. 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 owned websites, impressions do not represent unique individuals, as one person may have viewed multiple pages on the website, with each considered an "impression."

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. 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.

Page views on getIQOS.com 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 Attachment 4 were by verified consumers age 21+ who continued through the electronic age verification process to view marketing content

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

Branded Social Media Page Impressions

PM USA used an Instagram branded page during the Reporting Period to drive product awareness and offer customer support. Instagram posts were primarily aimed at driving product awareness and educating adult smokers who are at least 21 years old about the products. Branded social media page impressions consist of posts, followers, shares, and likes. There were 31 posts on the IQOS® branded Instagram page, with 133 followers, resulting in (b) (4) post impressions, as reflected in Attachment 4, Figure 4-1. Impressions do not represent unique individuals, as one person may have liked multiple posts, with each considered an "impression."

Paid Digital Media Impressions

PM USA used paid digital banner advertisements targeted to adults age 21+ to raise awareness and educate adult smokers about IQOS®. The intended audience was sourced from either "first party" data from the PM USA Adult Tobacco Consumer Database (ATCD) or "second party" data collected by competent and reliable sources as outlined in the marketing order. A paid digital media impression consists of a digital paid advertisement served. Impressions do not represent unique individuals, as one person may have been served multiple digital paid advertisements.

(b) (4) manages PM USA's paid digital media campaign. (b) (4) a web-based ad management system, to serve paid digital

advertisements. (b) (4) reported (b) (4) total paid digital advertisements served, as shown in Attachment 4, Figure 4-1.

Audience Demographics for Advertising Impressions
Attachment 4, Figures 4-2 and 4-3 provides demographic data collected as part of the age verification process for the channels on which we report. PM USA does not collect data on ethnicity or race. We do not currently track social media impressions by gender or age, so no data is available to report for these categories.

Figure 4-2 shows advertising impressions by gender for email, website, and paid digital media during the Reporting Period. Gender is not available for all paid digital media impressions, as (b) (4) (66 percent of total impressions) were an undefined gender.

Figure 4-3 shows advertising impressions by age for email, website and paid digital media during the Reporting Period. Advertisements via email and the owned websites were served exclusively to persons at least age 21. All paid digital media impressions were matched to age-verified adults age 21+ by a third-party company (b) (4) through a deterministic model with first- and second-party age-verified data points prior to being served, as described in the August 23rd, 2019 30-Day Notification of advertising[6].

(b) (4) a specialized third-party media measurement and analytics service, provides third-party verification and reports the demographics of paid digital advertising impressions after the paid digital media advertisements are served (b) (4) uses a probabilistic model based on observed website visitation from (b) (4) (b) (4) (b) (4) confirms that all filters were in place to deliver paid digital advertisements only to adults age 21+ and that no impressions were served to persons under age 21. PM USA is actively utilizing technology to minimize delivery to unintended audiences and (b) (4) (b) (4)

Advertising impressions by state are provided in Table 4-1, 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.

V. 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 during the Reporting Period.

[6] 30-Day Notification for PM0000424 -PM0000426 and PM0000479, August 23, 2019, Attachment 1, pp. 4.

Print

For print advertisements (b) (4), one of the largest media networks worldwide and a part of the (b) (4) manages IQOS® print media buys based on (b) (4) reports, 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 3.

Email

Emails were only sent to consumers who were at least 21 years old, identified through PM USA's ATCD, as described in the June 7, 2019 30-Day Notification of advertising.[7] The ATCD registration process uses LexisNexis 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

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 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 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 Attachment 4.

Paid Digital Media Adverting

PM USA used digital banner advertisements delivered to age-verified adults age 21+ to raise awareness and educate adult smokers about IQOS®. The intended audience was sourced from either "first party" data from the PM USA Adult Tobacco Consumer Database (ATCD) or "second party" data collected by competent and reliable sources as outlined in the Marketing Order. The following process was used to age verify the intended audience by our data providers ("second party") and limit access to youth:

- (b) (4)

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

- (b) (4)
-

Branded Social Media Pages

PM USA used Instagram to drive product awareness and provide customer support. Using the platform's age restriction capabilities, we posted product-branded content aimed at adult smokers who are at least 21 years old. PM USA used Twitter solely for customer support issues, such as device troubleshooting, and took steps to limit those interactions to smokers and IQOS® users at least 21 years of age who are registered on PM USA's ATCD. Twitter was not used for advertising purposes, so no optimizations or impressions were reported.

(b) (4)

ATTACHMENT 1

Table 1-1: Summary of Device Units & HeatStick® Volume Sales by Geography and Channel (for HeatSticks®, in number of packs) Reporting Period: September – November 2019

Geography	Item Description	Total Sales	Company Owned	E-Commerce	Convenience Store	Supermarket / Grocery	Drug	Gas
Atlanta	Device Kits	(b) (4)						
Atlanta	Device Holders							
Atlanta	Marlboro HS Smooth Menthol							
Atlanta	Marlboro HS Original Non-Menthol							
Atlanta	Marlboro HS Fresh Menthol							
Richmond	Device Kits							
Richmond	Device Holders							
Richmond	Marlboro HS Smooth Menthol							
Richmond	Marlboro HS Original Non-Menthol							
Richmond	Marlboro HS Fresh Menthol							
South Census Region	Device Kits							

ATTACHMENT 1

Geography	Item Description	Total Sales	Company Owned	E-Commerce	Convenience Store	Supermarket / Grocery	Drug	Gas
South Census Region	Device Holders	(b) (4)						
South Census Region	Marlboro HS Smooth Menthol							
South Census Region	Marlboro HS Original Non-Menthol							
South Census Region	Marlboro HS Fresh Menthol							

ATTACHMENT 1

Table 1-2: Summary of Device & HeatStick® Dollar Sales by Geography and Channel (for HeatSticks®, in number of packs) Reporting Period: September – November 2019

Geography	Item Description	Total Sales	Company Owned	E-Commerce	Convenience Store	Supermarket / Grocery	Drug	Gas
Atlanta	Device Kits	(b) (4)						
Atlanta	Device Holders							
Atlanta	Marlboro HS Smooth Menthol							
Atlanta	Marlboro HS Original Non-Menthol							
Atlanta	Marlboro HS Fresh Menthol							
Richmond	Device Kits							
Richmond	Device Holders							
Richmond	Marlboro HS Smooth Menthol							
Richmond	Marlboro HS Original Non-Menthol							
Richmond	Marlboro HS Fresh Menthol							
South Census Region	Device Kits							

ATTACHMENT 1

Geography	Item Description	Total Sales	Company Owned	E-Commerce	Convenience Store	Supermarket / Grocery	Drug	Gas
South Census Region	Device Holders							
South Census Region	Marlboro HS Smooth Menthol							
South Census Region	Marlboro HS Original Non-Menthol				**(b) (4)**			
South Census Region	Marlboro HS Fresh Menthol							

* Used 11/24/2019 as Quarter Ending to alig
Q1 = Week Ending 9/1/2019 to Week Ending

ATTACHMENT 2

Information about Product Purchasers from Registration
Base: Registered IQOS® Device Purchasers*
Reporting Period: 9/1/2019 - 11/30/2019

Table 2-1. Gender of Registered IQOS® Device Purchasers
Base: Purchasers for which we have an associated gender

Gender	Number of People	% of all purchasers**
Male	(b) (4)	
Female		
Non-Response[1]		

Table 2-2. Age of Registered IQOS® Device Purchasers
Base: Purchasers for which we have an associated age

Age Range	Number of People	% of all purchasers
21-24	(b) (4)	
25-29		
30-39		
40-49		
50-59		
60-69		
70+		
Unknown[2]		

Table 2-3. Registered IQOS® Purchasers by Geography[3]
Base: All IQOS® Purchasers[4,5]

Geography	Number of People	% of all purchasers
Atlanta Market	(b) (4)	
Richmond Market		
South Census Region		

ATTACHMENT 2

Table 2-4. Registered Purchasers by Tobacco Category Usage[6,7]

Base: Registered Purchasers who provided category usage

Tobacco Category	Number of People	% of all purchasers
Cigarettes	(b) (4)	
Cigars		
Smokeless Tobacco		
Snus		
E-Cigarettes/E-Vapor		
Exclusive Cigarette		

*Data collected from consumers who purchased an IQOS® device from a company owned store and elected to register the device to provide PM USA with their information or purchased the device on the IQOS® website.

**Percentages may not total 100 due to rounding.

[1]Gender is recorded via a scanned ID which connects us to a third-party database. Gender is assumed based on titles (i.e. "Mr.", "Mrs."). Non-responses occur when there is no available title or only generic titles, for which no gender can be assumed.

[2]While a consumer is always age verified upon engaging at one of our retail locations, age data has not been systematically captured and retained in all instances.

[3]Retail purchaser geography is attributed to store location. Ecommerce purchaser geography is based on associated consumer state address.

[4]A consumer purchasing multiple devices at one time is only counted once.

[5]Ecommerce sales are currently geo-restricted to GA and VA (South Census Region).

[6]Categories in addition to cigarettes represent dual/poly users.

[7]Consumer can provide multiple responses to this question; % of all purchasers represents the relative incidence of that category's appearance among the total number of people who provided this type of information.

ATTACHMENT 3

Print Media Readership Statistics

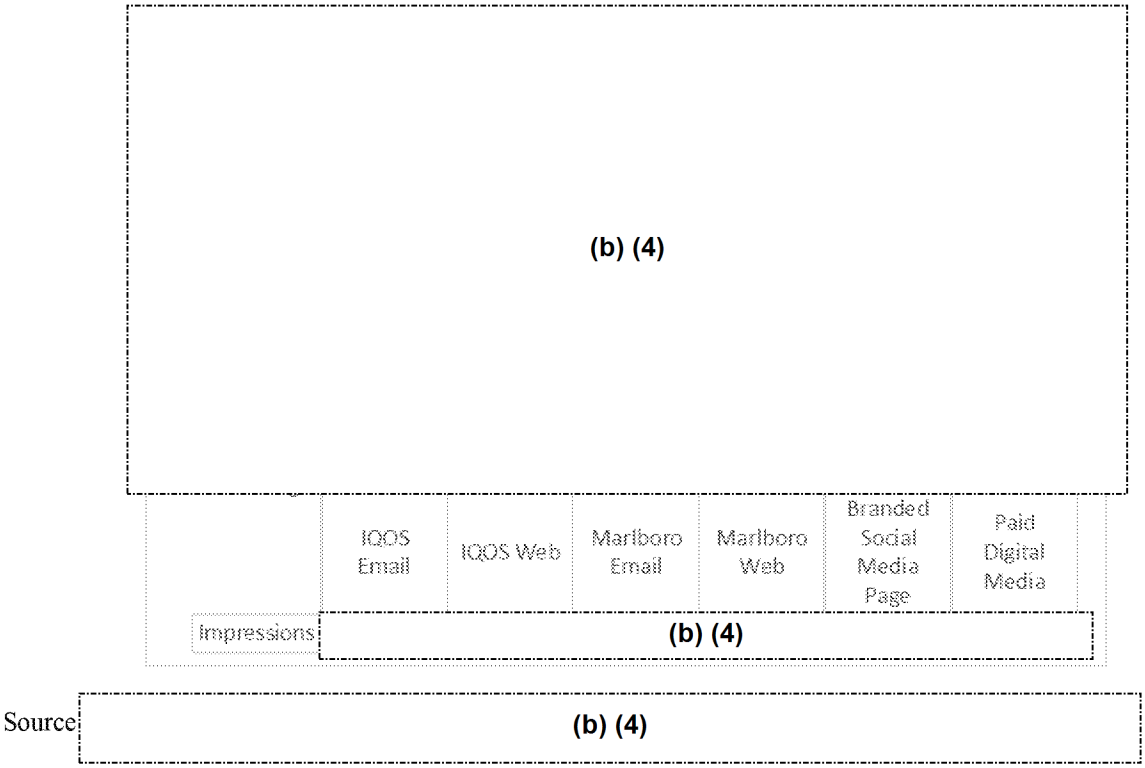
Recommended Publications for IQOS for 2019	2018 Total Readership	2018 Median Age	2018 12+ MRI Study National Compostion A18+ %	2018 12+ MRI Study National Compostion 12-17 %	2018 Projected # of A18+ readers (000s)	2018 Projected # of A12-17 readers (000s)
Esquire	(b) (4)					
GQ-Gentlemen's Quarterly						
Men's Journal*						
Popular Mechanics						
Popular Science						
Vanity Fair						
Vogue						
Wired						

(b) (4)

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

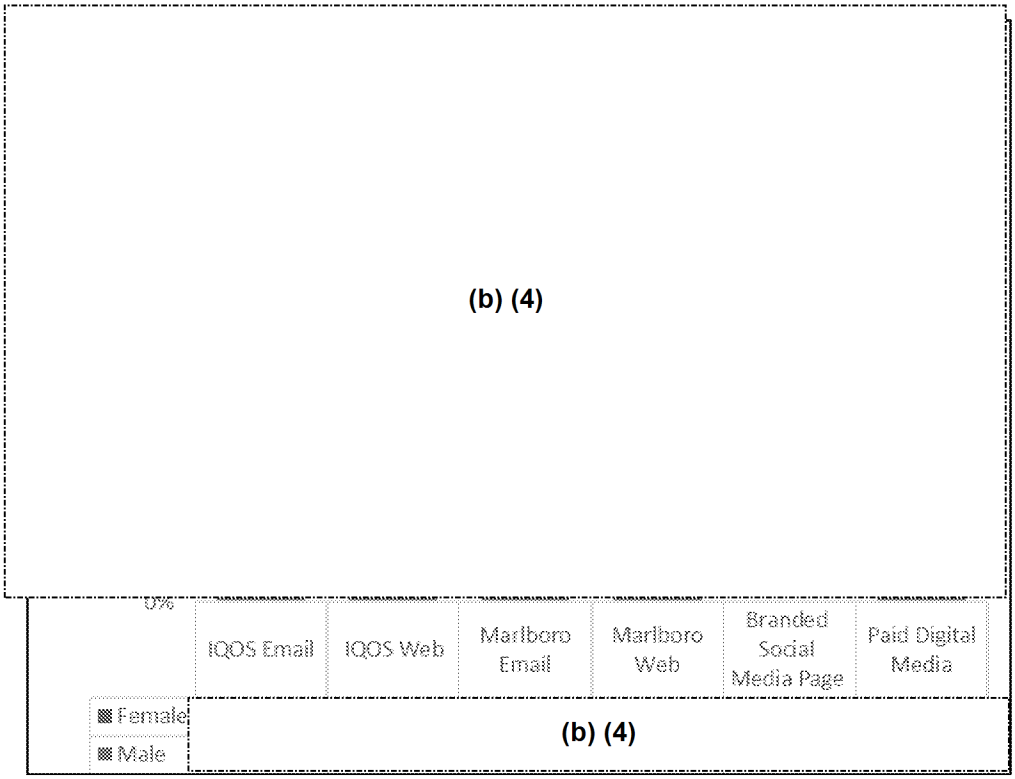
ATTACHMENT 4

Figure 4-1 Advertising Impressions by Advertising Channel



ATTACHMENT 4

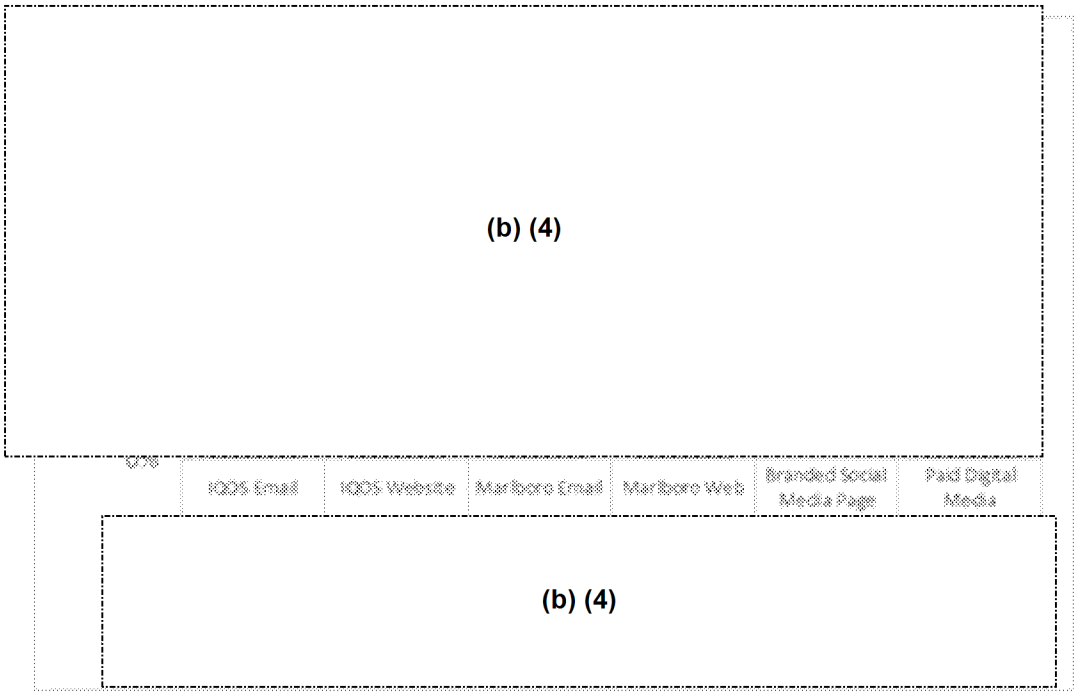
Figure 4-2 Advertising Impressions by Gender and Advertising Channel



Source: (b) (4)

ATTACHMENT 4

Figure 4-3 Advertising Impressions by Age and Advertising Channel



Source: (b) (4)

ATTACHMENT 4

Table 4-1 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						
Florida						
Georgia						
Hawaii						
Idaho						
Illinois						
Indiana						
Iowa						
Kansas						
Kentucky						
Louisiana						
Maine						
Maryland						
Massachusetts						
Michigan						
Minnesota						
Mississippi						
Missouri						
Montana						
Nebraska						
Nevada						
New Hampshire						
New Jersey						
New Mexico						
New York						
North Carolina						
North Dakota						
Ohio						

ATTACHMENT 4

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

(b) (4)

Source: (b) (4)