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.