



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

December 07, 2020

MARKETING GRANTED ORDER

Philip Morris Products S.A.
Attention: Dr. Jeffrey Walker, CEO
Teton Regulatory Sciences
1441 E South Temple
Salt Lake City, UT 84102-1844

FDA Submission Tracking Number (STN): PM0000634

Dear Dr. Walker:

We completed review of your PMTA¹ and are issuing a marketing granted order for the tobacco product identified in Appendix A.

Based on our review of your PMTA, we determined that the new tobacco product, as described in your application and specified in Appendix A, is appropriate for the protection of the public health. The issuance of this marketing granted order confirms that you have met the requirements of section 910(c) of the FD&C Act and authorizes marketing of your new tobacco product. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the tobacco product, in accordance with the marketing order requirements outlined in this order, including all appendices.

Our finding does not mean FDA has “approved” the new tobacco product specified in Appendix A; therefore, you may not make any express or implied statement or representation in a label, labeling, or through the media or advertising, that the new tobacco product specified in Appendix A is approved by FDA (see Section 301(tt) of the FD&C Act).

The authority to market the new tobacco product under this order is also contingent upon the conditions listed in this order and subject to the requirements in the enclosed appendices.

Additionally, this order is conditioned upon the product conforming with any applicable current or future tobacco product standards, unless specifically exempted under this order or the product standard(s).

The requirements in this order are intended to help ensure that the marketing of your product 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 product 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 product. 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

¹ Premarket Tobacco Product Application (PMTA) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (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.

The product subject to this marketing granted order is subject to withdrawal or temporary suspension as described in section 910(d) of the FD&C Act.

You may be eligible to submit a supplemental PMTA for modification(s)² made to tobacco products that received marketing granted orders, by cross-referencing content in the PMTA and postmarket reports for the tobacco product subject of this letter. Applicants that have questions about whether it would be appropriate to submit a supplemental PMTA for modification(s) they are seeking to implement should contact their Regulatory Health Project Manager (RHPM) within the Office of Science for more information.

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

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

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

² We note that any modifications made to a tobacco product would render it a new tobacco product that would be subject to the premarket review requirements under section 910 of the FD&C Act.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{3,4} using eSubmitter.⁵ 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 FDA's 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 date⁶; 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, please contact Donna Cheung, Regulatory Health Project Manager, at (240) 402-5340 or Donna.Cheung@fda.hhs.gov.

If you have any questions regarding postmarket activities for the tobacco product subject of this order, please contact Lillian Ortega, Director, Division of Enforcement and Manufacturing, at OCE-Postmarket@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2020.12.07 12:22:25 -05'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

Appendix A – New Tobacco Product Subject of This Letter

Appendix B – Postmarket Recordkeeping and Retention

Appendix C – Postmarket Reporting

Appendix D – Marketing Requirements

³ <https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

⁴ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁵ <https://www.fda.gov/industry/fda-esubmitter>

⁶ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

Appendix A
New Tobacco Product Subject of This Letter

Attributes of PMTA	
Submission date	March 30, 2020
Receipt date	April 1, 2020
Applicant	Philip Morris Products S.A.
Product manufacturer	Philip Morris Products S.A.
Product category	Cigarettes
Product subcategory	Non-Combusted
STN	PM0000634
Product name	IQOS 3 System Holder and Charger ⁷
Package type	Box
Package quantity	1 Holder, 1 Charger
Characterizing flavor	None ⁸
Length	92.25 mm (Holder) 114.90 mm (Charger)
Diameter	14.40 mm (Holder) (smallest) 14.90 mm (Holder) (largest area with protruding button)
Ventilation	Not provided
Source of energy	Electric (rechargeable battery)
Additional property	Thickness: 23 mm (Charger) Width: 46.35 mm (Charger) Battery Capacity: > 110 milliAmpere hour (mAh) (Holder) Battery Capacity: > 2600 mAh (Charger)

⁷ Brand/sub-brand or other commercial name used in commercial distribution.

⁸ Provided as part of product labeling.

Appendix B

Postmarket Recordkeeping and Retention

Under section 910(f) of the FD&C Act, this order requires that you establish and maintain the records listed below. At any time during the retention period described in this order, FDA may request that you provide any of the documents described below. In addition, under section 704 of the FD&C Act, FDA may inspect your establishment(s) and request to inspect any record(s) described below.

The following records must be retained according to the retention periods described below. These records must be legible, in English, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request.

Record	Description	Retention Period
Prior PMTAs	Each PMTA submitted prior to marketing orders	4 years from the date that FDA issued the marketing order
Postmarket reports	Postmarket reports, including periodic and adverse experience reports as described in this order	4 years from the date the report was submitted to FDA or until FDA inspects the records, whichever occurs sooner
Correspondence with FDA	Correspondence with FDA pertaining to each authorized product	4 years from the date of distribution of the last batch of each product subject to this order
Study data	Nonclinical or clinical study documentation including: <ul style="list-style-type: none"> • Source data; • Study protocols (including statistical analysis plan) and amendments showing the dates and reasons for each protocol revision; • Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or nonapprovals; • 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/observations records; • Test article accountability records; • Study results/protocol summaries/study reports; and • Certifications and amendments to certifications 	4 years from the date of the order or 4 years from the conclusion of the study, whichever occurs later
Manufacturing records	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)	4 years from the date of distribution of each batch of each product subject to this order

	<p>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; and any deviation that may affect the characteristics of each final product⁹</p> <p>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.</p>	
Sales and/or distribution records	<p>A list of distributors and retailers of the products, including brick-and-mortar and digital¹⁰ (including internet/online and mobile)</p> <p>Any available information (not to include personally identifiable information) about product purchasers, 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)</p> <p>With respect to individuals under the legal purchasing age, policies and procedures regarding restrictions on access to the products, including purchaser age and identity verification processes</p>	4 years from the date of distribution of each batch of each product subject to this order
Complaints	Records pertaining to any and all complaints associated with the tobacco product that is the subject of this order; such records may also include your analysis of those complaints	4 years from the date of distribution of each batch of each product subject to this order
Health hazard analysis	Health hazard analyses, if performed voluntarily or directed by FDA	4 years from the date of distribution of each batch of each product subject to this order
Labeling	Specimens of all labeling (including all labeling variations, such as those reflecting different required warnings), labels, inserts/onserts, instructions, and other accompanying information	4 years from the date of initial dissemination to the public
Advertising, marketing and promotional materials and plans	<p>Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers</p> <p>Copies of all advertising and marketing plans including strategic creative briefs and paid media plans, by channel and by product,-dollar amount(s) and flighting of such plans, by channel and by product, including any:</p>	4 years from the date of initial dissemination to the public or implementation

¹⁰ For the purposes of this order, here and throughout the document, "digital" includes internet/online and mobile.

	<ul style="list-style-type: none"> • Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys; • Targeting of specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience(s), including the source of such data; • With respect to individuals under the legal purchasing age, actions taken to restrict access to the product and limit exposure to the products’ labeling, advertising, marketing, and promotion, or other consumer directed activities; • Use of owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the products; • Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the products; • Consumer engagements – whether conducted by you, on your behalf, or at your directions - including events at which the products were demonstrated and how access was restricted to individuals at or above the legal purchasing age; or • Use of public relations or other communications outreach to create labeling for, advertise, market, or promote the products <p>Copies of all records pertaining to the actual delivery of advertising impressions, including 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</p> <p>Policies and procedures for real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the minimum legal purchasing age, including documentation of such monitoring activities and implementation of corrective and preventive measures</p>	
<p>Formative consumer research</p>	<p>Copies of any formative research studies conducted among any audiences, in the formation of the labeling, advertising, marketing, or promotional materials, including qualitative and quantitative research studies used to determine message</p>	<p>4 years after the studies are completed</p>

	effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing	
Consumer evaluation research	Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of the 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	4 years after the studies are completed
Contractual agreements	Copies of any contractual agreements regarding the creation or dissemination of the products' labeling, advertising, marketing, or promotional materials, including, for example, in print media, online or through digital platforms (e.g., social media and mobile applications), such as influencers, bloggers, and ambassadors, on your behalf, or at your direction	4 years from the date of the contract termination

Appendix C

Postmarket Reporting

1. Periodic Reporting

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 six months from the date of this order or when the next report for PM0000479 is submitted, whichever is first. For each three-month reporting period, these periodic reports must include:

- A single submission with a cover letter that includes the following subject line: **PERIODIC REPORT for PM0000634**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and 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 submit the periodic reports to FDA on a quarterly basis beginning six months from the date of this order or when the next report for PM0000479 is submitted, whichever is first. 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 PM0000634**. 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 require that you submit the following postmarket reports to FDA on an annual basis, beginning twelve months from the date of the order¹¹ to help FDA determine whether continued marketing of each new tobacco product is appropriate for the protection of the public health or whether there is or may be grounds for withdrawing or temporarily suspending such order. For the 12-month reporting period, the report must include:

1. A single submission with a cover letter that includes the following subject line: **PERIODIC REPORT for PM0000634**. The cover letter should include the STN(s) and corresponding tobacco

¹¹ The Annual Report for PM0000634 can be submitted with the Annual Report for PM0000479 beginning April 2021.

product name(s), applicant name, date of report, reporting period, and marketing status outside the United States;

- 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.
 - 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.
 - All final printed labeling, including all labeling variations 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 – not previously submitted, 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 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.

2. 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 each new tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a customer complaint, request, or suggestion made as a result of an adverse experience, a manufacturing deviation analysis, 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 subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for PM0000634**.

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 adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption in 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 each tobacco product as described in the PMTA 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 persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

3. Notifications

Under sections 910(c)(1)(B) and 910(f) of the FD&C Act, **this order** also requires that for the first six months after the date of your marketing granted **order** you provide FDA a notification of all labeling, advertising, marketing, and/or promotional materials for which you plan on disseminating to the public or using to engage or communicate with consumers. 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 product is appropriate for the protection of the public health. Failure to comment on your 30-day notifications does not mean that FDA determined that your materials are compliant. You may begin disseminating the materials 30 days after providing notification to FDA. This notification must be received by FDA **at least 30 days** prior to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials.

Each 30-day notification must include:

1. A single submission with a cover letter that includes the following subject line: **30-DAY NOTIFICATION for PM0000634**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of notification, and planned dissemination date;
2. Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the product. The materials must be legible, 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 all lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text must be provided separately and clearly referenced.
3. All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
 - a. Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
 - b. Targeting specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience, including a list of all data sources used to target advertising and marketing plans and media buys;
 - c. With respect to individuals below the minimum purchasing age, actions taken to restrict access and exposure to the products' labeling, advertising, marketing, or promotion;
 - d. Use owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the product;
 - e. Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the product;
 - f. Conduct consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated and how access will be restricted to individuals at or above the legal purchasing age; or
 - g. Use public-relations or other communications outreach to create labeling for, advertise, market, or promote the product.

Appendix D Marketing Requirements

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

- 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 product 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 customer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties in order to restrict access to product promotion, through labeling, advertising, marketing, and to restrict such product 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 in order to restrict access to such product promotion through labeling, advertising, marketing, and to restrict such 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 running on another company’s website; paid advertising for the product 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 region). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to individuals under the minimum legal purchasing age. 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 product – 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 product, on your behalf, or at your direction.

At any time, FDA may request that you provide any of the documents described in Appendix D. In addition, under section 704 of the FD&C Act, FDA may inspect your establishment(s) and request to inspect any record(s) described in Appendix D.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution of **this** tobacco product and later decide to reintroduce the products into the market, please contact the Office of Science prior to reintroduction. Also, every person who owns or operates any domestic establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall update their product listing biannually to reflect certain changes, including any products that have been discontinued and/or reintroduced into interstate commerce.