

February 10, 2021

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**SUBJECT: MRTP and PMTA ANNUAL REPORT MARKETING STATUS CORRECTIONS for Submission Tracking Numbers - MR0000020-MR0000021 and PM0000010-PM0000011**

Dear Sir or Madam,

Per our most recent email correspondence from Eugene Chuang from the Center for Tobacco Products dated February 10, 2021 (**Attachment A**), relating to the List of General Tobacco Products that were submitted as part of the Swedish Match USA, Inc. ("Swedish Match", "our" or "us") General Snus MRTP Annual Report submission dated October 19, 2020, in which after closeout review by Mr. Chuang and his team, a discrepancy was noted in the content submitted, relating to the MRTP and PMTA Annual Reports, specifically MR0000021 & PM0000011 General Dry Mint Portion Original Mini and MR0000020 & PM0000010 General Loose.

We now submit the accurate revised table highlighting the corrected and current Marketing Status information, relative to the following General products, identified by their respective MRTP and PMTA assignments:

**LIST OF GENERAL TOBACCO PRODUCT SUBMISSIONS – Current Marketing Status**

Product Manufacturer	Swedish Match USA, Inc.
Product Category	Smokeless Tobacco Products
<b>STN: Product Name</b>	<b>MR0000020 &amp; PM0000010: General Loose</b>
<b>Product Sub-Category</b>	Loose Snus
<b>Package Type</b>	Cardboard Can with Plastic Lid
<b>Package Quantity</b>	45.0 g
<b>Characterizing Flavor</b>	None
<b>Marketing Status</b>	<b>Out of Market - Effective 6/12/2017 was taken off the market.</b>
<b>STN: Product Name</b>	<b>MR0000021 &amp; PM0000011: General Dry Mint Portion Original Mini</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	6.0 g
<b>Characterizing Flavor</b>	Mint
<b>Marketing Status</b>	<b>Out of Market - Effective 12/31/2020 was taken off the market.</b>
<b>STN: Product Name</b>	<b>MR0000022 &amp; PM0000012: General Portion Original Large</b>

<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	24.0 g
<b>Characterizing Flavor</b>	None
<b>Marketing Status</b>	In Market.
<b>STN: Product Name</b>	<b>MR0000024 &amp; PM0000013: General Classic Blend Portion White Large – 12 ct</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	10.8 g
<b>Characterizing Flavor</b>	None
<b>Marketing Status</b>	<b>Out of Market - effective 1/15/2016 was taken off the market.</b>
<b>STN: Product Name</b>	<b>MR0000025 &amp; PM0000014: General Mint Portion White Large</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	24.0 g
<b>Characterizing Flavor</b>	Mint
<b>Marketing Status</b>	In Market.
<b>STN: Product Name</b>	<b>MR0000027 &amp; PM0000015: General Nordic Mint Portion White Large – 12 ct</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	10.8 g
<b>Characterizing Flavor</b>	Mint
<b>Marketing Status</b>	<b>Out of Market - effective 1/15/2016 was taken off the market.</b>
<b>STN: Product Name</b>	<b>MR0000028 &amp; PM0000016: General Portion White Large</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	24.0 g
<b>Characterizing Flavor</b>	None
<b>Marketing Status</b>	In Market.
<b>STN: Product Name</b>	<b>MR0000029 &amp; PM0000017: General Wintergreen Portion White Large</b>
<b>Product Sub-Category</b>	Portioned Snus
<b>Package Type</b>	Plastic Can
<b>Package Quantity</b>	24.0 g
<b>Characterizing Flavor</b>	Wintergreen
<b>Marketing Status</b>	In Market.

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31 Per FDA request, we are submitting the files through the CTP eSubmitter, as well as a digital copy forwarded  
32 via email to Mr. Chuang.

33 If further information is required, please contact us.

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Sincerely yours, (b) (6)

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(b) (6)

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Gerard J. Roerty, Jr.

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Vice President, General Counsel & Secretary

**From:** [Chuang, Eugene](#)  
**To:** [Gerry Roerty](#); [Judy Lancaster](#)  
**Cc:** [Hanratty, Elizabeth](#)  
**Subject:** Annual Report Submission Clarifications  
**Date:** Wednesday, February 10, 2021 8:32:09 AM  
**Attachments:** [image002.png](#)

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Good Morning Gerry,

As we are closing out the reviews of the Annual Reports submitted, we noticed a discrepancy in the content that was submitted. Please see attachments.

Your MRTP Annual Report states that MR000021 General Dry Mint Portion Original Mini is no longer in Market in the US.

Your PMTA Annual Report states that for PM0000011 the in market date is 4/6/2016.

Your MRTP Annual Report states that MR0000020 General Loose and that it is currently marketed

Your PMTA Annual Report states that PM0000010 General Loose not marketed in the US. Last distribution date of 6/12/2017.

We are requesting the Swedish Match provide an accurate table of the current marketing statuses of **ALL** products subject to both orders as the Annual Reports presented conflicting information.

If a correction is necessary, please submit the accurate information through the portal, but we are kindly requesting a digital copy as well so we can move forward with close out.

Please respond at your earliest convenience.

**Eugene Y Chuang**

*Lead Regulatory Counsel*

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