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Please let us know if you encounter accessibility barriers by contacting the **FDA's Center for Tobacco Products** at AskCTP@fda.hhs.gov or call 1-877-287-1373.

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

June 30, 2026

MODIFIED RISK GRANTED ORDERS– RISK MODIFICATION

Swedish Match USA, Inc.
Attention: Sarah Amyot, Manager, US Regulatory Management
PMI US Corporate Services Inc.
1399 New York Avenue Northwest, Suite 400
Washington, DC 20005

FDA Submission Tracking Numbers (STNs): MR0000268.PD1 – MR0000268.PD20**,** see Appendix A

Dear Sarah Amyot:

We completed review of your MRTPAs[1] and are issuing modified risk granted orders for the tobacco products identified in Appendix A. Refer to Appendix B for a list of amendments and additional submissions received.

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, have satisfied the requirements of section 911(g)(1)(A) and (B), including that they, as actually used by consumers, would 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. Therefore, we authorize marketing of the tobacco products as modified risk tobacco products with the following modified risk information: "Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."

Under the provisions of section 911, you may introduce or deliver for introduction into interstate commerce the modified risk tobacco products specified in Appendix A, in accordance with these risk modification orders. These risk modification orders are subject to conditions of marketing under section 911(h) of the FD&C Act and your agreement to conduct postmarket surveillance and studies (PMSS) under section 911(i) of the FD&C Act, as outlined in all attached appendices. See Appendix C for information on required PMSS. See Appendix D for advertising and promotion requirements.

These modified risk orders are effective for 5 years from the issue date of this letter. We recommend you submit an application to renew your modified risk orders at least 365 days prior to the end of your effective timeframe. Your renewal application may cross-reference each MRTPA that is subject to these orders.

The requirements in these risk modification orders are intended to help ensure that your modified risk tobacco products will continue to satisfy the requirements of section 911(g)(1)(A) and (B), that is to "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

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

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" (section 911(g)(1)(A) and (B)). However, compliance with these requirements alone is not a guarantee that the marketing of your modified risk tobacco 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.

Relatedly, we support certain aspects of your marketing plans, such as the measures described in your MRTPAs and PMTAs that are intended to help address the potential for youth use of your products. We continue to encourage you to implement these measures as outlined on page 2 of your January 16, 2025, PMTAs' Marketing Granted Orders, given the known association between exposure to marketing and youth tobacco product use. We also recommend that you take additional steps to limit youth exposure to your products, including for example: requiring point-of-sale advertising to be placed only 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 print 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 those targeted to adults ages 21+; advertising rewards program offerings through an age-restricted website; and refraining from distributing branded merchandise or apparel and/or nontobacco item giveaways. Finally, we note your intention to use consumer testimonials and product reviews in your marketing and remind you that any statements indicating that these products are intended to be used for the treatment or mitigation of tobacco dependence, including as smoking or tobacco cessation aids, would render the products to not be modified risk tobacco products under section 911 and would subject the products to other requirements under the FD&C Act.

This order authorizing the marketing of these modified risk tobacco products does not mean we "approved" the 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).

These modified risk granted orders under 911(g)(1) are subject to withdrawal as described in section 911(j) of the FD&C Act.

The modified risk tobacco products specified in Appendix A are subject to the requirements of the associated January 16, 2025, PMTA orders and appendices.

We remind you that the modified risk tobacco products specified in Appendix A are subject to the requirements of the FD&C Act, FDA's implementing regulations, and all other applicable laws and regulations, including the relevant warning label requirements. 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.

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: 2026.06.30 06:51:39 -04'00'

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 – Required Postmarket Surveillance and Studies
Appendix D – Advertising and Promotion Requirements

[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

Appendix A
Tobacco Products Subject of This Letter

Common Attributes[6,7,8,9]	
Submit date	April 5, 2024
Receipt date	April 5, 2024
Applicant	Swedish Match USA, Inc.
Product manufacturer	Swedish Match North America LLC, Swedish Match North Europe AB
Application type	Standard
Product category	Other[10]
Product subcategory	Other[11]
Product order under 911(g)	911(g)(1) Risk Modification Order
Modified Risk Claim	Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
Attributes	**Tobacco Product**
STN	**MR0000268.PD1**
Product name	ZYN Cool Mint 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 grams (g)
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Cool Mint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 milligrams (mg)/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 millimeters (mm) Portion Width: 14 mm Portion Thickness: 4.5 mm

[6] We interpret package type to mean container closure system and product quantity to mean product quantity within the container closure system, unless otherwise identified.
[7] Product name is brand/sub-brand or other commercial name used in commercial distribution. Might also be identified by alternative names.
[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] Oral pouch products containing nicotine derived from tobacco.
[11] The applicant uses the term "flavors" or "varieties" to indicate product flavors.

STN	MR0000268.PD2
Product name	ZYN Cool Mint 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Cool Mint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD3**
Product name	ZYN Peppermint 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Peppermint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD4**
Product name	ZYN Peppermint 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Peppermint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

STN	MR0000268.PD5
Product name	ZYN Spearmint 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Spearmint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD6**
Product name	ZYN Spearmint 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Spearmint
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD7**
Product name	ZYN Wintergreen 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Wintergreen
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

STN	MR0000268.PD8
Product name	ZYN Wintergreen 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Wintergreen
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD9**
Product name	ZYN Citrus 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Citrus
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD10**
Product name	ZYN Citrus 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Citrus
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

STN	MR0000268.PD11
Product name	ZYN Coffee 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Coffee
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD12**
Product name	ZYN Coffee 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Coffee
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD13**
Product name	ZYN Cinnamon 3 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Cinnamon
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

STN	MR0000268.PD14
Product name	ZYN Cinnamon 6 mg
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Cinnamon
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD15**
Product name	ZYN Smooth 3 mg[12]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Smooth
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD16**
Product name	ZYN Smooth 6 mg[13]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Smooth
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

[12] Swedish Match might also market this product as ZYN Original 3 mg.
[13] Swedish Match might also market this product as ZYN Original 6 mg.

STN	MR0000268.PD17
Product name	ZYN Chill 3 mg[14]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Chill
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD18**
Product name	ZYN Chill 6 mg[15]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Chill
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm
STN	**MR0000268.PD19**
Product name	ZYN Menthol 3 mg[16]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Menthol
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 3 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

[14] Swedish Match might also market this product as ZYN Classic 3 mg.
[15] Swedish Match might also market this product as ZYN Classic 6 mg.
[16] Swedish Match might also market this product as ZYN Fresh 3 mg.

STN	MR0000268.PD20
Product name	ZYN Menthol 6 mg[17]
Package type	Polypropylene Can and Polypropylene Lid
Product quantity	6 g
Characterizing flavor (CF)	Menthol
Nicotine source	Tobacco
Additional properties	Nicotine Concentration: 6 mg/pouch Portion Count: 15 pouches Portion Mass: 0.40 g Portion Length: 28 mm Portion Width: 14 mm Portion Thickness: 4.5 mm

[17] Swedish Match might also market this product as ZYN Fresh 6 mg.

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
August 16, 2024	August 16, 2024	All	Yes	Inform FDA that additional study added to (b) (4)

Additional Submission(s) Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
February 24, 2025	February 24, 2025	Yes	Change in authorized points of contact

Appendix C

Required Postmarket Surveillance and Studies (PMSS)

Under section 911(i)(1) of the FD&C Act, FDA must require that an applicant conduct postmarket surveillance and studies for any tobacco product for which an applicant received an order under 911(g)(1) to "…determine the impact of the order issuance on consumer perception, behavior, and health, to enable [FDA] to review the accuracy of the determinations upon which the order was based, and to provide information that [FDA] 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 and consumer understanding and perception. Thus, to adequately assess the impact of the authorizations and demonstrate the products continue to satisfy these requirements, you must conduct PMSS that include assessing behavior and consumer understanding of the claim at multiple time points. Assessing use behavior and consumer understanding and perception at multiple time points is necessary to enable FDA to effectively monitor the impact of the MRTPs on individual and population health. In particular, relative to the premarket evaluation, once marketed, the MRTPs will be used in real-world settings, and a much larger population may be repeatedly exposed to the products and their modified risk labeling and advertising. Therefore, evaluating the effect of sustained marketing on use behavior and consumer perceptions at multiple time points is needed as part of PMSS.

Your PMSS must monitor use of the MRTPs to assess initiation, dual use with other tobacco products, and whether users have completely switched to the MRTPs. In particular, your PMSS must assess the tobacco use history of people who use the MRTPs (e.g., never, formerly, or currently smoke combusted cigarettes (CC); used other tobacco products before initiating use of 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 CC or other tobacco products.

Your current marketing for these ZYN products uses several tactics known to be appealing to youth and young adults, such as sponsorship of popular sporting events and concerts and brand loyalty and rewards programs that encourage consumer use of the products in exchange for high-dollar-value items. Even though the current evidence shows the relatively low risk of youth initiation of nicotine pouch use, this could change over time. Although it is well documented that exposure to marketing generally impacts youth initiation of tobacco products, there is uncertainty related to the impact of modified risk information on youth use, therefore your PMSS must be designed to monitor use of ZYN among youth under the age of 18 and among young adults below the minimum age of sale (i.e., ages 18-20), to help ensure that marketing of the MRTPs does not have unintended consequences for youth and young adult use. Assess youth and young adult use at multiple time points and include annual updates with each annual report submission.

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. Specifically, your PMSS must assess the extent to which people who use the MRTPs understand that the reduction in health risks is relative to smoking CC, as described in the modified risk claim, and that adults who currently smoke CC must use the MRTPs exclusively and stop smoking CC to reduce their health risks.

Your PMSS also must include items to assess perceptions of the risk of ZYN relative to cessation of all tobacco use, and relative to never using tobacco products. An assessment of exposure to, and awareness of, the modified risk claim is necessary to help elucidate the impact of real-world and repeated claim exposure on consumer understanding and perceptions.

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. Conducting a longitudinal cohort study may produce robust and reliable evidence to demonstrate the impact of the MRTPs in terms of uptake, dual use with other tobacco products, and complete switching over time. If you are unable to conduct such a longitudinal study, a repeated cross-sectional study that collects valid information on recalled history of tobacco use may also provide evidence across multiple time points to determine whether people who use the MRTPs used them to switch completely from CC smoking. 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 Institutional Review Board (IRB)-related information (e.g., consent forms) and recruitment strategy details (e.g., inclusion/exclusion criteria, recruitment materials, and statistical power calculations).

As part of these orders, you must initiate and conduct your PMSS per the timeframes established in your protocols and approved by FDA. Note that 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 the start and completion of participant recruitment, initiation of data collection (per wave, if applicable), completion of data collection, analysis, and report writing. Major deviations from these timelines must be reported to FDA.

Sales Data

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 provides 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 reports must include:

1. U.S. sales and distribution of the tobacco products by quarter since the date of issuance of the MRTP orders (for the initial reporting period) or the previous reporting period (for all reports that follow), including, for each MRTP STN.PD, total U.S. sales and distribution reported in dollars and units, and broken down by U.S. census region, major metropolitan areas[18] or states, and retail channels where the products were distributed and sold during the reporting period (e.g., convenience stores, food and drug stores, internet and digital retailers, tobacco specialty shops).

[18] See Metropolitan and Micropolitan Statistical Areas Totals: 2020-2025 for more information.

2. Whether any of the authorized modified risk products are being or have been sold or offered for sale under a different label or brand name, either by you or a different company, and report the sales and distribution data related to those relabeled or rebranded products.
3. Crosswalk table of MRTP STN.PDs to Universal Product Codes for the MRTPs by any product name, including relabeled or rebranded products.
4. Annual and quarterly growth rates (percent change) of total U.S. sales and distribution (dollars and units) for each MRTP STN.PD.
5. A brief narrative that synthesizes the sales and distribution data, describing high-level national trends in sales and any regional variations or unexpected patterns for each MRTP STN.PD for the reporting period.

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.

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 marketing granted orders (MGOs) for your tobacco products issued on January 16, 2025, 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 PM0000593.PD1 – PM0000612.PD1 and MR0000268.PD1 – MR0000268.PD20.** In addition, submit the information through our Safety Reporting Portal: https://www.safetyreporting.hhs.gov

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

1. Death;
2. A life-threatening condition or illness;
3. Inpatient hospitalization or prolongation of existing hospitalization;

4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect; or
6. 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, *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:

1. 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;
2. 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
3. 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 consumers, continue to benefit the health of the population as a whole, your PMSS must report any previously unreported findings from any internal and unpublished research studies regarding the MRTPs and consumer perception, behavior, or health, conducted by you or on your behalf, regardless of whether such studies were specifically required as part of PMSS.

Your PMSS report must include, but are not limited to:

- Any unpublished data about individuals under the age of 18 and/or below the minimum age of sale (i.e., ages 18-20) related to: (a) youth awareness of the MRTPs in order to evaluate how effectively any marketing is limiting unintended exposure to youth, and (b) youth use of the MRTPs, to help ensure that marketing of the MRTPs does not have unintended consequences for youth use.
- Detailed reports of the findings of any consumer surveys or related data collection efforts, including from members of consumer rewards programs, such as ZYN Rewards and Club 3|6. These reports should include any information related to member demographics (e.g., age); tobacco use behaviors; exposure to product marketing; and consumer understanding and perceptions of the MRTPs.

Submitting PMSS Protocols

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 STN.PDs. 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 review the protocol(s) and evaluate 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 designated by [FDA] as necessary to protect public health," pursuant to section 911(i)(2) of the FD&C Act.

FDA will notify you of any deficiencies in the submission and provide an opportunity to address them. If the PMSS protocol is amended after FDA approval, the amended protocol must be submitted to the FDA 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.

Submitting PMSS Reports

Section 911(i) of the FD&C Act requires that the results of the PMSS be submitted on an annual basis. These reports must be identified as "PMSS Report" and reference the MRTPA STN.PDs 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; and a summary of protocol amendments. For studies with more than one time point of data collection, once each time point is complete, include a report of the results of that time point and the corresponding data file in the subsequent PMSS Report. Once a study is completed, the PMSS Report should include the complete final study report with all time points reported together.

Appendix D

Advertising and Promotion Requirements

I. Notifications

Under section 911(h)(5) of the FD&C Act, FDA may require, with respect to a product for which an applicant obtained an order under section 911(g)(1), that the product complies with requirements relating to advertising and promotion of the tobacco product. Thus, these risk modification orders require that as of the authorization date of your modified risk orders, you submit the notifications of your marketing plans and materials to FDA, as described below.

This requirement to submit the products' 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. You may begin disseminating the materials 30 days after the notification is received by FDA.

These notifications 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:

- 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
- 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 MR0000268.PD1 – MR0000268.PD20**. The cover letter should include the STN(s), static product ID if applicable, corresponding tobacco product name(s), applicant name, date of notification, and planned dissemination date.
2. Full-color copies of all such labeling, advertising, marketing, and/or promotional materials for the 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.
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. 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;
c. 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;
d. Use owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
e. Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
f. Conduct consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated and how access will be restricted to individuals at or above the federal minimum age of sale of tobacco products; and/or
g. Use public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the products.

II. 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 these orders, to help FDA determine whether continued marketing of the products with the modified risk claims will benefit the population as a whole or whether there otherwise are or may be grounds for withdrawing or temporarily suspending such orders. For each 12-month reporting period, these annual reports must include:

1. A cover letter that includes the following text in your subject line: **ANNUAL REPORT for MR0000268.PD1 – MR0000268.PD20**. 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.
2. 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;
3. 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 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;

c. 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;
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., 21+, 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, 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.

4. 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.
5. 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.
6. 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, 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.
7. 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 section 905(i) or previously submitted at the last reporting period and no changes were made, 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.

8. A summary of the implementation and effectiveness of your policies and procedures regarding verification of the age and identity of purchasers of the products;
9. 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;
10. 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;
11. 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;

III. Additional Conditions for Marketing

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

1. 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.
2. 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.

3. 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:
    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 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:
        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.
4. 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 ages 2-11; and
        iii. All TV and radio programs must have reported audience indices of 99 or lower for youth ages 12-17.
5. 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 to be submitted to you or entities working on your behalf or at your direction from an accredited source.

6. 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 MRTPs, 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 MRTPs, 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:

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.

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 granted orders, after an opportunity for an informal hearing. See 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.