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

August 19, 2026

MARKETING GRANTED ORDERS

Helix Innovations LLC
Attention: Rebecca A. Rivas, Senior Director Regulatory Submissions
Altria Client Services LLC
601 East Jackson Street
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): PM0008766.PD2 and PM0008766.PD8, see Appendix A

Dear Rebecca A. Rivas:

We completed review of your PMTAs[1] and are issuing marketing granted orders for the tobacco products identified in Appendix A. Our finding that permitting the marketing of the new products is appropriate for the protection of the public health (APPH) does not mean FDA has "approved" the new tobacco products 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 products specified in Appendix A are approved by FDA (see Section 301(tt) of the FD&C Act). Refer to Appendix B for a list of amendments and additional submissions received.

Based on our review of your PMTAs, we determined that permitting the marketing of the new tobacco products, as described in your applications and specified in Appendix A, are APPH. It should be noted that our determination that the marketing of these products is APPH is based in part on the submitted microbial stability data.[2] The issuance of these marketing granted orders confirms that you have met the requirements of section 910(c) of the FD&C Act and authorizes marketing of your new tobacco products Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the tobacco products, in accordance with the marketing order requirements outlined in these orders, including all appendices.

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

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

[2] The data provided support microbial stability of the products over (b) (4) for PM0008766.PD2 and PM0008766.PD8. The stability data is acceptable and there are no other stability concerns. If you would like FDA to evaluate additional microbial stability data for a longer period, submit this information in a post-market report.

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, among other factors, 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.

Based on our review of your PMTAs, the marketing restrictions in Appendix E are necessary to our conclusion that permitting the marketing of the new tobacco products is appropriate for the protection of public health. Absent these restrictions, a marketing granted order for these applications could not issue consistent with the requirements of section 910(c) of the FD&C Act. Relatedly, we support certain aspects of your marketing practices, as described in your PMTAs, that are intended to help address the potential for youth use of your products. Specifically, you stated you intend to use the following measures to restrict youth access to your products and limit youth exposure to your labeling, advertising, marketing, and promotion:

- (b) (4) [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

We encourage you to implement these measures in addition to the requirements outlined in Appendix E because they are likely to help further mitigate risks to youth. We also recommend that you take additional steps to limit youth exposure to your products' labeling, advertising, marketing, and/or promotion, including but not limited to: requiring point-of-sale advertising to be placed inside the store, placing displays near other age-restricted products and away from toys and candy; selecting print publications that over-index for adults ages 25+ and do not over-index for youth ages 12-17, avoiding advertising placements on the front or back covers; avoiding the use of influencers, partners, bloggers and brand ambassadors to promote the products; limiting sponsorship of any athletic, musical, artistic, or other social or cultural events to only those that are restricted to adults ages 21+; and refraining from distributing branded merchandise or apparel.

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 products subject to these marketing granted orders are 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, in accordance with 21 C.F.R. § 1114.15, for modification(s)[3] 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 to this letter. Should you seek to market modifications made to tobacco products that received marketing granted orders, we encourage you to do so via the PMTA pathway (i.e., through submission of a supplemental PMTA or PMTA, as appropriate). 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 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 minimum age of sale. Additionally, modified risk claims (either explicit or implicit) cannot be made without an MRTP order granted. It is your responsibility to ensure the tobacco products specified in Appendix A comply/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 these tobacco products and later decide to reintroduce the products into the market, please contact the Office of Science prior to reintroduction.

[3] 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[4,5] using eSubmitter.[6] 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;[7] 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 Wendy Guan, Regulatory Health Project Manager, at (240) 402-6937 or Wendy.Guan@fda.hhs.gov.

If you have any questions regarding postmarket activities for the tobacco products subject of these orders, please contact Chad Burger, Director, Division of Product Compliance, at CTP-OCE-Postmarket@fda.hhs.gov.

Sincerely,

MATTHEW C. FARRELLY -S Digitally signed by MATTHEW C. FARRELLY -S Date: 2026.08.19 06:32:24 -04'00'

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

Enclosures:

Appendix A – New Tobacco Products Subject of This Letter
Appendix B – Amendments and Additional Submissions Received for This Applicant
Appendix C – Postmarket Recordkeeping and Retention
Appendix D – Postmarket Reporting
Appendix E – Marketing Restrictions

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

Appendix A
New Tobacco Products Subject to this Letter

Common Attributes[8,9,10,11]	
Submission date	September 25, 2024
Receipt date	September 25, 2024
Applicant	Helix Innovations LLC
Product manufacturer	U.S. Smokeless Tobacco Company LLC
Product category	Other
Product subcategory	Other
Attributes	**New Tobacco Product**
STN	**PM0008766.PD2**
Product Name	on! nicotine pouches 4 mg Rich Berry
Package Type	Plastic Can with Lid
Product Quantity	5.26 grams (g)
Nicotine Source	Tobacco
Characterizing Flavor (CF)	Flavored
Flavored CF, as identified	Rich Berry
Additional property	Nicotine Concentration: 4 milligrams/pouch (mg/pouch) Portion Count: 20 pouches Portion Mass: 0.260 g Portion Length: 24 millimeters (mm) Portion Width: 14 mm
STN	**PM0008766.PD8**
Product Name	on! nicotine pouches 4 mg Autumn Spice
Package Type	Plastic Can with Lid
Product Quantity	5.26 g
Nicotine Source	Tobacco
Characterizing Flavor (CF)	Flavored
Flavored CF, as identified	Autumn Spice
Additional property	Nicotine Concentration: 4 mg/pouch Portion Count: 20 pouches Portion Mass: 0.260 g Portion Length: 24 mm Portion Width: 14 mm

[8] We interpret package type to mean container closure system and Product Quantity to mean quantity within the container closure system, unless otherwise identified.
[9] Product name includes the brand/sub-brand or other commercial name(s) used in commercial distribution. The product might also be identified by alternative names.
[10] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.
[11] Attributes in Appendix A may display converted values.

Appendix B

Amendments and Additional Submissions Received for This Applicant

Amendments Received for These Applications

Submit Date	Receipt Date	Applications being amended	Reviewed	Brief Description
October 22, 2024	October 22, 2024	All STNs.PDs	Yes	Updated references for (b) (4) and Addition of Actual Use Study Data
January 9, 2025	January 9, 2025	All STNs.PDs	Yes	Updated references for (b) (4), Actual Use Study data, and updated HPHC information
September 24, 2025	September 24, 2025	All STNs.PDs	Yes	Contents of (b) (4)
October 15, 2025	October 15, 2025	All STNs.PDs	Yes	Status and implementation plan for product packaging
October 17, 2025	October 17, 2025	All STNs.PDs	Yes	Testing and methodology data requested in October 9, 2025, teleconference with FDA
October 17, 2025	October 17, 2025	All STNs.PDs	Yes	Product characterization data requested in October 9, 2025, teleconference with FDA
October 22, 2025	October 22, 2025	All STNs.PDs	Yes	Additional product characterization data requested in October 9, 2025, teleconference with FDA
October 22, 2025	October 22, 2025	All STNs.PDs	Yes	Additional method validation data requested in October 9, 2025, teleconference with FDA
October 23, 2025	October 23, 2025	All STNs.PDs	Yes	Additional product characterization data requested in October 9, 2025, teleconference

				with FDA
October 23, 2025	October 23, 2025	All STNs.PDs	Yes	Supporting documentation for product packaging and Environmental Assessment (EA)
October 24, 2025	October 24, 2025	All STNs.PDs	Yes	Unredacted EA
October 31, 2025	October 31, 2025	All STNs.PDs	Yes	Additional testing and methodology data requested by FDA on October 27, 2025
November 3, 2025	November 3, 2025	All STNs.PDs	Yes	Translation documents related to October 17, 2025, amendment
November 6, 2025	November 6, 2025	All STNs.PDs	Yes	Unredacted EA
November 13, 2025	November 13, 2025	All STNs.PDs	Yes	Additional testing and methodology data requested by FDA on October 17, 2025
February 11, 2026	February 11, 2026	All STNs.PDs	Yes	Response to January 12, 2026, Deficiency letter
March 17, 2026	March 17, 2026	All STNs.PDs	Yes	Response to clarifying questions from FDA

Additional Submissions Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
January 15, 2026	January 15, 2026	Yes	Clarifying questions for FDA regarding the January 12, 2026, Deficiency letter
February 25, 2026	February 25, 2026	Yes	Addition of point of contact

Appendix C

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 issues 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: • 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; • 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;	4 years from the date of the order or 4 years from the conclusion of the study, whichever occurs later

	• 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	
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	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[12] (including internet/online and mobile) Any available information (not to include personally identifiable information) about product purchasers, such as purchasers' demographics (e.g., age, sex, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use) With respect to individuals under the federal minimum age of sale of tobacco products, policies and procedures regarding restrictions on 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 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

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

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	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 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(s) of such data; • With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the products and limit exposure to the products' labeling, advertising, marketing, and/or promotion; • Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;	4 years from the date of initial dissemination to the public or implementation

	• Use of broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including copies of media buy schedules pre-launch, program lists, projected percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, projected audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency goals, and any other targeting or purchasing parameters; • Use of partners, influencers, bloggers, 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 will be demonstrated and how access will be restricted to individuals at or above the federal minimum age of sale of tobacco products; or • Use of public relations or other communications outreach to create labeling for, advertise, market, and/or promote the products Copies of all records pertaining to the actual delivery of advertising impressions, including media tracking and optimization, by channel, by product (if applicable), by program (where applicable), and by audience demographics (e.g., age, sex, race/ethnicity, geographic region), media buy summaries, program lists, number of units by program, impressions by program, percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency, any other parameters purchased against the buying demographics, post-logs that verify TV/radio ads ran within the approved parameters, and all post-launch	

	delivery-verification reports for other paid media submitted to you or entities working on your behalf or at your direction from an accredited source Policies and procedures for real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, 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 after the studies are completed
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, 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 the contract or until the contract expires, whichever is later

Appendix D
Postmarket Reporting

I. Annual Reporting

Under 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 twelve months from the date of the order to help FDA determine whether continued marketing of each new tobacco products are appropriate for the protection of public health or whether there is or may be other grounds for withdrawing or temporarily suspending such order. For each 12-month reporting period, the report must include:

1. A single submission with a cover letter that includes the following subject line: **ANNUAL REPORT for PM0008766.PD2 and PM0008766.PD8.** 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. 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 must be provided separately and clearly referenced. Digital media, such as videos and animations must be submitted in a format that FDA is able to open and review;

4. 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, if any, a listing of any associated changes; and
    c. The basis for concluding that each change does not result in a new tobacco product that is outside the scope of the marketing granted order.

5. A summary of any stability monitoring, and testing of the products, including the monitoring and

testing protocol(s) (including batch/lot sampling) and results;

6. A complete list of ongoing and completed studies about the tobacco products conducted by, or on your behalf, that have not been previously reported;

7. Full reports of information published or known to you, or which should be reasonably known to you, concerning scientific investigations and literature about the tobacco products that have not been previously reported, as well as significant findings from publications not previously reported;

8. A summary and analysis of <u>all serious and unexpected adverse experiences</u> associated with the tobacco products that have been reported to you or that you are aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco products, and a summary of any changes in the health risks, including the nature and frequency of the adverse experience, and potential risk factors;

9. A summary of sales and distribution of the tobacco products for the reporting period, to the extent that you collect or receive such data, including:
    a. 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 products are sold;
    b. All Universal Product Codes that correspond to the products covered in the PMTA by product name and STN.PD; and
    c. Demographic characteristics of products purchasers, such as age, sex, race/ethnicity, geographic region, and tobacco use status;

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

11. A summary of the implementation and effectiveness of your policies and procedures regarding restrictions on access to the products for individuals under the federal minimum age of sale of tobacco products;

12. 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;

13. 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;

14. 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;

15. A description of the implementation of all advertising and marketing plans – whether conducted by you, on your behalf, or at your direction - not previously submitted, 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 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 group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect the intended audience(s), including the source(s) of such data;
    c. With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the products and limit exposure to the products' labeling, advertising, marketing, and/or promotion;
    d. Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
    e. Use of broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including media buy summaries, program lists, number of units by program, program and network TRPs, impressions by program, percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency, any other parameters purchased against the buying demographics;
    f. Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    g. Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated and how access was restricted to individuals at or above the federal minimum age of sale of tobacco products; or
    h. Use of public-relations or other communications 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;

16. A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, sex, race/ethnicity, geographic region), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, and including a summary of implementation of any corrective and preventive measures, not previously submitted;

17. An analysis of the actual delivery of advertising impressions, by channel, by product (if applicable), by program (where applicable), and by audience demographics, (e.g., age, sex, race/ethnicity, geographic region), not previously submitted, and verified against post-logs (for

TV/radio) and post-launch delivery-verification reports for other paid media submitted to you or entities working on your behalf or at your direction from an accredited source; and

18. An overall assessment of how the marketing of the tobacco products continues to be appropriate for the protection of public health.

The products subject to these marketing granted orders are subject to withdrawal or temporary suspension as described in section 910(d) of the FD&C Act. Grounds that FDA will consider for withdrawal under section 910(d) of the FD&C Act include scenarios in which FDA finds that the continued marketing of the product is no longer APPH. These scenarios may include, but are not limited to, certain changes in product use behaviors that were not expected in FDA's assessment of the PMTA (e.g., increases in the percentage or number of youth and young adults who report use of your products, fewer users of potentially more harmful products switching to your products than anticipated), changes in FDA's understanding of the net effects of your products on the population as a whole, or new scientific evidence that demonstrates that the products present a greater risk to health than FDA understood during the review process.

II. Serious and Unexpected Adverse Experiences Reporting and Reporting of Certain Manufacturing Deviations

Under section 910(f) of the FD&C Act, these orders require 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 any source including 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 PM0008766.PD2 and PM0008766.PD8**.

For purposes of reporting under these orders, 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 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 these orders, 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 of adverse experiences 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.

For products that have been distributed, if a manufacturing 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.

III. Notifications

Under sections 910(c)(1)(B) and 910(f) of the FD&C Act, these orders also requires that, as of the authorization date of your marketing granted orders, you submit the following notifications of your marketing plans and materials to FDA. This requirement to submit the product's labeling, advertising, marketing, and promotional materials and plans in advance of their use is not for pre-approval – that is, FDA is not requiring that it review and approve such materials or plans before they may be used. Rather, such advance notification will provide FDA timely access to such materials and plans and, if needed, allow FDA to provide advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation. 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. The duration of these notification requirements is as follows:

1. On an ongoing basis, provide notification of any labeling, advertising, marketing or promotion in broadcast, satellite, or cable TV media or broadcast or satellite radio media; and
2. For a period of six months starting with the initial dissemination of the materials, provide notification of all other labeling, advertising, marketing, and promotion.

Each 30-day notification must include:

1. A single submission with a cover letter that includes the following subject line: **30-DAY NOTIFICATION for PM0008766.PD2 and PM0008766.PD8**. 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 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 must be provided separately and clearly referenced; and

3. 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:
    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 the source(s) of such data;
    c. With respect to individuals below the federal minimum age of sale of tobacco products, actions taken to restrict access and exposure to the products' labeling, advertising, marketing, and/or promotion;
    d. Use owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
    e. Use broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including copies of media buy schedules pre-launch, program lists, projected percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, projected audience indices by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency goals, and any other targeting or purchasing parameters;
    f. Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    g. 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 federal minimum age of sale of tobacco products; or
    h. Use public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the products.

Appendix E

Marketing Restrictions

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

1. 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 age of sale of tobacco products.

2. 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, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.

3. 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 such promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.

4. For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the products running on another company's website; paid advertising for the products running in social media; paid distribution of influencer content; paid advertising in streaming/Over-The-Top video programming; paid advertising in streaming/internet radio content) – whether conducted by you, on your behalf, or at your direction:

    a. 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 or above the federal minimum age of sale of tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:

        i. "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

ii. "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.

iii. "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.

5. For any of the products' labeling, advertising, marketing, and/or promotion appearing **in broadcast, satellite, or cable TV media, and/or broadcast or satellite radio media** (e.g., video advertisements for the products airing during broadcast cable television programming; audio advertisements for the products airing through radio media channels; ads airing via multichannel video programming distributors; ads airing during Video on Demand/Full Episode Player extensions to network buys; addressable TV ads) – whether conducted by you, on your behalf, or at your direction:

   a. Establish, maintain, and monitor use of independent, competent, and reliable data sources, methodologies, and technologies to target delivery of such labeling, advertising, marketing, and/or promotion to individuals who are at or above the federal minimum age of sale of tobacco products. Such targeting must adhere to the following requirements, at a minimum:

      i. All TV and radio programs must have reported audience compositions of 85% or more adults who are at or above the federal minimum age of sale of tobacco products;

      ii. All TV and radio programs must have reported audience indices of 99 or lower for youth aged 2-11; and

      iii. All TV and radio programs must have reported audience indices of 99 or lower for youth aged 12-17.

6. 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, sex, 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 federal minimum age of sale of tobacco products. Such monitoring also requires post-logs that verify TV/radio ads fan within the approved parameters and post-launch

delivery verification reports for other paid media be submitted to you or entities working on your behalf or at your direction from an accredited source.

7. 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.

The marketing restrictions in these orders were determined based on review of the information submitted in your PMTAs, including information about how you intend to advertise and market the products, and in consideration of other marketing restrictions that currently apply to and/or affect the marketing of your products, including policies and practices of media entities (e.g., no broadcast TV network currently accepts tobacco advertising). Any change in the policies or practices of media entities that has the effect of expanding opportunities for manufacturers of tobacco products to reach youth and any subsequent changes in your use of such media entities may, in turn, affect the APPH analysis of your products, based on our obligation to consider how products are likely to be used, including by youth.