

February 10, 2021

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FOOD AND DRUG ADMINISTRATION
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Building 71, Room G335
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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
STN: Product Name	MR0000020 & PM0000010: General Loose
Product Sub-Category	Loose Snus
Package Type	Cardboard Can with Plastic Lid
Package Quantity	45.0 g
Characterizing Flavor	None
Marketing Status	Out of Market - Effective 6/12/2017 was taken off the market.
STN: Product Name	MR0000021 & PM0000011: General Dry Mint Portion Original Mini
Product Sub-Category	Portioned Snus
Package Type	Plastic Can
Package Quantity	6.0 g
Characterizing Flavor	Mint
Marketing Status	Out of Market - Effective 12/31/2020 was taken off the market.
STN: Product Name	MR0000022 & PM0000012: General Portion Original Large

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

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

If further information is required, please contact us.

Sincerely yours, (b) (6)

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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](#)

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

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