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

MARKETING GRANTED ORDER

22nd Century Group, Inc.
ATTENTION: Karen Delaney, Program Manager
8560 Main Street, Suite 4
Williamsville, NY 14221

FDA Submission Tracking Numbers (STNs): PM0000491 and PM0000492

Dear Ms. Delany:

We completed review of your PMTAs[1] and are issuing *marketing granted* orders for the tobacco products identified in Appendix A.

Based on our review of your PMTAs, we find that the new tobacco products, as described in your applications and specified in Appendix A, are appropriate for the protection of public health. The issuance of these marketing granted orders confirms that you have met the requirements of section 910(c) of the FD&C Act and permits marketing of your new tobacco products. Therefore, you may introduce or deliver for introduction into interstate commerce the new tobacco products listed in Appendix A.

Our finding does not mean that FDA has "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 (see section 301(tt) of the FD&C Act).

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

Additionally, these orders are conditioned upon the products conforming with any applicable current or future tobacco product standards, unless specifically exempted under these orders or the product standard(s).

The requirements in these orders 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.

The products subject to these marketing granted orders are subject to withdrawal or temporary

[1] Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

suspension as described in section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the tobacco products 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. Labeling and/or advertising that represents explicitly or implicitly that a tobacco product contains a reduced level of a substance or presents a reduced exposure to a substance (e.g. nicotine) would render that product a Modified Risk Tobacco Product ("MRTP") (sec. 911(b)(2)(A)(i)(II)). Additionally, tobacco product labeling and/or advertising that uses the descriptors "light", "low", or "mild" or similar descriptors would render that product an MRTP (sec. 911(b)(2)(A)(i)). A product may not be marketed as modified risk tobacco product (MRTP) without an order from FDA under 911(g) of the FD&C Act. 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.

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

As a reminder, you must comply with applicable requirements under section 4 of Federal Cigarette Labeling and Advertising Ac t (15 U.S.C. 1333), e.g., you must submit a warning plan to the United States Federal Trade Commission (FTC).

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[2,3] using eSubmitter.[4] 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 date[5]; 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.

[2] https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[3] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[4] https://www.fda.gov/industry/fda-esubmitter
[5] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions, please contact Kristopher Van Amburg, Regulatory Health Project Manager, at (301) 348 - 3032 or kristopher.vanamburg@fda.hhs.gov.

If you have any questions regarding postmarket activities for the products within this order, please contact Rose Bianchi, at (301) 796 – 2382 or Rose.Bianchi@fda.hhs.gov.

Sincerely,

/S/

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

Enclosures:

Appendix A - List of Tobacco Products That Are Subject of This Letter
Appendix B - Postmarket Record Keeping and Retention
Appendix C - Postmarket Reporting
Appendix D - Marketing Requirements

Appendix A
List of Tobacco Products That Are Subject of This Letter

Common Attributes of PMTAs	
Date of Submission:	December 4, 2018
Date of Receipt:	December 4, 2018
Product Manufacturer:	22nd Century Group, Inc.
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
PM0000491	
Product Name:[6]	Moonlight®
Package Type:	Hard Pack
Package Quantity:	20 Per Pack
Characterizing Flavor:	None
Length:	83 mm
Diameter:	7.9 mm
Ventilation:	13%
PM0000492	
Product Name:[6]	Moonlight® Menthol
Package Type:	Hard Pack
Package Quantity:	20 Per Pack
Characterizing Flavor:	Menthol
Length:	83 mm
Diameter:	7.9 mm
Ventilation:	13%

[6] Brand/sub-brand or other commercial name used in commercial distribution.

Appendix B

Postmarket Recordkeeping and Retention

Under section 910(f) of the FD&C Act, these orders require 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 cumulatively, that is, for a period of not less than four years from the date of distribution of the *last batch of each product* subject to this order, as 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.

Type of Record	**Description**	**Retention Period**
Prior PMTAs	Each PMTA submitted prior to marketing order	4 years from the date of distribution of the last batch of each product subject to this order
Postmarket reports	Postmarket periodic reports submitted to FDA, including documents such as: status report of ongoing studies conducted by, or on behalf of, the applicant; adverse experience reports and all relevant documentation associated with the experience; summary of how the new product continues to be appropriate for the protection of the public health	4 years from the date of distribution of the last batch of each product subject to this order
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: ▪ Source data; ▪ Study protocols (including statistical analysis plan); Amendments showing the dates and reasons for each protocol revision; ▪ Institutional Review Board (IRB) or Independent Ethics Committee (IEC) 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/observations records; ▪ Test article accountability records; ▪ Study results/protocol summaries/study reports; and ▪ Certifications and amendments to certifications	4 years from the date of distribution of the last batch of each product subject to this order

The following records must be retained on a rolling basis, that is, for a period of not less than four years from the date of distribution of *each batch of each product* subject to this order or four years from the date of initial dissemination of materials to the public, as specified 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.

Type of Record	**Description**	**Retention Period**
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). 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 product.[7]	4 years from the date of distribution of each batch of each product subject to this order
Sales and/or distribution records	A list of distributors and retailers of the products, including brick-and-mortar, and digital (including internet/online, and mobile); 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); Policies and procedures regarding restrictions on youth-access to the products, including purchaser age and identity verification processes.	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(s) that is/are the subject of this order(s). 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

[7] 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.

Health hazard analyses	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 dissemination to the public
Advertising marketing and promotional materials and plans	Copies of all advertising, marketing and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers Copies of all advertising and marketing plans including strategic creative briefs and paid media plans, by channel and by product, and the details, 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, including a list of all data sources used to target 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 psychographic characteristics that reflect your intended target audience(s), how the target audience(s) were defined and the insights used to develop the target audience profiles(s) and the source of such insights; ▪ Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and promotion; ▪ Use of owned, earned, shared/social, 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 directions - including events at	4 years from the date of dissemination to the public

	which the products will be demonstrated and/or; ▪ Use of 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. 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.	
Formative consumer research	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.	4 years from the date of dissemination to the public
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 from the date of dissemination to the public
Contractual agreements	Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/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 dissemination to the public

Appendix C
Postmarket Reporting

I. Periodic Reporting

Per section 910(f) of the FD&C Act, these orders require that you submit periodic reports every 6 months to FDA once during the month of June of each year and once during the month of December of each year, beginning June 2020, to help FDA determine whether continued marketing of each new tobacco product is appropriate for the protection of public health or whether there is or may be grounds for withdrawing or temporarily suspending such order. For the six-month reporting period, the report must include:

1. A single submission with a cover letter that includes the following subject line: **PERIODIC REPORT for STN PM0000491 and PM0000492**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and reporting period.

2. All final printed labeling (including all variations, such as those reflecting different required warnings) not previously submitted (e.g., if previously submitted under section 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), 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.

3. 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 (e.g., if previously submitted under 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), 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 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 lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text may be provided separately and clearly referenced. Digital media, such as videos must be submitted in a format that FDA is able to open and review.

Per section 910(f) of the FD&C Act, these orders require that you submit the following postmarket reports to FDA on an annual basis, beginning November 2020, to help FDA determine whether continued marketing of each new tobacco product is appropriate for the protection of 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 STN PM0000491 and PM0000492**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, reporting period, and marketing status outside the United States.

2. A summary of how the new product continues to be appropriate for the protection of the public health, including:

    a. A status report of ongoing studies and a summary of completed studies about the product conducted by, or on behalf of, the applicant;

    b. A summary of significant findings on publications not previously reported, with copies of the full articles included. 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 use by youth and young adults must also be reported;

    c. All serious or unexpected adverse experiences reported to you, including a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors)

    d. A summary of sales and distribution of the new product, including total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, digital platforms, tobacco specialty shops); and

    e. 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, and race/ethnicity, geographic location) and must not include personally identifiable information. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analyses.

3. A summary of the implementation and effectiveness of your policies and procedures regarding verification of the age and identity of purchasers of the products.

4. A summary of the implementation and effectiveness of your policies and procedures regarding restrictions on youth access to the products.

5. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:

    a. A comparison of each change to what was described in the PMTAs;

    b. The rationale for making each change; and

    c. 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 constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; and the basis for concluding that each change did not result in any modification to the final product. Modifications to any component or part of the previously authorized tobacco product would render the modified tobacco product a new product, for which premarket authorization is required. These modifications should not be provided in a periodic report.

6. A summary of any stability monitoring, and testing of the Moonlight products, including the monitoring and testing protocol(s) (including batch/lot sampling) and results.

7. 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, not previously submitted, 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 or these studies and copies of the stimuli used in testing..

8. A summary of all consumer evaluation research studies conducted – whether by you, on your behalf, or at your direction – among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing and/or promotional materials and 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.

9. 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.

10. A description of the implementation of all advertising and marketing plans not previously submitted, 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:
    a. 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;
    b. Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and psychographic characteristics that reflect the intended target audience, including how the target audience(s) are defined and the insights used to develop the target audience profiles(s), including the source of such insights;
    c. Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    d. Use of owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
    e. Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    f. Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
    g. Use of 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.

11. 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.

12. 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.

II. Serious Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, these orders require that you report to the FDA all adverse experiences that are serious, whether expected or 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 ADVERSE EXPERIENCE REPORT for STN PM0000491 and PM0000492**.

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 postmarket reports and studies;
- 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.

III. 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 orders you provide FDA a 30-day notification for all labeling, advertising, marketing, and/or promotional materials for which you plan on disseminating to the public. 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. 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.

- Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the products. 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 may be provided separately and clearly referenced.

- All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the details, 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, including a list of all data sources used to target 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 psychographic characteristics that reflect your intended target audience, including how the target audience(s) are defined and the insights used to develop the target audience profile(s);
    - Restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    - Use owned, earned, shared/social, and/or paid 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 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

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 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.

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 these tobacco products and later decide to reintroduce the products into the market, please contact the Office of Science prior to reintroduction.

You may be eligible to submit a supplemental PMTA for modification(s) made to tobacco products that received marketing granted orders, by cross-referencing content in the PMTA and postmarket reports for the original tobacco products 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.