



September 17, 2018

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SUBMISSION TRACKING NUMBERS (STNs): MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029

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: RESPONSE AMENDMENT for MR0000020-MR0000022, MR0000024-MR0000025, and MR0000027-MR0000029

Dear Sir or Madam:

Swedish Match North America ("Swedish Match", the "Company", or "we") seeks to amend the eight Modified Risk Tobacco Product applications (MRTPAs) originally submitted 10 June 2014 for the following products:

- MR0000020, General Loose
- MR0000021, General Dry Mint Portion Original Mini
- MR0000022, General Portion Original Large
- MR0000024, General Classic Blend Portion White Large – 12 ct
- MR0000025, General Mint Portion White Large
- MR0000027, General Nordic Mint Portion White Large – 12 ct
- MR0000028, General Portion White Large
- MR0000029, General Wintergreen Portion White Large

This amendment addresses the three deficiencies and the two requests/recommendations mentioned in the scientific review referenced in the letter from the Center for Tobacco Products (CTP) dated 14 December 2016.

Swedish Match believes the evidence provided in this amendment is the final documentation necessary to determine that the use of General Snus products instead of combustible cigarettes may significantly reduce harm and the risk of certain tobacco-related diseases to individual users and meets the criteria for modified risk orders.

We appreciate your consideration of this response amendment to our MRTPAs identified above. If further information is required, please contact us.

Sincerely yours, (b)(6)

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