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

November 07, 2024

MODIFIED RISK GRANTED ORDERS–RISK MODIFICATION

Swedish Match U.S.A. Inc.
Attention: Gerard J. Roerty, Jr., General Counsel
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Gerard J. Roerty, Jr.:

We completed review of your MRTPAs[1] and are issuing modified risk granted orders for the tobacco products identified in Appendix A.

Based on our review of your MRTPAs, we determined that the proposed modified risk tobacco products, as described in your applications and specified in Appendix A, as actually used by consumers will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. The issuance of these modified risk granted orders confirms that you have met the requirements of section 911(g)(1) of the FD&C Act and authorizes marketing of the tobacco products as modified risk tobacco products with the following modified risk information: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

These risk modification orders are subject to conditions of marketing under section 911(h) of the FD&C Act, postmarket surveillance and studies under section 911(i) of the FD&C Act, as well as requests related to other record retention and reporting, as outlined in all attached appendices. Under the provisions of section 911, you may introduce or deliver for introduction into interstate commerce the tobacco products in accordance with the risk modification order requirements outlined in these orders, including all appendices.

These modified risk orders are effective for eight years from the issue date of this letter. We recommend you submit a renewal at least 365 days prior to the end of your expiration date. Your renewal may cross-reference your application for each MRTPA that is subject to these orders.

The requirements in these risk modification orders are intended to help ensure that the marketing of your tobacco products will continue to significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. However, compliance with these requirements alone is not a guarantee that the marketing of the tobacco

[1] Modified Risk Tobacco Product Applications (MRTPAs) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

products will continue to comply with the requirements of section 911, particularly if, despite these measures, there is a significant increase in youth initiation or initiation by non-users, for example. FDA will continue to monitor the marketing of your products and their impact on the population.

These orders authorizing the marketing of these modified risk tobacco products do not mean FDA "approved" the modified risk 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 modified risk tobacco products specified in Appendix A are "approved" by FDA (see Section 301(tt) of the FD&C Act). The modified risk tobacco products subject to these risk modification orders are subject to withdrawal as described in section 911(j) of the FD&C Act.

Your previous October 22, 2019, MRGO for these products contained appendices with provisions addressing both section 910 and section 911 requirements. In this order, FDA has only listed the section 911 obligations within your appendices for MRTP renewal authorization of these products. This order does not exempt compliance with other 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. 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.

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 Tamirra Glover M.S., Regulatory Health Project Manager, at (301) 796-6727 or Tamirra.Glover@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,

Digitally signed by Benjamin Apelberg -S
Date: 2024.11.07 09:58:38 -05'00'

Benjamin Apelberg, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

- Appendix A – Tobacco Products Subject of This Letter
- Appendix B – Amendments and Additional Submissions Received for This Applicant
- Appendix C – Postmarket Surveillance and Studies
- Appendix D – Advertising and Promotion Requirements
- Appendix E – Manufacturing Information

Appendix A[6,7,8,9]

Tobacco Products Subject of This Letter

Common Attributes of MRTPA	
Submission date	July 17, 2023
Receipt date	July 17, 2023
Applicant	Swedish Match U.S. A. Inc.
Product manufacturer	Swedish Match U.S. A. Inc.
Product category	Smokeless Tobacco Products
Product order under 911(g)	911(g)(1) Risk Modification Order
Modified Risk Claim	Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
Attributes	
STN	**MR0000256.PD1[10]**
Product subcategory	Loose Snus
Product Name	General Loose
Package Type	Cardboard Can with Plastic Lid
Product Quantity	45.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Additional Properties	Tobacco Cut Size: (b) (4)
STN	**MR0000256.PD2[11]**
Product subcategory	Portioned Snus
Product Name	General Dry Mint Portion Original Mini
Package Type	Plastic Can with Lid
Product Quantity	6.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	20 pouches
Portion Mass	300 mg
Portion Length	28 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size: (b) (4)

[6] We interpret package type to mean container closure system and product quantity to mean quantity within the container closure system, unless otherwise identified.

[7] Product name is brand/sub-brand or other commercial name used in commercial distribution.

[8] 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.

[9] Attributes in Appendix A may display converted values.

[10] Originally authorized under MR0000020.

[11] Originally authorized under MR0000021.

Attributes	Tobacco Product
STN	MR0000256.PD3[12]
Product subcategory	Portioned Snus
Product Name	General Portion Original Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	33 mm
Portion Width	18 mm
Portion Thickness	6 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD4[13]
Product subcategory	Portioned Snus
Product Name	General Classic Blend Portion White Large - 12 ct
Package Type	Plastic Can with Lid
Product Quantity	10.8 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	12 pouches
Portion Mass	900 mg
Portion Length	34 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD5[14]
Product subcategory	Portioned Snus
Product Name	General Mint Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size (b) (4)

[12] Originally authorized under MR0000022.
[13] Originally authorized under MR0000024.
[14] Originally authorized under MR0000025.

Attributes	Tobacco Product
STN	MR0000256.PD7[15]
Product subcategory	Portioned Snus
Product Name	General Nordic Mint Portion White Large - 12 ct
Package Type	Plastic Can with Lid
Product Quantity	10.8 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Mint
Portion Count	12 pouches
Portion Mass	900 mg
Portion Length	34 mm
Portion Width	14 mm
Portion Thickness	5 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD8[16]
Product subcategory	Portioned Snus
Product Name	General Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Tobacco
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size: (b) (4)
STN	MR0000256.PD9[17]
Product subcategory	Portioned Snus
Product Name	General Wintergreen Portion White Large
Package Type	Plastic Can with Lid
Product Quantity	24.0 g
Nicotine Source	Tobacco
Characterizing Flavor	Flavored
Flavored, as identified	Wintergreen
Portion Count	24 pouches
Portion Mass	1000 mg
Portion Length	34 mm
Portion Width	18 mm
Portion Thickness	5.5 mm
Additional Properties	Tobacco Cut Size: (b) (4)

[15] Originally authorized under MR0000027.
[16] Originally authorized under MR0000028.
[17] Originally authorized under MR0000029.

Appendix B
Amendments and Additional Submissions Received for This Applicant

Amendment(s) Received for These Applications

Submit Date	Receipt Date	Applications Being Amended	Reviewed	Brief Description
December 13, 2023	December 13, 2023	All	Yes	Response to December 13, 2023, FDA Information Request
January 17, 2024	January 17, 2024	All	Yes	Unsolicited amendment for EAs
January 30, 2024	January 30, 2024	All	Yes	Response to January 17, 2024, Deficiency Letter
February 13, 2024	February 13, 2024	All	Yes	Response to January 17, 2024, FDA Information Request

Additional Submission(s) Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
Not applicable (N/A)	N/A	N/A	N/A

Appendix C

Postmarket Surveillance and Studies (PMSS)

Under Section 911(i)(1) of the FD&C Act, FDA must require postmarket surveillance and studies for any product for which an applicant received an order under 911(g)(1) in order to: "…determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product."

MRTP Use Behavior and Consumer Understanding and Perception

After receiving authorization, the determination of whether the MRTPs authorized under this order, as actually used by consumers, continue to satisfy the requirements of Section 911(g)(1)(A) and (B), is driven, in part, by use behavior. Therefore, monitoring use of the MRTPs authorized under this order in terms of initiation, dual use with other tobacco products, and complete switching is required. In particular, your PMSS must assess the tobacco use history of people who use the MRTPs (e.g., never, formerly, or currently smoke cigarettes; used other tobacco products before initiating the MRTPs). Also, your PMSS must assess the current tobacco use behaviors among people who use the MRTPs, including whether people exclusively use or dual use the MRTPs with cigarettes or other tobacco products. To adequately assess these impacts, you must conduct PMSS that include assessing behavior and consumer understanding among people who use the MRTPs at multiple time points.

Your PMSS must also include an assessment of exposure to the modified risk claim, understanding of the modified risk claim, and perceptions of the MRTPs among people who use the MRTPs. Your PMSS must assess the extent to which people who use the MRTPs understand that to reduce their health risks relative to smoking as described in the modified risk information, they must switch from smoking cigarettes to using the MRTPs exclusively.

Your PMSS must have clear research objectives, including assessing whether the MRTPs are leading to changes in product use behaviors that are expected to benefit population health. Your PMSS protocols must include a statistical analysis plan describing, among other things, how you plan to conduct inferential statistical analyses to address these objectives and table shells reflecting how you plan to report your results. In addition, for each study involving human subjects, submit IRB-related information (e.g., consent forms) and recruitment strategy details (e.g., inclusion/exclusion criteria, recruitment materials, and statistical power calculations).

In addition, FDA has determined that assessing the impact of your MRTP orders on use of the MRTPs requires surveillance of sales and distribution of the MRTPs authorized under this order, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting sales and distribution of the MRTPs authorized under this order in the United States by product, major metropolitan areas, and channels where the products are sold (e.g., stores and kiosks, convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops). Your annual PMSS report must include:

- U.S. sales and distribution of the MRTPs by quarter since the granting of your modified risk granted order (for the initial reporting period) or the previous reporting period (for all reports that follow), including, total U.S. sales and distribution reported in dollars and units, and broken down by major metropolitan areas and channels where the product was distributed and sold during the reporting period (e.g., convenience stores, food and drug stores, internet and digital

retailers, tobacco specialty shops).
- A brief synthesis and summary of the sales and distribution data for the initial reporting period or the previous reporting period (for all reports that follow), including annual and quarterly growth rate (percent change) in total U.S. sales and distribution of the MRTPs since this order was issued.

MRTP Use and Health Risks – Serious and Unexpected Adverse Experiences

In order for FDA to determine whether the MRTPs authorized under this order, as actually used by consumers, continue to benefit the health of the population as a whole, your PMSS must include ongoing surveillance of all adverse experiences associated with the use of the MRTPs authorized under these orders. 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; or tobacco product defect, or failure, reported to you, or identified in the literature or media. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported serious and unexpected adverse experiences for the MRTPs, which includes a listing of all serious and unexpected adverse experiences during the reporting period and a cumulative list, including all 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 MRTPs including nature, frequency, and potential aggravating factors.
- In addition, the PMTA orders for your tobacco products issued on November 10, 2015, require you to 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 the 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, tobacco product defect, or failure, reported to you, or identified in the literature or media. We request that when submitting such reports, you reference both your PMTAs and your MRTPAs for these products. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT FOR PM0000010-PM0000017, MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029, MR0000256.PD1-MR0000256.PD5, and MR0000256.PD7-MR0000256.PD9.** In addition, submit the information through our Safety Reporting Portal: https://www.safetyreporting.hhs.gov

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

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

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

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the MRTPA (including the results of human subject investigations) 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 person(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

Surveillance of New Research Study Findings on the MRTPs and Consumer Perception, Behavior, or Health

In order for FDA to determine whether the MRTPs authorized under this order, as actually used by the consumer, continue to benefit the health of the population as a whole, your PMSS must include surveillance of new research study information about the MRTPs and consumer perception, behavior, or health. In particular, your PMSS protocol must include procedures for monitoring and assessing previously unreported (new) findings both in published or unpublished studies conducted by you or on your behalf and in published or otherwise available studies regarding the MRTPs and consumer perception, behavior, or health. Your PMSS report must include:

- A summary of significant findings about the MRTPs from any internal and unpublished research studies conducted by you or on your behalf, and whether or not such studies were specifically required under this order.
- A bibliography of relevant publications about the MRTPs.

Submitting PMSS Protocols and Reports

Within 30 days of receiving this notice, you must submit complete protocols for your PMSS as required under section 911(i)(2) of the FD&C Act.

Label your submission clearly as a "PMSS Protocol," and reference your MRTPA Submission Tracking Numbers (STNs). If you have more than one protocol, submit each protocol as a separate submission. If applicable, each protocol should include the name(s) of the principal investigator(s) and materials that demonstrate the relevant professional credentials and training that qualify them to lead the study.

Within 60 days of receipt of the protocol(s), FDA will determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol(s) will result in collection of the data or other information that FDA designates as necessary to protect public health, pursuant to section 911(i)(2) of the FD&C Act.

FDA will notify you of and provide opportunities to address, any deficiency in the submission. If the PMSS protocol is amended subsequent to FDA approval, FDA must receive the amended protocol promptly. For protocol amendments that are administrative in nature (e.g., corrections in punctuation or titles), the amended protocol must be received by FDA within 30 days of the update. For protocol amendments that seek to modify the study design (including endpoints, sites, questionnaires, methodology, etc.) or other scientific parameters, you may not initiate the change until you receive FDA approval.

As part of the requirement to conduct PMSS, you must initiate and conduct your PMSS per the timeframes established in your protocols and approved by FDA. Note that for PMSS that involve human subjects, the anticipated start date for each study must account for the time required for securing IRB approval, as needed. In addition to specifying the start date, your protocols must contain timelines for completion of major study milestones including, as applicable, the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. If you deviate from these timelines, we request that you report the deviation within 30 days to FDA.

Section 911(i) of the FD&C Act requires that the results of the PMSS be submitted on an annual basis based on the timeline outlined in the order letter. These reports must be identified as "PMSS Report" and reference the MRTPA STNs for each report. The PMSS Report must indicate the beginning and ending date of the period covered by the report and must include accomplishments since the last reporting period. For quantitative updates on studies in progress (e.g., participant accrual), reports should describe both interim (since the last reporting period) as well as cumulative (since study initiation) accomplishments. The PMSS Report describing studies in progress must describe the status of PMSS, including, as applicable, the status of recruitment, data collection, and analysis; a summary of the study milestones achieved and any deviations from the approved timelines in the protocol; a summary of protocol amendments; and a summary of any preliminary analyses conducted. Once a study is completed, the PMSS Report should include the complete final study report.

Appendix D

Advertising and Promotion Requirements

I. Recordkeeping and Retention

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to establish and maintain the following records:

- Records pertaining to the products' labeling, advertising, marketing, and/or promotion – whether conducted by you, on your behalf, or at your direction – including:
  - Specimens of all labeling, (including all labeling variations, such as those reflecting different required warnings), labels, inserts/onserts, instructions, and other accompanying information;
  - Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers;
  - Copies of any formative research studies conducted among any audiences in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
  - Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing;
  - Copies of any contractual agreements regarding the creation and/or dissemination of the products' labeling, advertising, marketing, and/or promotional materials, 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;
  - Copies of all advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including any:
    - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys;
    - Targeting of specific groups by age-range(s), including young adult audiences, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience(s);
    - With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the product 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;
    - 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 were 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 media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), and all post-launch delivery-verification reports submitted to you from an accredited source, by channel, by product, and by audience demographics; and
- Policies and procedures for real-time digital media monitoring to identify, correct, and prevent any delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, including documentation of such monitoring activities and implementation of corrective and preventive measures.

II. Notifications

Under section 911(h)(5) of the FD&C Act, these risk modification orders require that as of the authorization date of your modified risk orders, and for a period of six months after the date of your modified risk order, you submit the following notifications of your marketing plans and materials to FDA and all other labeling, advertising, marketing, and promotion. 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.

This 30-day notification requirement to submit the product's labeling, advertising, marketing, and/or 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 and on the finding that continued marketing of your products will benefit the health of the population as a whole. You may begin disseminating the materials 30 days after the notification is received by FDA.

Each 30-day notification must include:

- A single submission with a cover letter that includes the following subject line: **30-DAY NOTIFICATION for MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9**. The cover letter should include the STN(s), static product ID if applicable, corresponding tobacco product name, applicant name, date of notification, and planned dissemination date;
- Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the products. The materials must include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the material does not allow for text to be read easily, the text may be provided separately and referenced. Digital media, such as videos, must be submitted in a format that FDA is able to open and review.
- 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 an media buys;
  - Target specific groups by age-range(s), including young adult audiences, 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 below the federal minimum age of sale of tobacco products, actions taken to restrict access to the product and limit exposure to the products' labeling, advertising, marketing, and/or promotion;
- Use owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
- Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
- 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; and/or
- Use public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the products.

III. Annual Reporting

Under section 911(h)(5) of the FD&C Act, these risk modification orders require that you submit the following reports to FDA **on an annual basis**, beginning twelve months from the date of this order. For each twelve-month reporting period, these annual reports must include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029, MR0000256.PD1-MR0000256.PD5 and MR0000256.PD7-MR0000256.PD9**. The cover letter should include the STN(s), static product ID if applicable, corresponding tobacco product name(s), applicant name, date of report, and reporting period.
- A summary of the creation and dissemination of the products' labeling, advertising, marketing, and/or promotional materials 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 – 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:
  - 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 groups 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;
  - With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the product and limit exposure to the product's 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;
  - 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 were demonstrated and how access was 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; 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 region), not previously submitted. This analysis should be verified against post-launch delivery-verification reports for paid media submitted to you or entities working on your behalf or at your direction 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 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.
- 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.
- 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.

IV. Additional Conditions for Marketing

Under section 911(h)(5) of the FD&C Act, these risk modification orders require you to:

- 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.
- 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 or above the federal minimum age of sale of 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; paid advertising in streaming/Over-The-Top video programming; paid advertising in streaming/internet radio) – 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 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:
        - "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 federal minimum age of sale of tobacco products. Such monitoring also requires post-launch delivery verification reports for paid media be submitted to you or entities working on your behalf or at your direction 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.

The requirements above are intended to help ensure that your eight modified risk tobacco products, as actually used by consumers, will continue to benefit the health of the population as a whole. Limiting

youth initiation of the products and, relatedly, youth exposure to advertising and marketing materials for the products are important factors in the population health benefit analysis. Accordingly, FDA also recommends limiting youth-exposure to any of the tobacco products' labeling, advertising, marketing, and/or promotion appearing in print media publications.

After receiving authorization, the determination of whether the eight modified risk tobacco products, as actually used by consumers, continue to benefit the health of the population as a whole is likely to be driven by use behavior. An uptake in youth initiation and use of the products would have a significant negative impact on the population health benefit analysis. To help ensure that your products, as actually used by consumers, continue to benefit the health of the population as a whole, we strongly recommend that you take measures to limit youth initiation and use of the products, beyond limiting advertising and promotion as required in this order. For example, we strongly recommend you adopt the following measures related to all digital sales of your products:

- 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.

Relatedly, we request that you submit the following information to CTP on an annual basis:

- A summary of the implementation and effectiveness of any policies and procedures regarding verification of the age and identity of purchasers of the products.
- A summary of the implementation and effectiveness of any policies and procedures regarding restrictions on youth access to the products.

We remind you that if FDA can no longer make the determination that your products, as actually used by consumers, will benefit the health of the population as a whole, FDA must withdraw the modified risk orders, after an opportunity for an informal hearing. See under section 911(j)(1) of the FD&C Act. Although adopting the measures above is not in itself a guarantee that the products will continue to benefit the health of the population as a whole, it is an important step in helping to ensure that there are no grounds for withdrawal of your orders.

Appendix E
Manufacturing Information

The PMTA orders for your tobacco products issued on November 10, 2015, require you to report to the FDA manufacturing information. We request that when submitting such reports, you reference both your PMTAs and your MRTPAs for these products. When cross-referencing, please provide the date of submission and location in the submission where the information is covered.

For each twelve-month reporting period, the annual reports should include:

- A cover letter that includes the following text in your subject line: **ANNUAL REPORT for PM0000010-PM0000017, MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029, MR0000256.PD1-MR0000256.PD5, and MR0000256.PD7-MR0000256.PD9**. The cover letter should include the STN(s), static product ID if applicable, and corresponding tobacco product name(s), firm name, date of report, and reporting period.
- 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 PMTA(s)/MRTPA(s);
    - 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 product(s) and the basis for concluding that each manufacturing change did not result in any modification to the product(s).[19]
- 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. For additional information on manufacturing deviations, see below.

Manufacturing Deviations

You should promptly investigate all manufacturing deviations including, but not limited to, those associated with processing, testing, packing, labeling, storage, holding, and distribution. The PMTA orders for your tobacco products issued on November 10, 2015, require that, for products that have been distributed, if a deviation occurs that you determine presents a reasonable probability that these tobacco products contain 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. We request that when submitting such reports, you reference both your PMTA(s) and your MRTPA(s) for these products.

Discontinuation and Reintroduction

If you discontinue the manufacture, preparation, compounding, or processing for commercial distribution of these modified risk tobacco products and later decide to reintroduce the modified risk tobacco products into the market, please contact the Office of Compliance and Enforcement prior to reintroduction. Section 905(i)(3) of the FD&C Act requires you to update your product listing biannually to reflect any products that have been discontinued and/or reintroduced into interstate commerce.

[19] 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.