

1 November 20, 2020

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12 SUBMISSION TRACKING NUMBERS (STNs): MR0000020-MR0000022, MR0000024-
13 16 MR0000025, and MR0000027-MR0000029
14

15 Food and Drug Administration
16 Center for Tobacco Products
17 Document Control Center
18 Building 71, Room G335
19 10903 New Hampshire Avenue
20 Silver Spring, MD 20993-0002
21

22 **Subject: .MP4 (Video) and Digital files for General Snus Brand Consumer**
23 **Communications – MRTTP Annual Report Submission dated October 19, 2020 (PS0000064)**
24

25 Dear Sir or Madam:

26 Per our most recent email correspondence with Eugene Chuang from the Center for Tobacco Products on
27 Thursday, November 19, 2020 (see **Attachment A**), relating to the General Snus Consumer
28 Communications videos (.MP4), or digital banner ad files, that were to be submitted as part of the
29 Swedish Match USA, Inc. ("Swedish Match", "our" or "us") General Snus MRTTP Annual Report
30 submission (pages 314-321, 480-482, 485, 536, 550, 602-603, 615, 620-621, 623, 625, 627 and 629)
31 dated October 19, 2020 –we now resubmit the media files in a stand-alone format for each file. We are
32 also submitting additional video (.mp4), and digital banner ad files that were not listed on Mr.
33 Chuang's list, but were referenced on pages 322, 345, 349-352, 366, 409, 413-416, 444, 448-451,
34 477-479, 483-484, 560, 562, 569 and 573, to ensure that all video (.mp4) and digital banner ad files are
35 submitted.

36 As we have experienced that links to the media files in the body of the submission become static in
37 Adobe format, going forward, we will ensure that media files are included, apart from the submission
38 document, for all required future transmissions.
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40 Per FDA request, we are submitting the files through the CTP eSubmitter, in acceptable format outlined
41 on the FDA *Electronic Submission File Formats and Specifications* document, dated January 2018.

42 Please do not hesitate to contact us if you have any questions or if there is anything further that we can
43 provide.

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48 Gerard J. Roerty, Jr.
49 Vice President, General Counsel & Secretary
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51 File Attachment Outline
 52 See Tables Below:
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Annual Report Page Number	Stand-alone Video/Media Files Referenced as Files 1 -23 in Email Correspondence (Attachment A)
Page 314	Pg 314 OurProcess Path to Perfection.mp4
Page 315	Pg 315 OurProcess Harvest.mp4
Page 316	Pg 316 OurProcess CuringGrinding.mp4
Page 317	Pg 317 OurProcess SaltWater.mp4
Page 318	Pg 318 OurProcess HeatingCooling.mp4
Page 319	Pg 319 OurProcess OtherFlavors.mp4
Page 320	Pg 320 OurProcess Packaging.mp4
Page 321	Pg 321 OurProcess Chilled.mp4
Page 480	Pg 480 General Digital Ad Banner File 970x250.mp4
Page 481	Pg 481 General Digital Ad Banner File 1600x400.mp4
Page 482	Pg 482 General Digital Ad Banner File 160x600.mp4
Page 485	Pg 485 General Digital Ad Banner File 300x250.mp4
Page 485	Pg 485 General Digital Ad Banner File 300x600.mp4
Page 485	Pg 485 General Digital Ad Banner File 970x250.mp4
Page 536	Pg 536 Nov 2019 FB Post 11-7-Gen-FB Tobacco-Curing.mp4
Page 550	Pg 550 Dec 2019 FB Post 12-31-Gen-FB NYE.mp4
Page 602	Pg 602 Jul 2020 FB Post 7-4 GEN-July-FBIndependence-Day.mp4
Page 603	Pg 603 Jul 2020 FB Post 7-6 Gen July-FB.mp4
Page 615	Pg 615 Aug 2020 FB Post 8-12-Gen-FB-Finals.mp4
Page 620	Pg 620 Sept 2020 FB Post 9-2-Gen-Remote-Work.mp4
Page 621	Pg 621 Sept 2020 FB Post 9-5-Trailkeepers.mp4
Page 623	Pg 623 Sept 2020 FB Post 9-9 Riddle.mp4
Page 625	Pg 625 Sept 2020 FB Post 9-15 Desert-1.mp4
Page 627	Pg 627 Sept 2020 FB Post 9-22 Equinox-UPDATE.mp4
Page 629	Pg 629 Sept 2020 FB Post 9-28-Gen-Kebab-Pizza R2b.mp4

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Annual Report Page Number	Stand-alone Additional Video/Media Files Referenced in MRTP Annual Report
Page 322	Pg 322, 345, 366 OurStory This is Sweden NOPRODUCT 1.mp4
Page 345	Pg 322, 345, 366 OurStory This is Sweden NOPRODUCT 1.mp4
Page 349	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 350	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 351	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 352	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 366	Pg 322, 345, 366 OurStory This is Sweden NOPRODUCT 1.mp4
Page 409	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 413	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 414	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 415	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 416	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 444	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 448	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 449	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 450	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 451	Pg 349-352, 409, 413-416, 444, 448-451 GeneralSnus MRTP 2019 Q3 WebVideo.mp4
Page 477	Pg 477 GEN MRTP banner ad-300x250 FINAL.mp4
Page 478	Pg 478 GEN MRTP banner ad-300x600 FINAL.mp4
Page 479	Pg 479 728x90.mp4
Page 479	Pg 479 GEN MRTP banner ad-728x90 FINAL.mp4
Page 483	Pg 483 800x120.mp4
Page 484	Pg 484 640x400.mp4
Page 560	Pg 560 2-11-Gen-FB-Everyday.mp4

Page 562	Pg 562 2-17-Gen-FB-AmericanTreks mp4
Page 569	Pg 569 3-11-Gen-FB.mp4
Page 573	Pg 573 3-19-Gen-FB-March-Outdoors.mp4

From: [Judy Lancaster](#)
To: [Judy Lancaster](#)
Subject: FW: MRTTP Annual Report Submission
Date: Thursday, November 19, 2020 4:27:30 PM
Attachments: [image002.png](#)

From: Chuang, Eugene <Eugene.Chuang@fda.hhs.gov>
Sent: Thursday, November 19, 2020 1:42 PM
To: Gerry Roerty <gerry.roerty@swedishmatch.com>
Cc: Judy Lancaster (b) (6) >; Hanratty, Elizabeth
 <Elizabeth.Hanratty@fda.hhs.gov>
Subject: MRTTP Annual Report Submission

Good Afternoon Gerry,

Hope you and your family are well, sir. This email is in regards to your recent MRTTP Annual Report Submission. Below includes a list of the video, gifs, and/or digital banner ads from SMUSA's MRTTP Annual Report submission (PS0000064) that was referenced in your submission but there was no actual file to review.

Missing Video Files

1. Pg 314: Our Process_Path_to_Perfection.mp4
2. Pg 315: OurProcess_Harvest.mp4
3. Pg 316: OurProcess_CuringGrinding.mp4
4. Pg 317: OurProcess_SaltWater.mp4
5. Pg 318: OurProcess_HeatingCooling.mp4
6. Pg 319: OurProcess_OtherFlavors.mp4
7. Pg 320: OurProcess_Packaging.mp4
8. Pg 321: OurProcess_Chilled.mp4
9. Pg 480: General Digital Ad Banner File 970X250
10. Pg 481: General Digital Ad Banner File 1600x400
11. Pg 482: General Digital Ad Banner File 160x600
12. Pg 485: General Digital Ad Banner File (Seen all but) 970x250.mp4
13. Pg 536: Nov 2019 FB Post: 11-7-Gen-FB_Tobacco-Curing.mp4
14. Pg 550: Dec 2019 FB Post: 12-31-Gen-FB_NYE.mp4
15. Pg 602: Jul 2020 FB Post: 7-4-Gen-JulyFBIndependence-Day.mp4
16. Pg 603: Jul 2020 FB Post: 7-6-Gen-JulyFB.mp4
17. Pg 615: Aug 2020 FB Post: 8-12-Gen-FB-Finals.mp4
18. Pg 620: Sept 2020 FB Post: 9-2-Gen-Remote-Work.mp4
19. Pg 621: Sept 2020 FB Post: 9-5-Trailkeepers.mp4
20. Pg 623: Sept 2020 FB Post: 9-9 Riddle.mp4
21. Pg 625: Sept 2020 FB Post: 9-15_Desert-1.mp4
22. Pg 627: Sept 2020 FB Post: 9-22_Equinox-Update.mp4
23. Pg 629: Sept 2020 FB Post: 9-28-Gen-Kebab-Pizza_R2b.mp4

With that being said, I hope that moving forward we will no longer encounter these issues as they are causing a delay in our review schedule. As this is not the first instance where video files were referenced, but not submitted, I urge you and your team to do a thorough scrub of **both the MRTTP and PMTA submissions** to make sure all referenced items are submitted. Please acknowledge this

request by **COB Friday 11/20** and let me know when we would be receiving these items. Additionally, please ensure any further submission is accurately referenced to either the MRTTP or the PMTA.

I hope to hear from you soon. I will be out of the office Nov 23-27 so if there are any additional updates, please reply all so that my supervisor, Elizabeth Hanratty, may address any needs in a timely fashion.

Eugene Y Chuang

Lead Regulatory Counsel

**Center for Tobacco Products
Office of Compliance and Enforcement
U.S. Food and Drug Administration**

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