U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

April 30, 2019

MARKETING ORDER

Philip Morris Products S.A.
ATTENTION: Dr. Jeffrey Walker, CEO Teton Regulatory Sciences
1125 E. Glacier Road
Jackson, Wyoming 83001-4876

FDA Submission Tracking Numbers (STNs): PM0000424-PM0000426, PM0000479

Dear Dr. Walker:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Applications (PMTAs) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), specified in Appendix A.

Based on our review of your PMTAs, we find that the marketing of the new tobacco products specified in Appendix A is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. This marketing order is subject to marketing requirements under section 910(c)(1)(B) of the FD&C Act and record retention and reporting requirements under section 910(f) of the FD&C Act, as outlined in Appendix B. Additionally, this order is conditioned upon the products conforming with any applicable current or future tobacco product standards, unless specifically exempted under this order or the product standard(s). Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco products, in accordance with the order requirements outlined in Appendix B.

The requirements in this order are intended to help ensure that the marketing of your products will continue to be appropriate for the protection of the public health, taking into account initiation among non-users, particularly youth. However, compliance with these requirements alone is not a guarantee that the marketing of the products will remain appropriate for the protection of the public health, particularly if, despite these measures, there is a significant uptake in youth initiation, for example. FDA will continue to monitor the marketing of your products.

This order does not constitute a finding that any of the products outside the scope of this authorization are in compliance with the FD&C Act and its implementing regulations. FDA has not evaluated other components or parts, or accessories that you may choose to market with the iQOS system, such as A/C power adapters, USB cables, charging docks, cleaners, disposal units, and pouches. To the extent that any premarket authorization requirements of section 910 of the FD&C Act apply, FDA does not intend to enforce them with respect to such products. However, it is your responsibility to ensure that these products comply with all other applicable laws and regulations. For example, if you choose to include the brand name “IQOS” on items other than the products authorized in these orders, you need to evaluate whether that would comply with 21 CFR 1140.34(a). In addition, we recommend you evaluate whether any of the branded accessories you plan to market would constitute advertising that requires the applicable warnings.

We note that, in your September 5, 2018 and March 25, 2019 amendments to your PMTAs, you include representations about your marketing plan for your products in the United States and indicate that you intend to focus marketing on adult cigarette smokers while limiting reach to unintended audiences. FDA encourages you to consider measures to limit youth-exposure to any of the products' labeling, advertising, marketing, and/or promotion appearing in print media publications. Limiting youth exposure and initiation and use of the products as you have indicated in your PMTAs (i.e., complete switching to IQOS by adult cigarette smokers) are important components of consideration for the marketing of these products to continue to be appropriate for protection of the public health.

Also, in accordance with 40 CFR 1506.6, we will make your environmental assessments publicly available.

This order authorizing the marketing of these new tobacco products does not mean FDA "approved" the new tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco products specified in Appendix A are "approved" by FDA.[1] The products subject to this marketing order are subject to withdrawal or temporary suspension as described in section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution of these tobacco products and later decide to reintroduce the products into the market, please contact the Office of Science prior to reintroduction.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting us at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/uc

[1] See Section 301(tt) of the FD&C Act.

m515047.htm)[2] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[3]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Donna Cheung, Regulatory Health Project Manager, at (240) 402-5340 or Donna.Cheung@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.04.30 08:29:11 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

[2] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[3] See http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm

Appendix A

List of new tobacco products that FDA has determined appropriate for the protection of public health

Common Attributes of PMTAs	
Date of Submission:	May 15, 2017
Date of Receipt:	May 15, 2017
Product Manufacturer:	Philip Morris Products S.A.
Product Category:	Cigarettes
Product Sub-Category:	Non-Combusted
PM0000424: Marlboro Heatsticks[5]	
Package Type:	Box
Package Quantity:	20 Heatsticks
Characterizing Flavor:	None
Length:	45 mm
Diameter:	7.42 mm
Ventilation:	Not Applicable[4]
Source of energy:	Electric (rechargeable battery)[5]
PM0000425: Marlboro Smooth Menthol Heatsticks[5]	
Package Type:	Box
Package Quantity:	20 Heatsticks
Characterizing Flavor:	Menthol
Length:	45 mm
Diameter:	7.42 mm
Ventilation:	Not Applicable[4]
Source of energy:	Electric (rechargeable battery)[5]

[4] For this product, neither filter efficiency or ventilation are used to control aerosol deliveries.

[5] The components and assemblies control the delivery of energy. The critical items include the (b) (4) (b) (4)) comprising the heating blade and the battery.

PM0000426: Marlboro Fresh Menthol Heatsticks[5]	
Package Type:	Box
Package Quantity:	20 Heatsticks
Characterizing Flavor:	Menthol
Length:	45 mm
Diameter:	7.42 mm
Ventilation:	Not Applicable[4]
Source of energy:	Electric (rechargeable battery)[5]
PM0000479: IQOS System Holder and Charger[6]	
Package Type:	Box
Package Quantity:	1 Holder, 1 Charger
Characterizing Flavor:	None
Length:	93.60 mm (Holder)
Diameter:	15.04 mm (Holder)
Length:	112.50 mm (Charger)
Width:	51.20 mm (Charger)
Ventilation:	Not Applicable[4]
Source of Energy:	Electric (rechargeable battery)[5]
Additional Properties:	Depth: 21.86 mm (Charger) Battery Capacity: (b) (4) (Holder) Wattage: (b) (4) (Charger)[7] Battery Capacity: (b) (4) (Charger)

[6] To be sold individually or as co-packaged product.

[7] Wattage provided for the charger battery

Appendix B

Postmarket Recordkeeping, Retention, Reporting, and Marketing Requirements

I. Record Retention

Under section 910(f) of the FD&C Act, this order requires that you establish and maintain the records listed below. The records must be retained for a period of not less than four years from the date of distribution of the last batch of the new tobacco products listed in your marketing authorization. The records must be legible, written in English, and available for inspection and copying by officers or employees duly designated by the Secretary upon request:

- The PMTA submitted prior to product order
- Periodic postmarket reports, as described below, and adverse experience reports, including all relevant documentation associated with the experience
- Records of all nonclinical or clinical studies, including:
  - Source data;
  - Study protocols (including statistical analysis plan);
  - Amendments showing the dates and reasons for any protocol revisions;
  - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
  - Informed consent forms;
  - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
  - Investigator financial disclosure statements;
  - Progress reports;
  - Monitoring reports;
  - Adverse experience reports;
  - Case report forms/subject diaries/medical records/laboratory reports;
  - Subject data line listings/observation records;
  - Test article accountability records;
  - Study results/protocol summaries/study reports; and
  - Certifications and amendments to certifications
- Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the products
- Records pertaining to the sale, distribution, or other disposition of the products, specifically:
  - A list of distributors and retailers of the products, including brick-and-mortar and digital[8];
  - Any available information (not to include personally identifiable information) about product purchases, such as purchasers' demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use);
  - Policies and procedures regarding verification of the age and identity of purchasers of the products; and
  - Policies and procedures regarding restrictions on youth access to the products

[8] For the purposes of this order, here and throughout the document, "digital" includes internet/online and mobile.

- Records pertaining to the products' labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
  - Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information;
  - Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
  - Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
  - Copies of any consumer evaluation research studies conducted 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, and including copies of the stimuli used in testing;
  - Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/or promotional materials;
  - Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
    - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
    - Targeting of specific adult audiences by age-range(s), including young adult audiences, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
    - Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    - Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
    - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
    - Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products
  - Copies of all records pertaining to media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and
  - Policies and procedures for real-time digital media monitoring to identify, correct, and prevent any delivery of advertising impressions to youth, ages 17 years and under, including documentation of such monitoring activities and implementation of corrective and preventive measures
- Health hazard analyses, if performed voluntarily or directed by FDA
- Records pertaining to any and all complaints associated with any of the products that you receive or of which you are aware

II. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, this order requires that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product(s) within 15 calendar days after the report is received by you. These experiences may become known to you through any source including a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure, reported to you, or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT FOR STN(s) XXX.**

For purposes of reporting under this order, *serious adverse experience* means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening condition or illness;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, *unexpected adverse experience* means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA (including the results of human subject investigations) and other relevant sources of information, such as product labeling and postmarket reports;
- The expected natural progression of any underlying disease, disorder, or condition of the person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

III. Manufacturing Deviations

Under section 910(f) of the FD&C Act, this order requires that you establish and maintain records and reports of all manufacturing deviations, investigations, and corrective and preventive actions including, but not limited to, those deviations associated with processing, testing, packing, labeling, storage, holding, and distribution. For products that have been distributed, if a deviation occurs that you determine presents a reasonable probability that the tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death you are required to report the deviation to FDA within 15 calendar days of identification.

IV. Periodic Reporting

The information in the following postmarket periodic reports will help FDA determine whether continued marketing of your tobacco products is appropriate for the protection of public health and/or there are or may be other grounds for withdrawing or temporarily suspending the marketing authorization order.

Under section 910(f) of the FD&C Act, this order requires that you submit the following periodic reports to FDA **on a quarterly basis, for a period of two years**, beginning three months from the date of this order. For each three-month reporting period, these periodic reports must include:

- A cover letter that includes the following text in your subject line: **PERIODIC REPORT for PM0000424-PM0000426, PM0000479.** The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A summary of U.S. sales and distribution of the tobacco products, including total U.S. sales reported in dollars, units, and volume, and broken down by U.S. census region, major retail markets, and channels where the products are sold (e.g., convenience stores, food and drug markets, big box retailers, digital platforms, tobacco specialty shops, company-owned stores). This summary must also be broken down by product (e.g., specific HeatStick flavor).
- Data on product purchasers. Report any data collected about new purchasers, those who have switched tobacco products, and/or multiple product users. The results must be broken down by purchaser demographics (e.g., age, gender, race/ethnicity, geographic location) and must not include personally identifiable information.

Under section 910(f) of the FD&C Act, this order also requires that you also submit periodic reports to FDA **on a quarterly basis**, beginning three months from the date of this letter. For each three-month reporting period, these periodic reports must include:

- A cover letter that includes the following text in your subject line: **PERIODIC REPORT for PM0000424-PM0000426, PM0000479.** The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). This analysis must be verified against post-launch delivery-verification reports submitted to you from an accredited source.
- A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to youth, ages 17 and under, and including a summary of implementation of any corrective and preventive measures.

Under section 910(f) of the FD&C Act, this order also requires that you submit the following periodic reports to FDA **on an annual basis**, beginning twelve months from the date of this order. For each twelve-month reporting period, these periodic reports must include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for PM0000424-PM0000426, PM0000479**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A summary of how the marketing of the tobacco products continues to be appropriate for the protection of public health, which includes:

- A status report of ongoing studies and a summary of completed studies about the tobacco products conducted by you, or on your behalf.
- A summary of significant findings in publications not previously reported and full copies of the articles. This must include any new scientific data (published or otherwise) on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults.
- A summary of reported adverse experiences for the tobacco products, which includes a listing of all adverse experiences, including the serious and unexpected adverse experiences previously reported. The summary must be accompanied by an analysis of the reports and a statement of any changes to risk information related to the products including nature, frequency, and potential aggravating factors.
- A summary of U.S. sales and distribution of the tobacco products, not previously submitted, including total U.S. sales reported in dollars, units, and volume, and broken down by U.S. census region, major retail markets, and channels where the products are sold (e.g., convenience stores, food and drug markets, big box retailers, digital platforms, tobacco specialty shops, company-owned stores). This summary must also be broken down by product (e.g., specific HeatStick flavor).
- Data on product purchasers not previously submitted. Report any data collected about new purchasers, those who have switched tobacco products, and/or multiple product users. The results must be broken down by purchaser demographics (e.g., age, gender, race/ethnicity, geographic location) and must not include personally identifiable information.
- A summary of the implementation and effectiveness of your policies and procedures regarding verification of the age and identity of purchasers of the products.
- A summary of the implementation and effectiveness of your policies and procedures regarding restrictions on youth access to the products.
- A description of each change made to the manufacturing process, facilities, or controls during the reporting period including:
  - A comparison of each change to what was described in the PMTAs;
  - The rationale for making each change; and
  - A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke or aerosol constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of the tobacco products and the basis for concluding that each manufacturing change did not result in any modification to the products.
- A summary of all manufacturing deviations, investigations, and corrective and preventive actions, including, but not limited to, those deviations associated with processing, testing, packing, labeling, storage, holding, and distribution and indicate any deviation(s) that may affect the characteristics of the products.
- A summary of any stability monitoring and testing of the HeatSticks products, including monitoring and testing protocol (including batch/lot sampling) and results.
- All final printed labeling (including all labeling variations, such as those reflecting different required warnings) not previously submitted, including the date the labeling was first disseminated and the date when the labeling was discontinued, and a description of all changes to the labeling. The labeling must include all the panels and be presented in the actual size and color with legible text. The labeling must include labels, inserts/onserts, instructions, and any other accompanying information or materials for the products.

- All final full-color advertising, marketing, and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers not previously submitted, along with the original date such materials were first disseminated and the date they were discontinued, and a description of all changes to the materials. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the text may be provided separately and referenced.
- A summary of all formative consumer research studies conducted – whether by you, on your behalf, or at your direction – among any audiences, in the formation of new labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing.
- A summary of all consumer evaluation research studies conducted – whether by you, on your behalf, or at your direction – among any audiences, to determine the effectiveness if labeling, advertising, marketing and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing.
- A summary of the creation and dissemination of the products' labeling, advertising, marketing, and/or promotional materials – whether conducted by you, on your behalf, or at your direction – including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities.
- A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans – whether conducted by you, on your behalf, or at your direction – by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:
  - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
  - Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect the intended target audience, including a list of all data sources used to target advertising and marketing plans and media buys;
  - Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
  - Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
  - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
  - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
  - Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products;

including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel and by product.

- An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under), not previously submitted. This analysis must be verified against post-launch delivery-verification reports submitted to you from an accredited source.
- A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to youth, ages 17 and under, and including a summary of implementation of any corrective and preventive measures, not previously submitted.

Under sections 910(c)(1)(B) and 910(f) of the FD&C Act, this order also requires that you provide the following notifications to FDA. These notifications are not for pre-approval, but are required so that FDA can have timely access to your marketing plans and materials, and if needed, provide you advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of your products is appropriate for the protection of the public health. You may begin disseminating the materials 30 days after providing notification to FDA.

- Provide FDA notification of all labeling, advertising, marketing, and/or promotional materials for which you have not previously provided notification, **at least 30 days prior** to the initial publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials, and include in your notification:
  - Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the products. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the text may be provided separately and referenced.
  - All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
    - Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
    - Target specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience, including a list of all data sources used to target advertising and marketing plans and media buys;
    - Restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    - Use owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
    - Use partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;

- Conduct any consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated; and/or
- Use earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products.

V. Marketing Requirements

Under section 910(c)(1)(B) of the FD&C Act and in accordance with section 202(a) of the Family Smoking Prevention and Tobacco Control Act, this order requires:

- Inclusion of the warning statement: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." on the package labels of all HeatSticks packs and of all kits containing HeatSticks packs as well as in all advertisements for such products and kits.[9] Specifically, the warning statement must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping as follows:
  - Be located in a conspicuous and prominent place on the two principal display panels of the package and the warning area must comprise at least 30 percent of each of the principal display panels;
  - Be printed in at least 12-point font size and the warning statement must occupy the greatest possible proportion of the warning area set aside for the required text;
  - Be printed in conspicuous and legible Helvetic bold or Arial bold type (or other sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other printed material on the package;
  - Be capitalized and punctuated as indicated in this order; and
  - Be centered in the warning area in which the text is required to be printed and positioned such that the text of the warning statement and the other information on the principal display panel have the same orientation.
- For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, shelf-talkers, websites, mobile applications, and e-mail), the warning statement must appear in the upper portion of the area of the advertisement within the trim area as follows:
  - Occupy at least 20 percent of the area of the advertisement;
  - Appear in at least 12-point font size and the warning statement must occupy the greatest possible proportion of the warning area set aside for the required text;
  - Appear in conspicuous and legible Helvetica bold or Arial bold type (or other similar sans serif fonts) and in black text on a white background or white text on a black background in a manner that contrasts by typography, layout, or color, with all other material on the advertisement;
  - Be capitalized and punctuated as indicated in this order;
  - Be centered in the warning area in which the text is required to appear and positioned such that the text of the warning statement and the other textual information in the advertisement have the same orientation; and

[9] This warning must appear on each package and each advertisement, in addition to the rotating Surgeon General warnings required under FCLAA (except the carbon monoxide warning, which is to be removed from the rotation of the Surgeon General warnings as described in this order). When FDA promulgates a final rule with respect to health warnings for cigarettes, FDA will reevaluate the conditions of marketing with respect to warnings for the products subject to this order.

  - Be surrounded by a rectangular border that is the same color as the text of the warning statement and that is not less than 3 millimeters (mm) or more than 4 mm.
- Removal of the warning: "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide." from the required warnings to be displayed on the product package labels and advertisements under the Federal Cigarette, Labeling and Advertising Act (FCLAA).
- As a reminder, under section 4 of FCLAA (15 U.S.C. 1333), you must submit a warning plan to the United States Federal Trade Commission (FTC).

Under section 910(c)(1)(B) of the FD&C Act, this order requires you to:

- For any **digital sales** – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale of the products to individuals who are under the federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in your **owned digital properties** (e.g., your company-owned, consumer-directed, product-branded website(s) and/or mobile applications) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare consumer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your products on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content-(e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product(s) running on another company's website; paid advertising for the product(s) running in social media; paid distribution of influencer content) – whether conducted by you, on your behalf, or at your direction:
  - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:
    - "First-party" age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and

  - "Second-party" age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.
  - "First-party" and "second-party" data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.
- Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to youth, ages 17 and under. Such monitoring also requires post-launch delivery verification reports be submitted to you from an accredited source.
- For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the products – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as "sponsored by [firm name]" in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the products, on your behalf, or at your direction.