SWEDISH MATCH®

March 11, 2015

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

Re: **Premarket Tobacco Product Application for Swedish Match North America Snus Product, General Loose**

Dear Sir or Madam:

Swedish Match North America ("Swedish Match" or the "Company") submits this Premarket Tobacco Product Application (the "PMTA" or "Application") to the U.S. Food and Drug Administration ("FDA" or the "Agency") seeking a premarket approval order under Section 910(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"), for its General Loose product (SKU 4852) (the "Snus Product"). This PMTA is being submitted in connection with the Modified Risk Tobacco Product Application ("MRTPA") for General Loose that was submitted to FDA's Center for Tobacco Products ("CTP") on or about June 10, 2014 and is currently pending before the Agency.

Prior to submitting the MRTPA, Swedish Match engaged in numerous communications with FDA about the submission, including meeting with FDA representatives on several occasions beginning in 2011 regarding the Agency's requirements for obtaining the requested MRTP order. In January 2014, FDA advised Swedish Match to submit a Substantial Equivalence Report ("SE Report") to cover the MRTPA's proposed labeling change for the Snus Product and certain other product changes. Accordingly, in June 2014, Swedish Match submitted an MRTPA and SE Report for General Loose in a single regulatory submission in accordance with FDCA Section 911(l)(4). These submissions are currently pending before the Agency.

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In a teleconference with the CTP Ombudsman and Office of Science Staff on February 12, 2015, the Agency (b) (4) and suggested that the Company instead consider filing a PMTA for the Snus Product. Because of the similarity of the submission requirements and legal standards governing PMTAs and MRTPAs, FDA further advised the Company that it would not be required to resubmit the extensive data and information already provided in the MRTPA. Rather FDA indicated that it would accept a PMTA consisting of a cover letter with cross-references to sections of the MRTPA containing

the information required in a PMTA submission.[1] FDA further explained that all three applications—the MRTPA, the SE Report, and the PMTA—would proceed concurrently through FDA review. Although Swedish Match does not concede that the Company's proposed changes to the packaging and/or labeling for General Loose render it a "new tobacco product" for which either an SE Report or a PMTA is required, the Company nonetheless appreciates FDA's advice and is submitting this PMTA accordingly. Notwithstanding this submission, the Company maintains its position on this issue and reserves the right to take future action in accordance therewith.

Swedish Match also appreciates FDA's recognition that the MRTPA contains extensive data and information regarding the health effects of Swedish Snus—including more than 100,000 pages of evidence from governmental and academic cohort studies, clinical trials, premarket consumer perception research, and secondary data analysis and modeling. The Company believes that the MRTPA contains ample evidence to demonstrate that the Snus Product will (i) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and (ii) benefit the health of the population as a whole, taking into account both users and non-users of tobacco products. The Company further believes that this same evidence is sufficient to establish that the Snus Product meets the PMTA standard of being "appropriate for the protection of the public health" with respect to the risks and benefits of the population as a whole, including users and nonusers of the product.

Accordingly, and as directed by FDA, Swedish Match hereby provides the following information and cross-references in support of this PMTA:

Company Name and Address:
Swedish Match North America Inc.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

Authorized Contacts:
Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600

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[1] Consistent with the approach discussed on the February 2015 conference call, this PMTA has been organized in accordance with the statutory provisions governing such a submission, and not in accordance with FDA's Draft PMTA Guidance. To the extent that the Agency's Guidance requests information not otherwise cross-referenced herein (e.g., a list and summary of all Standard Operating Procedures, together with examples of relevant forms and records), Swedish Match submits that such information is (comprehensively) provided for in the MRTPA. In the Company's view, the MRTPA—and, likewise, this PMTA via cross-reference—substantively addresses all the issues implicated by the non-binding recommendations in the Draft PMTA Guidance.

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Name of New Tobacco Product:

General Loose

Previous Regulatory History:

Previous Regulatory Submission	FDA Submission Tracking Number (STN)	Date of Regulatory Submission and Associated Amendments	Date of Ingredient Listing Submissions
General Loose Provisional SE (SKU 4852)	SE0000140	3/18/11 2/15/13	6/17/10 12/16/10 1/20/12 7/25/12 4/5/13
General Loose MRTPA (SKU 4852)	MR0000020	06/10/14 12/03/14 12/09/14 01/27/15 02/20/15	—
General Loose SE Report (SKU 4852)	SE0010524	06/10/14 11/06/14 03/06/15	—

Dates of Prior Meetings with FDA:

Swedish Match and CTP Staff discussed the Company's plan to submit this Application in a teleconference on February 12, 2015.

Separately, Swedish Match and CTP Staff met to discuss Swedish Match's plan to submit the

MRTPA associated with this Application on the following dates:

- June 27, 2012
- December 19, 2012
- May 8, 2013
- December 19, 2013
- January 9, 2014
- March 12, 2014

Review of the Application by the Tobacco Products Scientific Advisory Committee:

Swedish Match does not request review of this Application by the Tobacco Products Scientific Advisory Committee ("TPSAC" or the "Committee"). However, if FDA chooses to refer the Application to TPSAC on its own initiative, the Company respectfully requests that the Committee's review be consolidated with its review of the MRTPA on April 9-10, 2015.

Statement of Our Action to Comply with Requirements of Section 907 of the Act:

Section 910(b)(1)(D) of the FDCA requires that a PMTA contain "an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard."

There are no tobacco product standards issued under FDCA Section 907 that are currently applicable to smokeless tobacco. Section 907 bans certain characterizing flavors in cigarettes, but no such ban applies to smokeless tobacco products. 21 U.S.C. 387g(a)(1)(A). Section 907 also mandates compliance with certain federally established pesticide tolerances, 21 U.S.C. 387g(a)(1)(B), but no such federal tolerances have been established to date. Because there are no Section 907 standards applicable to smokeless tobacco, there is no action required to be taken by Swedish Match in order to ensure that the Snus Product described in this Application complies with Section 907.

Sample of Tobacco Product and Components Thereof:

Section 910(b)(1)(E) of the Act requires such samples of the tobacco product and of components thereof as the Secretary may reasonably require. Although FDA has not issued any binding regulation requiring the submission of such samples or components, the Draft PMTA Guidance recommends that product samples be provided. In accordance with this non-binding Guidance, Swedish Match is working diligently to prepare such samples and will provide them to FDA under separate cover.

Executive Summary:

FDA's Draft PMTA Guidance requests an executive summary of the submission, including an overview of the application, a description of the tobacco product, a summary of the nonclinical and clinical studies and major findings, and an explanation as to why the marketing of the new tobacco product is appropriate for the protection of public health. All such information may be

found in the Summary of the MRTPA, on pages 83-137 of that submission.

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Swedish Match appreciates FDA's careful consideration of this Application and looks forward to working with the Agency to secure premarket approval under Section 910(b) for the Snus Product discussed herein. Please do not hesitate to contact the undersigned with any questions.

Respectfully,

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Gerard J. Roerty, (b) (6)
Vice President, General Counsel & Secretary
Swedish Match North America

PMTA			MRTPA		
Statutory Reference	**Requirement**	**Description**	**Statutory Reference**	**Requirement**	**Description***
FDCA § 910(b)(1)(A)	Investigations of Health Risks	Full reports of all published information and information that is or should reasonably be known to, the applicant, concerning investigations regarding the health risks of the tobacco product and whether the tobacco product presents less risk than other tobacco products.	FDCA § 911(d)(5)	All documents (including underlying scientific information) relating to research findings regarding the effect of the product on tobacco-related diseases and health related conditions and relating to human health, whether favorable or unfavorable.	• *See* "Summary of All Research Findings" (MRTPA pp. 396-748) and accompanying Appendices for a summary of study results concerning the health risks of the Snus Products described in this Application. • *See* "Scientific Studies and Analyses" (MRTPA p. 749) and all documents (including all studies, clinical findings, testing protocols, and other documents and scientific information) relating to product analyses, nonclinical studies, human studies, secondary data and modeling, and other documents which accompanied the MRTPA. • *See* "Postmarket Surveillance and Studies" (MRTPA pp. 751-762) describing the postmarket surveillance and study program proposed to evaluate the benefit of the proposed labeling changes and collect information regarding the Snus Products once they are introduced into the market. • *See also* the SE Report submitted in connection with the MRTPA for additional information regarding the Snus Product described in this Application.
FDCA § 910(b)(1)(B)	Components, ingredients, additives, properties, and principles of operation	Full statement of the components, ingredients, additives, and properties, and of the principle or principles of operations, of such tobacco product.	FDCA § 911(d)(2) FDCA § 911(d)(3) FDCA § 911(d)(6)	Full statement of the conditions for using the product, the formulation of the product, and data and information on how consumers actually use the tobacco product.	• *See* "Descriptive Information" (MRTPA pp. 138-355) and accompanying Appendices for a full statement of the components, ingredients, additives, properties, and principles of operation of the Snus Product. • *See also* the SE Report submitted in connection with the MRTPA for additional information regarding the ingredients, materials and design features for the Snus

**Where applicable, please also consult any underlying appendices and/or subsequent amendments to the MRTPA for the most complete response.*

PMTA			MRTPA		
Statutory Reference	**Requirement**	**Description**	**Statutory Reference**	**Requirement**	**Description***
					Product.
FDCA § 910(b)(1)(C)	Manufacturing methods and processing	Full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product.	—	—	• *See* "Descriptive Information" (MRTPA pp. 138-355) and accompanying Appendices for a description of the methods and facilities used to manufacture the Snus Product described in this Application.
FDCA § 910(b)(1)(D)	Tobacco Product Standards	Identify any tobacco product standards under FDCA § 907 that would be applicable to the new tobacco product and provide adequate information to show that the new tobacco product fully meets the standard or justifies any deviation from the standard.	—	—	• *NB: For reasons noted in the cover letter to this Application, there are no tobacco product standards under Section 907 that are applicable to smokeless tobacco. Therefore, there is no action required to be taken by Swedish Match in order to ensure that the Snus Product complies with Section 907.*
FDCA § 910(b)(1)(E)	Tobacco Product and Component Samples	Such samples of such tobacco product and of components thereof as the Secretary may reasonably require.	—	—	• *NB: Product samples are not required for MRTPA submissions. By contrast, Section 910(b)(1)(E) permits the Secretary to "reasonably require" such samples for PMTA submissions. Although FDA has not issued any binding regulations requiring the submission of such samples, the Draft PMTA Guidance recommends that product samples be provided. In accordance with this non-binding Guidance, Swedish Match is working diligently to prepare such samples and will provide them to FDA under separate cover.*
FDCA § 910(b)(1)(F)	Proposed Labeling	Specimens of all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information/materials.	FDCA § 911(d)(1) FDCA § 911(d)(4)	A description of any proposed advertising and labeling, and Sample product labels and labeling.	• *See* "Labels, Labeling and Advertising" (MRTPA pp. 344-355) for a description and specimens of all proposed labels for the Snus Product. As noted therein, Swedish Match does not plan to otherwise promote the proposed modified risk claims to consumers using other labeling or advertising.

PMTA			MRTPA		
Statutory Reference	**Requirement**	**Description**	**Statutory Reference**	**Requirement**	**Description***
FDCA § 910(b)(1)(G)	Other Information	Such other information relevant to the subject matter of the application as the Secretary may require	FDCA § 911(d)(7)	Such other information as the Secretary may require	• *See* "Foreign Language Certification" (MRTPA p. 750) for a certification of the accurate translation to English of foreign language documents submitted in support of the MRTPA.
21 C.F.R. § 25.15(a)	Environmental Assessment	A concise public document that must accompany a request for agency action and permit the agency to determine whether the proposed action may significantly affect the quality of the human environment	21 C.F.R. § 25.15(a)	Environmental Assessment	• *See* "Environmental Assessments" (MRTPA pp. 355-395) for the environmental assessment required by this Application.