July 17, 2023

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FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Modified Risk Tobacco Product Application Renewal for MR0000020 - MR0000022, MR0000024- MR0000025, MR0000027- MR0000029

Swedish Match USA, Inc. ("Swedish Match", "we", or "our") submits this application under section 911(g)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act to request renewal of the Modified Risk Granted Order (MRGO) – Risk Modification issued on October 22, 2019, for eight (8) General Snus products (MR0000020 - MR0000022, MR0000024- MR0000025, MR0000027- MR0000029**)** with this 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."**

In authorizing this claim, FDA stated the following:

> **"The FDA's review determined that the claim proposed by the company in its application is supported by scientific evidence, that consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes, and that the modified risk products, 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."**

Confidentiality Statement

All of these points from the initial authorization remain valid as evidenced by our ongoing annual reporting and surveillance (i.e., 2015 – present day), as well as results from external scientific research, including government surveys. The original rationale for FDA's decision was that these products are appropriate for the protection of public health (APPH), and our surveillance/updated data continues to support this rationale, including each of the following factors: (1) our manufacturing controls and continued product testing indicate that our General Snus products maintain their relatively low levels of HPHCs; (2) our ongoing Post-Market Surveillance Studies "PMSS" have shown that consumers continue to understand and are not misled by the authorized MRTP claim; (3) and FDA's National Youth Tobacco Survey "NYTS" indicates that all varieties of General Snus product are still not appealing to youth. Having General Snus on the US market, with the authorized MRTP claim, is a benefit to the population as whole considering users and nonusers, and maintaining the MRTP authorization for General Snus is appropriate for the protection of public health.

Additionally, since the 2019 authorization, FDA has not raised any concerns about the information that has been provided by us to FDA related to its APPH finding. Accordingly, FDA should renew each MRGO. Swedish Match expands on this rationale and provides additional details in subsequent sections of this Renewal Request.

With respect to the information we are supplying, Swedish Match submits that it is trade secret, proprietary information and thereby protected under state and federal law from public disclosure. Further, this information should be handled in accordance with the security procedures adopted by your agency, in connection with enforcement of the Act.

If further information is required, please contact us.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr.

General Counsel, Swedish Match USA, Inc.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Swedish Match USA, Inc..

MRTP Renewal

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1. EXECUTIVE SUMMARY

Swedish Match USA, Inc. submits this application under section 911 of the Tobacco Control Act to request renewal of the Modified Risk Granted Order (MRGO) – Risk Modification issued on October 22, 2019, for eight (8) General Snus products (see **Table 1**). This authorization allows the marketing of these products with the following authorized reduced 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."*

When authorizing the products, FDA concluded that "the claim proposed by the company in its application is supported by scientific evidence, that consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes, and that the modified risk products, 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."[1]

FDA should continue to hold these conclusions. The rationale used by FDA in authorizing these products under both the PMTA and MRTP pathways still holds true today: these products with an authorized MRTP claim remain appropriate for the protection of the public health. FDA has not raised concerns since the 2019 authorization about the information provided by us to FDA about the MRTPs being APPH. Accordingly, FDA should renew each MRGO, based upon the rationale in the subsequent paragraphs.

1.1. PMTA Authorization Rationale

The MRGO-authorized products continue to be appropriate for the protection of public health under the PMTA pathway. FDA issued marketing granted orders through the PMTA pathway authorizing eight (8) General Snus products on November 10, 2015. The primary reasons for granting authorization for the proposed eight products include the following:

- The products are produced with a voluntary, proprietary manufacturing process that distinguishes Swedish snus from other types of Smokeless Tobacco (ST). The proprietary standard for Swedish snus products was developed to ensure product quality.

- The products have significantly lower levels of NNN and NNK when compared to over 97% of the ST products currently on the U.S. market. Since NNN and NNK are among the most carcinogenic constituents in tobacco products, this reduction of NNN and NNK levels in General Snus products likely reduces the cancer risk for consumers. To date, the GOTHIATEK

[1] Scientific Review of MRTPA under Section 911(d) of the FD&C Act – Technical Project Lead, available at: https://www.fda.gov/media/131923/download

standard[2] remains well adhered to as evidenced by results from our extensive routine testing of all of its components, confirming General Snus products maintain their exceptionally low HPHC levels.

- The totality of the literature, including that of the post-PMTA authorization period, does not identify external research that contradicts the notion that when these products are used exclusively instead of cigarettes, they offer lower risk of developing any of the disease endpoints in the claim.
- The rationale was further supported by FDA's recent MRTPA authorization of Copenhagen Classic, in which the claim "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer"[3]. While our General Snus products are not identical to Copenhagen Classic, they are both examples of smokeless tobacco products utilizing information from the "Swedish Experience" in their applications. The above authorized claim, like our own, promotes respiratory health via switching, and is informative for the purposes of evaluating this application. Further, a finding of appropriateness of the protection of the public health for the Copenhagen product would reasonably apply in equal force to that of the General Snus products.
- It is anticipated that the marketing of General Snus will be associated with a low likelihood of uptake of these products by unintended users (non-users of tobacco and youth). It is also anticipated that the marketing would not be associated with a decreased or delayed cessation of combustible products or other significant shifts in user demographics.
- Robust evidence from government agencies such as the 2021-2022 National Youth Tobacco Survey (NYTS) and the Population Assessment of Tobacco and Health (PATH) indicate no significant uptake of snus by non-users including youth[4].

1.2. MRTP Authorization Rationale

FDA authorized a claim for these General Snus products through the MRTPA pathway on October 22, 2019. The primary reasons for granting authorization for the eight products include the following:

- FDA stated that the claim associated with these products are "supported by scientific evidence", in particular the GOTHIATEK manufacturing standard results in the products having low levels of NNN and NNK thereby lowering the risk for respiratory disease,

[2] https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard
[3] Scientific Review of MRTPA under Section 911(d) of the FD&C Act – Technical Project Lead, available at: https://www.fda.gov/media/166255/download
[4] Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022; 71 (No. SS-5): 1–29. Accessed from: https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf

cardiovascular disease, and some cancers (e.g., lung, oral). To date, The GOTHIATEK standard[5] remains well adhered to as evidenced by results from our extensive routine testing of all of its components, confirming General Snus products maintain their exceptionally low HPHC levels.

- The totality of the literature, including that of the post-MRTP authorization period, does not identify external research that contradicts the notion that when these products are used exclusively instead of cigarettes, they offer lower risk of developing any of the disease endpoints in the claim.

- "Consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes."

Our post-market surveillance studies have illustrated that, since authorization, consumers of General Snus have maintained this comprehension of the claim and nationally representative surveys indicate there has been little to no uptake by non-users and youth. FDA has not raised concerns since the 2019 authorization about the information provided by us to FDA about the MRTPs being APPH. If FDA believed that new information and data changed this conclusion, it would be expected that they would convey concerns to Swedish Match.

At this time, the MRGOs have been effective for a period of five (5) years and will expire on October 22, 2024. Accompanying FDA's authorization were postmarket requirements allowing FDA access to data and information about the effects of these authorized products on the U.S. market. Swedish Match agreed with FDA's initial assessment and in complying with all requirements, provided FDA with relevant information in our annual reporting including, but not limited to, ongoing and completed consumer research studies, advertising, marketing plans, sales data, information on current and new users, manufacturing changes, and adverse experiences. This transparency enabled FDA to monitor the U.S. market for these products since the time of claim authorization and continues to reinforce and support the conclusions for the initial authorization as well as this renewal.

2. PRODUCTS SUBJECT OF RENEWAL

The authorized tobacco products subject of this renewal (also referred to as General Snus products) are:

[5] https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard

Table 1: Products Subject of Renewal

Product Name	Product Category	Product Subcategory	Submission Tracking Number	PM#s
General Loose	Smokeless tobacco	Loose Snus	MR0000020	PM000010
General Dry Mint Portion Original Mini	Smokeless tobacco	Portioned Snus	MR0000021	PM000011
General Portion Original Large	Smokeless tobacco	Portioned Snus	MR0000022	PM000012
General Classic Blend Portion White Large – 12ct	Smokeless tobacco	Portioned Snus	MR0000024	PM000013
General Mint Portion White Large	Smokeless tobacco	Portioned Snus	MR0000025	PM000014
General Nordic Mint Portion White Large – 12ct	Smokeless tobacco	Portioned Snus	MR0000027	PM000015
General Portion White Large	Smokeless tobacco	Portioned Snus	MR0000028	PM000016
General Wintergreen Portion White Large	Smokeless tobacco	Portioned Snus	MR0000029	PM000017

3. SUMMARY OF SCIENTIFIC EVIDENCE

All information submitted with the MRTPA for the eight General Snus products (see **Table 1**) remains valid and continues to support FDA's initial rationale for authorization. The following section provides an overview and discussion of internal and external data pertaining to the General Snus products since FDA's initial authorization. In light of the below discussion, Swedish Match reiterates its intention to renew all of the previously listed STNs. Maintaining a robust variety of non-combustible options with MRTPA authorization will benefit intended adult consumers interested in switching away from combustible products.

3.1. Relative Health Risks of the MRTPs to Individual Tobacco Users

Our initial PMTAs and MRTPAs included long-term scientific evidence (e.g., decades of Swedish epidemiological studies) demonstrating that consumers who exclusively used Swedish snus products had a lower risk of developing tobacco-related disease than consumers who smoked cigarettes. Seven years of post-market tracking and annual reporting continue to support this conclusion. Further, literature reviews of external scientific research directly assessing snus products are provided on an annual basis. These reviews, found in **Attachment C** (Tab 8), and **Attachment D** (App. H), support the conclusions made in the original applications: (1) the low disease risk associated with snus use relative to combustible use continues to be validated in contemporary peer-reviewed external scientific research, (2) the patterns of use of the authorized products indicate a move away from combusted products, (3) low youth use of snus products continues (e.g., 2022 NYTS and PATH),

and (4) consumers continue understanding that fully switching to General Snus from cigarettes would provide a reduction in risk of the health conditions in the claim.

FDA's position on the continuum of risk across tobacco products aligns with that of Swedish Match, in that moving users of combustible products down the continuum of risk benefits the population at large.[6] We continue to agree with FDA's position, that for tobacco harm reduction to be successful, there must be a diverse marketplace of innovative FDA-authorized, reduced-risk products. In this context, having multiple varieties and flavors of General Snus can help adult consumers transition to products lower on the continuum of risk.

Further evidence includes the following:

- No serious or adverse experiences were reported for PM0000010 – PM0000017 from Oct. 1, 2015, to Nov. 30, 2022.

- Swedish Match does not make direct-to-consumer sales of General Snus. Information on Swedish Match's responsible marketing practices can be found in Appendix 2A (3) of each MRTP periodic report.

- No manufacturing deviations were reported for PM0000010 – PM0000017 from Oct. 1, 2015, to Nov. 30, 2022. There has been no change to the manufacturing facility or controls due to the production of PM0000010 – PM0000017 from Oct. 1, 2015, to Nov. 30, 2022. The General Snus products continue to remain appropriate for the protection of public health and, therefore, should retain their status as modified-risk tobacco products via an MRTP renewal.

- The GOTHIATEK standard[7] remains well adhered to as evidenced by the results from our extensive routine testing of all of its components. Thus, consumers who either continue to use snus or switch from other high constituent products like combustible cigarettes would be exposed to reduced harmful and potentially harmful chemicals.

On March 16, 2023, the FDA authorized U.S. Smokeless Tobacco Company's Copenhagen Classic Snuff as a modified risk tobacco product, allowing the company to market the product with the claim, "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes

[6] FDA policy should "move addicted smokers down that continuum of risk to these less harmful products" (Gottlieb 2017): "Protecting American Families: Comprehensive Approach to Nicotine and Tobacco" Remarks by Scott Gottlieb, M.D., Commissioner of Food and Drug Administration, July 28, 2017, White Oak, MD, Remarks as prepared for delivery, accessed 7/13/2023 from https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017

[7] https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard

reduces risk of lung cancer." While it's important to note that General Snus is not identical to Copenhagen Classic Snuff, they are both smokeless tobacco products, and this authorization provides additional support for the continued use of products like General Snus as less-harmful alternatives. Additionally, internal FDA memoranda have concluded that as a product class, SLT (including our General Snus products) presents a lower-risk alternative to combusted cigarettes. The memorandum "Summary of Health Effects of Smokeless Tobacco Products for Epidemiology Branch Product Application Review"[8] states that "though SLT products are generally considered higher risk than NRT, they are of considerably lower risk than continued smoking. The overall epidemiological literature supports that cigarette smokers who completely switch to SLT products are likely to substantially lower their risks of cardiovascular disease, lung cancer, and respiratory disease compared to smoking." FDA's evaluation of SLT products as a class only reinforces its initial evaluation of General Snus as a reduced-risk product and provides additional justification to renew this MRTP claim authorization.

3.2. Consumer Understanding and Perceptions

The scientific evidence in our initial application demonstrated consumer comprehension of the claim (i.e., fully switching to these products from combustible products would provide risk reduction), as well as a correct consumer perception of risk associated with the MRTP products (i.e., relative to cigarettes).

Our PMSS and annual reporting continue to support this contention, namely:

- 85% of those who understood the modified risk messaging correctly responded that cigarette smokers must switch completely to General Snus (answered "zero cigarettes") in order to reduce risks of developing certain diseases.[9]
- As FDA declared when authorizing the MRTP, the available evidence does not demonstrate significant youth initiation of these products, and evidence annually submitted by Swedish Match from 2015 until now continues to demonstrate low levels of intention by non-users (including youth and young adults) to buy the product. Most importantly, Swedish Match found in internal and external scientific research that the inclusion of the modified risk claim on the label, labeling, and packaging material did not affect these intentions.

In 2019, FDA stated that the claim associated with these General Snus products is "supported by scientific evidence" and "consumers understand the claim and appropriately perceive the relative risk

[8] FDA memorandum from September 10, 2020, entitled "Summary of Health Effects of Smokeless Tobacco Products for Epidemiology Branch Product Application Review" https://vaping.org/wp-content/uploads/2023/02/SLTComparativeHealthEffects.pdf

[9] ("General Snus® Patterns of Use Study", most recently provided in the December 5, 2022 amendment (Appendix 1C-(1.5)) for the "PMTA and MRTP Postmarket Annual Report"

of these products compared to cigarettes." In terms of consumer perceptions, the presence of the modified risk claim on these products is working as FDA expected.

3.3. Tobacco Use Behavior and Impact to the Population as a Whole

Our postmarket surveillance (i.e., "*General* Snus® Patterns of Use Study") provides continuing efforts by Swedish Match to understand how consumers view the General Snus products post-MRTP authorization. Seven years of post-market tracking and annual reporting continue to support the conclusion that consumers of General Snus, even while reducing the amount of the product they use longitudinally, remain committed to a reduction of combustible products. For example, when measured over successive waves, the study participants' use of lower-risk products to help stop smoking significantly increased and their use of General Snus was not replaced with more harmful products, such as cigarettes. Instead, respondents transitioned to lower-risk products, such as nicotine pouches and/or aids to help stop smoking. With the General Snus products inclusion in this study, Swedish Match reasonably concludes that flavors are playing a role in helping these study participants transition away from cigarettes. As demonstrated in seven years of periodic PMTA reporting and three years of periodic MRTPA reporting by Swedish Match, these authorizations contributed to reducing the harm caused by combustible tobacco products by providing reduced risk options to adult consumers.

Internal longitudinal Patterns of Use studies continue to demonstrate that (a) consumers' use of tobacco products in the most recent waves did not significantly differ from their use in the initial wave of our PMSS assessments, and (b) these respondents understood the claim that using General Snus instead of smoking cigarettes puts users at a lower risk of developing certain diseases. Our most recent PMSS studies confirm these findings.

One of FDA's original intentions of authorizing General Snus as an MRTP product was to transition "addicted smokers down that continuum of risk" (Gottlieb 2017). Maintaining a robust selection of non-combustible options with MRTPA authorization, including flavored options, benefits intended consumers potentially interested in switching away from combustible products. Systematic literature review concludes that the availability of reduced -risk products with adequate nicotine delivery and in a variety of flavors is associated with switching away from combusted products.[10] Furthermore, evidence has indicated that the use of more than one flavor of product was common among users of reduced-risk products and could potentially lead to greater rates of switching away from combusted

[10] Gades MS, Alcheva A, Riegelman AL, Hatsukami DK. The Role of Nicotine and Flavor in the Abuse Potential and Appeal of Electronic Cigarettes for Adult Current and Former Cigarette and Electronic Cigarette Users: A Systematic Review. Nicotine Tob Res. 2022 Aug 6;24(9):1332-1343. doi: 10.1093/ntr/ntac073. PMID: 35305014; PMCID: PMC9356694.

cigarettes.[11,12,13] Real-world data is supportive of the data found in this literature. Indeed, FDA-authorized flavored snus products were on the U.S. market with no serious or adverse experiences reported from Oct. 1, 2015, to Nov. 30, 2022, and sales data indicate that they appealed to adult combustible tobacco product users with little interest to non-adults. Since traditional smokeless tobacco products, like snus, are available in minty flavors, offering these products could help consumers more easily transition to a lower-risk product.

While the current tobacco marketplace features numerous varieties (strengths, flavors) of snus, recent data continue to demonstrate an absence of appeal and uptake among youth.[14] For example, NYTS and PATH data do not demonstrate significant interest in snus by young adults:

- The 2022 NYTS does not demonstrate significant use of snus by young adults. Of the 28,291 students surveyed, 1% (i.e., 404 respondents) answered "yes" when queried, "Have you ever used snus, even just one time?" Further, 0.5% of respondents indicated that they have used the product at least once in the past 30 days.
- Past 30-day snus use rates among U.S. adults remain low. For example, Liber et al. (2023) reported only 0.3% past 30-day adult users of snus in 2020 path studies.[15] This is consistent with previous waves of PATH (e.g., PATH Wave 1), which did not demonstrate significant use of snus by adult tobacco consumers (>18 years of age). Of the 32,320 surveyed, only 101 respondents identified as "Current Established Pouched Snus Users, Excluding Current Users of Other SLT". The researchers "excluded youth samples (aged 12–17 years) because of the low prevalence of SLT use among youths".[16]
- FTC Snus use shows a flat average use of 13,067 cans per year by adult tobacco consumers in 2019 – 2021 (i.e., the period after General Snus received MRTP authorization).[17]

[11] Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Spyrou A, Voudris V. Impact of flavour variability on electronic cigarette use experience: an internet survey. Int J Environ Res Public Health. 2013 Dec 17;10(12):7272-82. doi: 10.3390/ijerph10127272. PMID: 24351746; PMCID: PMC3881166.

[12] Romijnders KA, Krüsemann EJ, Boesveldt S, Graaf K, Vries H, Talhout R. E-Liquid Flavor Preferences and Individual Factors Related to Vaping: A Survey among Dutch Never-Users, Smokers, Dual Users, and Exclusive Vapers. Int J Environ Res Public Health. 2019 Nov 22;16(23):4661. doi: 10.3390/ijerph16234661. PMID: 31766776; PMCID: PMC6926905.

[13] Gentry SV, Ward E, Dawkins L, Holland R, Notley C. Reported patterns of vaping to support long-term abstinence from smoking: a cross-sectional survey of a convenience sample of vapers. Harm Reduct J. 2020 Oct 6;17(1):70. doi: 10.1186/s12954-020-00418-8. PMID: 33023583; PMCID: PMC7541214.

[14] Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(No. SS-5):1–29. DOI: http://dx.doi.org/10.15585/mmwr.ss7105a1external icon.

[15] Liber AC, Seidenberg AB, Pesko MF. Tob Control Epub ahead of print: [accessed 7/13/2023]. doi:10.1136/tc-2022-057890

[16] Cheng YC, Rostron BL, Day HR, Stanton CA, Hull LC, Persoskie A, Travers MJ, Taylor K, Conway KP, Ambrose BK, Borek N. Patterns of Use of Smokeless Tobacco in US Adults, 2013-2014. Am J Public Health. 2017 Sep;107(9):1508-1514. doi: 10.2105/AJPH.2017.303921. Epub 2017 Jul 20. PMID: 28727534; PMCID: PMC5551607.

[17] This information is located in more detail in Table 5E Number of Units Sold-By Package Size for 2008-2021 (Snus) at https://www.ftc.gov/system/files/ftc_gov/pdf/p114508smokelesstobaccoreport2021.pdf (accessed 3/7/2023).

In 2019, FDA stated that the claim associated with these General Snus products is "supported by scientific evidence" and "consumers understand the claim and appropriately perceive the relative risk of these products compared to cigarettes." In terms of tobacco use behavior, the presence of the modified risk claim on these products (1) has continued to transition intended consumers "down that continuum of risk" (Gottlieb 2017) and (2) does not demonstrate significant use of snus by young adults (NYTS 2022).

4. LISTING OF ATTACHMENTS

Swedish Match includes the following attachments as support for this MRTPA renewal:

Attachment A – PMTA Marketing Orders
Attachment B –Modified Risk Granted Order (MRGO)
Attachment C – Summary of Previous Periodic Reporting (Excel (.xlsx))
Attachment D – PDF Version of Attachment C

Listing of Appendices

Swedish Match incorporates, by reference, information from all previous periodic PMTA and MRTPA reporting. All appendices would be applicable for STNs MR0000020 - MR0000022, MR0000024- MR0000025, and MR0000027- MR0000029, which are also identified as PM0000010 – PM0000017.

Table 2: Listing of Periodic Reporting Sections and their Corresponding Locations

Periodic Reporting Section	Location in Attachment C	Location in Attachment D
Summary of In-market Status	**Attachment C**, Tab 1	**Attachment D** (App. A)
Summary of Research and Surveillance	**Attachment C**, Tab 2	**Attachment D** (App. B)
Sales and Distribution Reporting	**Attachment C**, Tab 3	**Attachment D** (App. C)
Adverse Experience Reporting	**Attachment C**, Tab 4	**Attachment D** (App. D)
Advertising and Marketing Plans Summary	**Attachment C**, Tab 5	**Attachment D** (App. E)
Labeling	**Attachment C**, Tab 6	**Attachment D** (App. F)
Manufacturing Deviations and Facility Changes	**Attachment C**, Tab 7	**Attachment D** (App. G)
Literature Review Summaries	**Attachment C**, Tab 8	**Attachment D** (App. H)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000010

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Loose
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000010**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000010**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

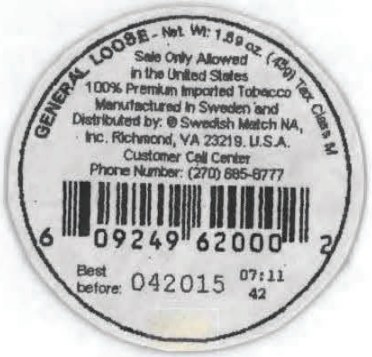
Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 05:58:03 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Loose Labeling



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000011

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Dry Mint Portion Original Mini
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
Portion Count:	20 pouches
Portion Mass:	300 mg
Portion Length:	28 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000011**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000011**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
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   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
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5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

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For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

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Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

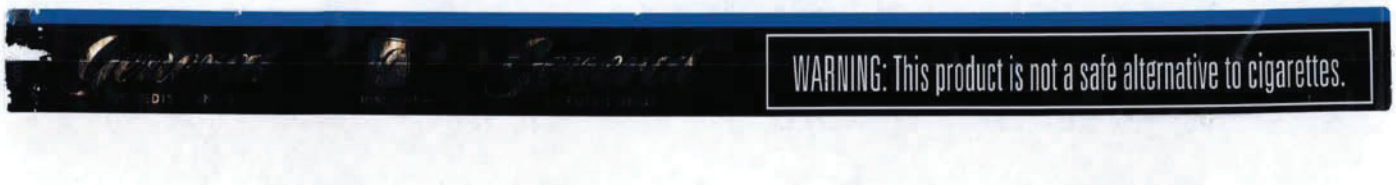
Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 05:59:58 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Dry Mint Portion Original Mini Labeling



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000012

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Portion Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	33 mm
Portion Width:	18 mm
Portion Thickness:	6 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instru.ctions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000012**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000012**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
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   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

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Center for Tobacco Products
Document Control Center
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:00:57 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Portion Original Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000013

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Classic Blend Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b) (4)

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
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    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000013**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000013**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
    b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
    c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
    d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
    e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
    a. A comparison of each change to what was described in the PMTA;
    b. The rationale for making each change; and
    c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
    a. The labeling should include all the panels, be presented in the actual size and color with legible text.
    b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:01:52 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Classic Blend Portion White Large - 12ct

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000014

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Mint Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
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    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000014**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

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1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000014**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
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   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
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6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

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For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:03:46 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Mint Portion White Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000014

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Mint Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

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    - Certifications and amendments to certifications.
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- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
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POSTMARKET REPORTS

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- Death;
- A life-threatening adverse event;
- 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
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1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000014**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
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   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
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In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

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We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:03:46 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Mint Portion White Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000015

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Nordic Mint Portion White Large - 12ct
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint
Portion Count:	12 pouches
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size:[2]	(b) (4)

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided f(b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000015**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000015**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;
    b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
    c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
    d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
    e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
    a. A comparison of each change to what was described in the PMTA;
    b. The rationale for making each change; and
    c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.

4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
    a. The labeling should include all the panels, be presented in the actual size and color with legible text.
    b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:04:40 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

Page 7, PM0000015

General Nordic Mint Portion White Large - 12ct Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000016

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

---

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided f(b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000016**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000016**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
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5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:05:34 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Portion White Large Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

MARKETING ORDER

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
via Certified Mail

FDA Submission Tracking Number (STN): PM0000017

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name:[1]	General Wintergreen Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size:[2]	(b) (4)

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant provided (b) (4) to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
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- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
    - study protocols (including statistical analysis plan);
    - amendments showing the dates and reasons for each protocol revision;
    - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
    - Informed consent forms;
    - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
    - Investigator financial disclosure statements;
    - Progress reports;
    - Monitoring reports;
    - Adverse experience reports;
    - Case report forms/subject diaries/medical records/laboratory reports;
    - Subject data line listings/observations records;
    - Test article accountability records;
    - Study results/protocol summaries/study reports; and
    - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to 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. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000017**.

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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 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 PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. 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. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000017**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
    a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

   b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
   c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
   d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
   e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
   a. A comparison of each change to what was described in the PMTA;
   b. The rationale for making each change; and
   c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
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   a. The labeling should include all the panels, be presented in the actual size and color with legible text.
   b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

This order authorizing the marketing of this new tobacco product does not mean FDA "approved" the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is "approved" by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

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

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We are unable to accept regulatory submissions by electronic mail.

If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:06:25 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure

General Wintergreen Portion White Large Labeling

U.S. FOOD & DRUG ADMINISTRATION

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

October 22, 2019

MODIFIED RISK GRANTED ORDERS – –
RISK MODIFICATION

Swedish Match USA, Inc.
Attention: Gerard Roerty, Vice President, General
Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): MULTIPLE STNs, See Appendix A

Dear Mr. Roerty:

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 find that the 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. Therefore, we authorize the marketing of the 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."

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

These orders expire 5 years from the issue date of this letter. If you wish to renew your orders, we recommend a request for renewal is received by FDA 360 days prior to the expiration date. Your renewal may cross-reference your MRTPAs that are subject to these orders.

The requirements in these risk modification orders are intended to help ensure that your modified risk tobacco products, as actually used by consumers, 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

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

currently use tobacco products. However, compliance with these requirements alone is not a guarantee that the modified risk tobacco products, as actually used by consumers, 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, particularly if, despite these measures, there is a significant increase in youth initiation or initiation by non-users. FDA will continue to monitor the marketing of your modified risk tobacco 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.[2] The modified risk tobacco products subject to these risk modification orders are subject to withdrawal as described in section 911(j).

We remind you that all regulated tobacco products, including the modified risk tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the modified risk 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[3,4] using eSubmitter.[5] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[6]; 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] See Section 301(tt) of the FD&C Act.
[3] http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm
[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[5] https://www.fda.gov/industry/fda-esubmitter
[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions regarding these orders, please contact Shireen Fotelargias, Regulatory Health Project Manager, at (240) 402-0435 or Shireen.Fotelargias@fda.hhs.gov.

If you have any questions regarding postmarket activities for the modified risk tobacco products subject of these orders, please contact Eugene Y Chuang, at (240) 402-9302 or Eugene.Chuang@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.10.22 08:58:56 -04'00'

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

Enclosures:

Appendix A- List of Tobacco Products That Are Subject of This Letter
Appendix B- Required Postmarket Surveillance and Studies
Appendix C- Advertising and Promotion Requirements
Appendix D- Recordkeeping and Retention
Appendix E- Manufacturing Information

Appendix A

List of Tobacco Products That Are Subject of This Letter

Common Attributes of MRTPAs	
Submission Date:	June 10, 2014
Receipt Date:	June 10, 2014
Product Manufacturer:	Swedish Match USA, Inc.
Product Category:	Smokeless Tobacco Products
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.
MR0000020: General Loose[7]	
Product Subcategory:	Loose Snus
Package Type:	Cardboard Can with Plastic Lid
Package Quantity:	45.0 g
Characterizing Flavor:	None
MR0000021: General Dry Mint Portion Original Mini[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	6.0 g
Characterizing Flavor:	Mint
MR0000022: General Portion Original Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000024: General Classic Blend Portion White Large – 12 ct[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	None
MR0000025: General Mint Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Mint
MR0000027: General Nordic Mint Portion White Large – 12 ct[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	10.8 g
Characterizing Flavor:	Mint

[7] STN: Product Name (Brand/sub-brand or other commercial name used in commercial distribution)

MR0000028: General Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None
MR0000029: General Wintergreen Portion White Large[7]	
Product Subcategory:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	Wintergreen

Appendix B

Required 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."

I. PMSS Content

MRTP Use Behavior and Consumer Understanding and Perception

After receiving authorization, the determination of whether the eight General Snus products that are the subject of these applications, as actually used by consumers, continue to benefit the health of the population as a whole is likely to be driven by use behavior. Therefore, monitoring use of the eight General Snus products that are the subject of these applications in terms of uptake, dual use, and complete switching is required. In particular, your PMSS must assess the extent to which new MRTP users were non-users, smokers, or other tobacco product users before initiating the MRTPs and the extent to which new users of the MRTPs become exclusive users or dual users with cigarettes or other tobacco products over time. Relatedly, such surveillance must include an assessment of consumers' understanding of the claim and perceptions of the products. In particular, PMSS must assess the extent to which users of these products understand that, to reduce their risk of disease relative to smoking as described in the modified risk information, they must use General Snus exclusively. **To adequately assess these impacts, you must conduct PMSS that include assessing users' behavior and consumer understanding at multiple time points.**

In addition, FDA has determined that assessing the impact of your MRTP orders on uptake of the products requires surveillance of MRTP sales and distribution, which provide information to assess tobacco consumption at the population level. Your PMSS protocols must describe procedures for monitoring and reporting MRTP sales and distribution in the U.S. by product, major metropolitan areas, and channels where the products are sold (e.g., 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 tobacco products by quarter since the granting of your modified risk granted orders (for the initial reporting period) or the previous reporting period (for all reports that follow), including, for each MRTPA STN, total U.S. sales and distribution reported in dollars and units, and broken down by major metropolitan areas, and 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).
- 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 tobacco products for each MRTPA STN, post-MRTP authorization.

MRTP Use and Adverse Experiences

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, 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. 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. Your PMSS protocols must include procedures for monitoring and analyzing adverse experiences and your annual PMSS report must include:

- A summary of reported adverse experiences for the tobacco products, which includes a listing of all 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 products including nature, frequency, and potential aggravating factors.

In addition, the PMTA orders for your General snus products, issued on November 10, 2015, require you to report to the FDA all adverse experiences that are both serious and 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 you 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 STN(s) PM0000010-PM0000017 and MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029.**

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption 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, *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 PMTA (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 the MRTPs and Consumer Perception, Behavior, or Health

In order for FDA to determine whether the eight General Snus products that are the subject of these applications, as actually used by consumers, 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 findings both in your own studies (i.e., studies conducted by you or on your behalf) and in publications including any new scientific data (published or otherwise) regarding the MRTPs and consumer perception, behavior, or health. Your annual PMSS report must include:

- A summary of significant findings about the tobacco products from research studies conducted by you or on your behalf, whether or not such studies were specifically required under this order. A summary of significant findings in publications not previously reported and full copies of the articles. This must include any new scientific data (published or otherwise) on the MRTPs and consumer perception, behavior, or health.

II. 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 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) requires that the results of PMSS be submitted on an annual basis. These reports must be identified as "PMSS Report", and the MRTPA STNs should be referenced 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 agreed upon 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 C
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, 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;
  - 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 adult audiences by age-range(s), including young adult audiences, ages 18-24, and other demographic and/or psychographic characteristics that reflect your intended target audience;
    - Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
    - Use of owned, earned, shared, and/or paid social media to create labeling for, advertise, market, and/or promote the products;
    - Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    - Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
    - Use of earned media and/or public-relations outreach to create labeling for, advertise, market, and/or promote the products
  - 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 youth, ages 17 years and under, 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 for the first six months after the date of your modified risk order you provide FDA a 30-day notification for all labeling, advertising, marketing, and/or promotional materials for which you plan on disseminating to the public. These notifications are not for pre-approval, but are required so that FDA can have timely access to your marketing plans and materials, and if needed, provide you advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation and on the finding that continued marketing of your products will benefit the health of the population as a whole. You may begin disseminating the materials 30 days after providing notification to FDA. This notification must be received by FDA **at least 30 days prior** to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. The notification must include:

- 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 advertisement 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 adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and psychographic characteristics that reflect your intended target audience(s), including how the target audience(s) are defined and the insights used to develop the target audience profile(s) and the source of such insights;
  - Restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
  - Use owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
  - Use partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
  - Conduct any consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated; and/or
  - Use public-relations outreach to create labeling for, advertise, market, and/or promote the products.

III. Periodic Reporting

Under sections 911(h)(5) of the FD&C Act, these orders require that you submit periodic reports every 6 months to FDA once during the month of June of each year and once during the month of December of each year, beginning June 2020. For the six-month reporting period, the report must include:

- A cover letter that includes the following text in your subject line: **PERIODIC REPORT for MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and reporting period.
- 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. 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**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, reporting period.
- A description of the implementation of all advertising and marketing plans, including strategic creative briefs and paid media plans – whether conducted by you, on your behalf, or at your direction – by channel and by product, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:
  - Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

- Targeting of specific adult audiences by age-range(s), including young adults, ages 18-24, and other demographic and/or psychographic characteristics that reflect the intended target audience(s), how the target audience(s) were defined and the insights used to develop the target audience profiles(s) and the source of such insights;
- Actions taken to restrict youth-access and limit youth-exposure to the products' labeling, advertising, marketing, and/or promotion;
- Use of owned, earned, shared/social, and/or paid media to create labeling for, advertise, market, and/or promote the products;
- Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
- Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated; and/or
- Use of public-relations outreach to create labeling for, advertise, market, and/or promote the products; including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel and by product.

- An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under), not previously submitted. This analysis should be verified against post-launch delivery-verification reports submitted to you from an accredited source.
- A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to youth, ages 17 and under, and including a summary of implementation of any corrective and preventive measures, not previously submitted.

V. 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 consumer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.
- For any of the products' labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your products on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content-(e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such

labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the product(s) running on another company's website; paid advertising for the product(s) running in social media; paid distribution of influencer content) – whether conducted by you, on your behalf, or at your direction:
  - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are at least of federal minimum legal age to purchase tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:
    - "First-party" age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and
    - "Second-party" age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.
    - "First-party" and "second-party" data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.
- Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic location), including a breakout by age-group (i.e., adults, ages 25+; young adults, ages 18-24; and youth, ages 12-17 and ages 11 and under). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to youth, ages 17 and under. Such monitoring also requires post-launch delivery verification reports be submitted to you from an accredited source.
- For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the products – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as "sponsored by [firm name]" in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the products, on your behalf, or at your direction.

The requirements above are intended to help ensure that your 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 General Snus 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 legal age to purchase 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 D
Recordkeeping and Retention

The risk modification orders for your modified risk tobacco products are effective for 5 years from the issue date of the orders. If you wish to renew your orders, we recommend you submit a request for renewal 360 days prior to the end of your effective timeframe. In order to help ensure that your risk modification orders meet the standard for renewal and to help expedite the review of any renewal applications, we request that you establish and maintain the records listed below. The records should be retained for a period of not less than four years from the date of distribution of the last batch of the tobacco products listed in your orders under section 911(g)(1). The records should be legible, written in English, and upon request, available for inspection and copying by officers or employees duly designated by the Secretary. Please note that Appendices B and C require you to periodically submit some of these records to FDA (e.g., in PMSS reports and/or advertising and promotion-related reports). Additionally, we remind you that the PMTA orders for your General snus products issued on November 10, 2015, also require you to establish and maintain records, some of which overlap with the records listed below:

- The MRTPAs submitted prior to the orders
- Postmarket reports, as described in the Required PMSS Appendix, including adverse experience reports and all relevant documentation associated with the experience
- Records of all nonclinical or clinical studies, including:
  - Source data;
  - Study protocols (including statistical analysis plan);
  - Amendments showing the dates and reasons for any protocol revisions;
  - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals or non-approvals;
  - Informed consent forms;
  - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
  - Investigator financial disclosure statements;
  - Progress reports;
  - Monitoring reports;
  - Adverse experience reports;
  - Case report forms/subject diaries/medical records/laboratory reports;
  - Subject data line listings/observation records;
  - Test article accountability records;
  - Study results/protocol summaries/study reports; and
  - Certifications and amendments to certifications
- Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) of the products
- Records pertaining to the sale, distribution, or other disposition of the products, specifically:
  - A list of distributors and retailers of the products, including brick-and-mortar and digital[8];
  - Any available information (not to include personally identifiable information) about product purchases, such as purchasers' demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use);
  - Policies and procedures regarding verification of the age and identity of purchasers of the products; and

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

- Policies and procedures regarding restrictions on youth access to the products
- Health hazard analyses, if performed voluntarily or directed by FDA
- Records pertaining to any and all complaints associated with any of the products that you receive or of which you are aware

Appendix E

Manufacturing Information

The PMTA orders for your General Snus 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 you MRTPAs for these products. When cross-referencing, please provide the date of submission and location in the submission where the information is covered. 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 MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029**. The cover letter should include the STN(s) and corresponding tobacco product name(s), firm name, date of report, 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 MRTPAs;
  - The rationale for making each change; and
  - A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke or aerosol constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of the tobacco products and the basis for concluding that each manufacturing change did not result in any modification to the products.[9]
- 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 General snus products, issued on November 10, 2015, require that, for products that have been distributed, if the deviation may negatively impact public health, you promptly identify and report that deviation to CTP. We request that when submitting such reports, you reference both your PMTAs and you MRTPAs 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.

[9] 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.

Appendix A: Summary of In-Market Status

This tab summarizes the naming and in-market status of PM0000010 - 17 and MR0000020-22,24-25, 27-29

Product Name	Product Category	Product Subcategory	Submission Tracking Number	PM#s	In-market Status Summary Regardless of in-market status, all STNs included in PMTA and/or MRTPA periodic reporting
General Portion Original Large	Smokeless tobacco	Portioned Snus	MR0000022	PM0000012	Product currently marketed in the U.S.
General Mint Portion White Large	Smokeless tobacco	Portioned Snus	MR0000025	PM0000014	Product currently marketed in the U.S.
General Portion White Large	Smokeless tobacco	Portioned Snus	MR0000028	PM0000016	Product currently marketed in the U.S.
General Wintergreen Portion White Large	Smokeless tobacco	Portioned Snus	MR0000029	PM0000017	Product currently marketed in the U.S.
General Dry Mint Portion Original Mini	Smokeless tobacco	Portioned Snus	MR0000021	PM0000011	Product not currently in the U.S. market as of December 31, 2020.
General Loose	Smokeless tobacco	Loose Snus	MR0000020	PM0000010	Product not curently in the U.S. market as of June 17, 2017.
General Classic Blend Portion White Large - 12ct	Smokeless tobacco	Portioned Snus	MR0000024	PM0000013	Product never introduced into the U.S. market.
General Nordic Mint Portion White Large - 12ct	Smokeless tobacco	Portioned Snus	MR0000027	PM0000015	Product never introduced into the U.S. market.

Appendix B: Summary of Research and Surveilliance

Research Summaries for PM0000010 – PM0000017			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Summary of Research**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000012 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000012 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000012.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000012 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000012 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	•Survey: Attachment 2A2.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - 2018 Snus Health Evaluation Survey •Study: Attachment 2A3.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - Perceptions and Behavioral Intentions Study for General Snus
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Attachment 2A2.2019-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 - General Snus Users Research
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	•PMTA Research Summary: Attachment 2A2.2020-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 •Attachment 1A - Annual PMSS Use Behavior & Consumer Understanding & Perception •Attachment 1D - Annual PMSS Surveillance Consumer Perception Behavior & Health •MRTP Study Appendices: Appendix 1D (16.1) - Appendix 1D (16.4)
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000014 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000014 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000014.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000014 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000014 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	•Survey: Attachment 2A2.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - 2018 Snus Health Evaluation Survey •Study: Attachment 2A3.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - Perceptions and Behavioral Intentions Study for General Snus
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Attachment 2A2.2019-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 - General Snus Users Research
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	•PMTA Research Summary: Attachment 2A2.2020-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 •Attachment 1A - Annual PMSS Use Behavior & Consumer Understanding & Perception •Attachment 1D - Annual PMSS Surveillance Consumer Perception Behavior & Health •MRTP Study Appendices: Appendix 1D (16.1) - Appendix 1D (16.4)
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000016 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000016 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000016.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000016 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000016 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	•Survey: Attachment 2A2.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - 2018 Snus Health Evaluation Survey •Study: Attachment 2A3.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - Perceptions and Behavioral Intentions Study for General Snus
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Attachment 2A2.2019-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 - General Snus Users Research
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	•PMTA Research Summary: Attachment 2A2.2020-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 •Attachment 1A - Annual PMSS Use Behavior & Consumer Understanding & Perception •Attachment 1D - Annual PMSS Surveillance Consumer Perception Behavior & Health •MRTP Study Appendices: Appendix 1D (16.1) - Appendix 1D (16.4)
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)

Appendix B: Summary of Research and Surveilliance

Research Summaries for PM0000010 – PM0000017			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Summary of Research**
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000017 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000017 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000017.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000017 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000017 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	•Survey: Attachment 2A2.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - 2018 Snus Health Evaluation Survey •Study: Attachment 2A3.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - Perceptions and Behavioral Intentions Study for General Snus
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Attachment 2A2.2019-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 - General Snus Users Research
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	•PMTA Research Summary: Attachment 2A2.2020-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 •Attachment 1A - Annual PMSS Use Behavior & Consumer Understanding & Perception •Attachment 1D - Annual PMSS Surveillance Consumer Perception Behavior & Health •MRTP Study Appendices: Appendix 1D (16.1) - Appendix 1D (16.4)
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	•Survey Research: Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health; Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20 •Survey Research: Attachment 3A-FDA AFPPH Recommendations Letter for PM11, PM12, PM14, PM16 and PM17 dated 6/1/18 •Survey Appendices: Appendix 1C (1.1) - Appendix 1C (1.5); Appendix 3A (1)
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000011 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000011 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000011.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000011 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000011 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	•Survey: Attachment 2A2.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - 2018 Snus Health Evaluation Survey •Study: Attachment 2A3.2018-PM0000011,PM0000012,PM0000014,PM0000016 and PM0000017 - Perceptions and Behavioral Intentions Study for General Snus
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Attachment 2A2.2019-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 - General Snus Users Research
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	•PMTA Research Summary: Attachment 2A2.2020-PM0000011,PM0000012, PM00000014, PM0000016 and PM0000017 •Attachment 1A - Annual PMSS Use Behavior & Consumer Understanding & Perception •Attachment 1D - Annual PMSS Surveillance Consumer Perception Behavior & Health •MRTP Study Appendices: Appendix 1D (16.1) - Appendix 1D (16.4)
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Survey Research: •Attachment 2A.2016-PM0000010 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016 (Microsoft Word format) • Attachment 2B.2016-PM0000010 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June (Microsoft Excel format)
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	•Market Research: Attachment 2A1.2017-PM0000010.pptx-General Snus PMTA Post-Surveillance Market Research •Survey Research: Attachment 2A2.2017-PM0000010 – SM Market Tracker (FY16-User Groups) •Study Research: Attachment 2A3.2017-PM0000010 – SM Market Tracker (FY15 vs. FY16)
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

--- = Not applicable

*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix C: Sales and Distribution Reporting

Sales and Distribution Summaries for PM0000010 – PM0000017			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Attachment Name**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Attachment 2E.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	Attachment 2D.2017-PM0000012
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Attachment 2D.2018-PM0000012
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Attachment 2D.2019-PM0000012
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Attachment 2D.2020-PM0000012
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Attachment 2E.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	Attachment 2D.2017-PM0000014
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Attachment 2D.2018-PM0000014
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Attachment 2D.2019-PM0000014
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Attachment 2D.2020-PM0000014
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Attachment 2E.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	Attachment 2D.2017-PM0000016
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Attachment 2D.2018-PM0000016
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Attachment 2D.2019-PM0000016
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Attachment 2D.2020-PM0000016
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Attachment 2E.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	Attachment 2D.2017-PM0000017
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Attachment 2D.2018-PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Attachment 2D.2019-PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Attachment 2D.2020-PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1A (1-2) - Annual PMSS Sales & Distribution Reporting
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Attachment 2E.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	Attachment 2D.2017-PM0000011
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Attachment 2D.2018-PM0000011
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Attachment 2D.2019-PM0000011
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Attachment 2D.2020-PM0000011
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Attachment 2E.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	Attachment 2D.2017-PM0000010
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

--- = Not applicable

*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix D: Adverse Experience Reporting

Adverse Experience Summaries for PM0000010 – PM0000017			
No serious or adverse experiences reported for PM0000010 – PM0000017 from Oct. 1, 2015, to Nov. 30, 2022.			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Attachment Name**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Attachment 2D.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	Attachment 2C.2017-PM0000012
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Attachment 2C.2018-PM0000012
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Attachment 2C.2019-PM0000012
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Attachment 2C.2020-PM0000012
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1B - Annual PMSS Adverse Experiences Report
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1B PMSS Adverse Experiences Report
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Attachment 2D.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	Attachment 2C.2017-PM0000014
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Attachment 2C.2018-PM0000014
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Attachment 2C.2019-PM0000014
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Attachment 2C.2020-PM0000014
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1B - Annual PMSS Adverse Experiences Report
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1B PMSS Adverse Experiences Report
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Attachment 2D.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	Attachment 2C.2017-PM0000016
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Attachment 2C.2018-PM0000016
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Attachment 2C.2019-PM0000016
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Attachment 2C.2020-PM0000016
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1B - Annual PMSS Adverse Experiences Report
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1B PMSS Adverse Experiences Report
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Attachment 2D.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	Attachment 2C.2017-PM0000017
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Attachment 2C.2018-PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Attachment 2C.2019-PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Attachment 2C.2020-PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 1B - Annual PMSS Adverse Experiences Report
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 1B PMSS Adverse Experiences Report
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Attachment 2D.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	Attachment 2C.2017-PM0000011
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Attachment 2C.2018-PM0000011
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Attachment 2C.2019-PM0000011
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Attachment 2C.2020-PM0000011
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Attachment 2D.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	Attachment 2C.2017-PM0000010
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

--- = Not applicable

*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix E: Advertising and Marketing Plans Summary

Advertising and Marketing Plans Summary for PM0000010 – PM0000017			
Swedish Match does not make direct-to-consumer sales. Information on Swedish Match's responsible marketing practices can be found in Appendix 2A (3) of each MRTP periodic report.			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Attachment Name**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Attachment 5A.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	Attachment 5A.2017-PM0000012
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Attachment 5A.2018-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Attachment 5A.2019-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Attachment 5A.2020-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Attachment 5A.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	Attachment 5A.2017-PM0000014
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Attachment 5A.2018-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Attachment 5A.2019-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Attachment 5A.2020-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Attachment 5A.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	Attachment 5A.2017-PM0000016
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Attachment 5A.2018-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Attachment 5A.2019-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Attachment 5A.2020-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Attachment 5A.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	Attachment 5A.2017-PM0000017
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Attachment 5A.2018-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Attachment 5A.2019-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Attachment 5A.2020-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 2A - General Snus Analysis of Implementation of Marketing Plans; Appendices 2A(1) - 2A(7.1)
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Attachment 5A.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	Attachment 5A.2017-PM0000011
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Attachment 5A.2018-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Attachment 5A.2019-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Attachment 5A.2020-PM0000011,PM0000012, PM0000014,PM0000016 and PM0000017
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Attachment 5A.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	Attachment 5A.2017-PM0000010
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

--- = Not applicable

*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix F: Labeling

Labeling Summaries for PM0000010 – PM0000017			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Attachment Name**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Attachment 6A.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Attachment 6A.2018-PM0000012
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Attachment 6A.2020-PM0000012
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Appendix 2A (4) General Snus Packaging
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Appendix 2A (4) - General Snus Packaging
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Attachment 6A.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Attachment 6A.2018-PM0000014
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Attachment 6A.2020-PM0000014
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Appendix 2A (4) General Snus Packaging
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Appendix 2A (4) - General Snus Packaging
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Attachment 6A.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Attachment 6A.2018-PM0000016
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Attachment 6A.2020-PM0000016
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Appendix 2A (4) General Snus Packaging
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Appendix 2A (4) - General Snus Packaging
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Attachment 6A.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Attachment 6A.2018-PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Attachment 6A.2020-PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Appendix 2A (4) General Snus Packaging
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Appendix 2A (4) - General Snus Packaging
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Attachment 6A.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Attachment 6A.2018-PM0000011
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Attachment 6A.2020-PM0000011
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Attachment 6A.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	No changes were made to this product's labels during this reporting period.
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

--- = Not applicable

*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix G: Manufacturing Deviations and Facility Changes

Manufacturing Deviations Summaries for PM0000010 – PM0000017			
No manufacturing deviations reported for PM0000010 – PM0000017 from Oct. 1, 2015 to Nov. 30, 2022. There has been no change to the manufacturing facility or controls due to the production of PM0000010 – PM0000017 from Oct. 1, 2015, to Nov. 30, 2022.			
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Attachment Name**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Attachment 4A.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	Attachment 4A.2017-PM0000012
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Attachment 4A.2018-PM0000012
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Attachment 4A.2019-PM0000012
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Attachment 4A.2020-PM0000012
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 4A Annual Reporting Deviations Summary
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 4A.2022- PM10-17
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Attachment 4A.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	Attachment 4A.2017-PM0000014
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Attachment 4A.2018-PM0000014
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Attachment 4A.2019-PM0000014
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Attachment 4A.2020-PM0000014
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 4A Annual Reporting Deviations Summary
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 4A.2022- PM10-17
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Attachment 4A.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	Attachment 4A.2017-PM0000016
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Attachment 4A.2018-PM0000016
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Attachment 4A.2019-PM0000016
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Attachment 4A.2020-PM0000016
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 4A Annual Reporting Deviations Summary
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 4A.2022- PM10-17
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Attachment 4A.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	Attachment 4A.2017-PM0000017
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Attachment 4A.2018-PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Attachment 4A.2019-PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Attachment 4A.2020-PM0000017
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Attachment 4A Annual Reporting Deviations Summary
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Attachment 4A.2022- PM10-17
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Attachment 4A.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	Attachment 4A.2017-PM0000011
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Attachment 4A.2018-PM0000011
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Attachment 4A.2019-PM0000011
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Attachment 4A.2020-PM0000011
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Attachment 4A.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	Attachment 4A.2017-PM0000010
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020-MR0000022, MR0000024- MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---

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*at this time, FDA requested we combine annual reportings for the PMTA and MRTP

Appendix H: Literature Review Summaries

Literature Review Summaries for PM0000010 – PM0000017				
MR# PM#	**Reporting Period**	**Previous Periodic PMTA and MRTPA Reports**	**Summary of Publications**	**Full Texts**
MR0000022 PM0000012	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000012, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000012
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000012, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000012
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000012, dated October 29, 2018	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2018-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000012, dated October 28, 2019	Table 2.B. Summary of publications not previously reported.	Attachment 2B.2019-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000012, dated October 30, 2020	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2020-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000018
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Table 1.a. Summary of publications not previously reported	Attachments 3B.1 - 3B.4
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Table 1.a. Summary of Publications not Previously Reported	Attachments 3B.1 - 3B.7
MR0000025 PM0000014	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000014, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000014
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000014, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000014
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000014, dated October 29, 2018	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2018-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000014, dated October 28, 2019	Table 2.B. Summary of publications not previously reported.	Attachment 2B.2019-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000014, dated October 30, 2020	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2020-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000018
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Table 1.a. Summary of publications not previously reported	Attachments 3B.1 - 3B.4
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Table 1.a. Summary of Publications not Previously Reported	Attachments 3B.1 - 3B.7
MR0000028 PM0000016	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000016, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000016
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000016, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000016
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000016, dated October 29, 2018	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2018-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000016, dated October 28, 2019	Table 2.B. Summary of publications not previously reported.	Attachment 2B.2019-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000016, dated October 30, 2020	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2020-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000018
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Table 1.a. Summary of publications not previously reported	Attachments 3B.1 - 3B.4
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Table 1.a. Summary of Publications not Previously Reported	Attachments 3B.1 - 3B.7
MR0000029 PM0000017	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000017, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000017
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000017, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000017
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000017, dated October 29, 2018	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2018-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000017, dated October 28, 2019	Table 2.B. Summary of publications not previously reported.	Attachment 2B.2019-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000017, dated October 30, 2020	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2020-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000018
	Oct. 1, 2020 – Nov. 30, 2021*	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	Table 1.a. Summary of publications not previously reported	Attachments 3B.1 - 3B.4
	Oct. 1, 2021 – Nov. 30, 2022*	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	Table 1.a. Summary of Publications not Previously Reported	Attachments 3B.1 - 3B.7
MR0000021 PM0000011	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000011, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000011
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000011, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000011
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000011, dated October 29, 2018	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2018-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000011, dated October 28, 2019	Table 2.B. Summary of publications not previously reported.	Attachment 2B.2019-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000017
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000011, dated October 30, 2020	Table 2.b. Summary of publications not previously reported.	Attachment 2B.2020-PM0000011, PM0000012, PM0000014, PM0000016, and PM0000018
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---	---
MR0000020 PM0000010	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000010, dated October 21, 2016	Table 2b-1. Summary of publications.	Attachment 2C.2016-PM0000010
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000010, dated October 27, 2017	Table 2b-1. Summary of publications.	Attachment 2B.2016-PM0000010
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000010, dated October 29, 2018	---	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000010, dated October 28, 2019	---	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000010, dated October 30, 2020	---	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---	---
MR0000024 PM0000013	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000013, dated October 21, 2016	---	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000013, dated October 27, 2017	---	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000013, dated October 29, 2018	---	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000013, dated October 28, 2019	---	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000013, dated October 30, 2020	---	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---	---
MR0000027 PM0000015	Oct. 1, 2015 – Nov. 30, 2016	PERODIC REPORT for STN PM0000015, dated October 21, 2016	---	---
	Oct. 1, 2016 – Nov. 30, 2017	PERODIC REPORT for STN PM0000015, dated October 27, 2017	---	---
	Oct. 1, 2017 – Nov. 30, 2018	PERODIC REPORT for STN PM0000015, dated October 29, 2018	---	---
	Oct. 1, 2018 – Nov. 30, 2019	PERODIC REPORT for STN PM0000015, dated October 28, 2019	---	---
	Oct. 1, 2019 – Nov. 30, 2020	PERODIC REPORT for STN PM0000015, dated October 30, 2020	---	---
	Oct. 1, 2020 – Nov. 30, 2021	PMTA and MRTP POSTMARKET ANNUAL REPORTS for Submission Tracking Numbers –PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027-MR0000029, dated November 10, 2021	---	---
	Oct. 1, 2021 – Nov. 30, 2022	PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027 - MR0000029, dated October 28, 2022	---	---

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*at this time, FDA requested we combine annual reportings for the PMTA and MRTP