

1 August 3, 2020

2
3 Gerard J. Roerty, Jr.
4 Vice President, General Counsel & Secretary
5 Swedish Match USA, Inc.
6 Two James Center
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8 Richmond, VA 23219
9 Phone: 804-787-5100
10 e-mail: Gerry.Roerty@swedishmatch.com
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13 Food and Drug Administration
14 Center for Tobacco Products
15 Document Control Center (DCC)
16 Building 71, Room G335
17 10903 New Hampshire Avenue
18 Silver Spring, MD 20993-0002
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21 **SUBJECT: RESPONSE TO DEFICIENCY - DUE DATE REQUEST: PM0000593 – PM0000612**
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24 Dear Sir or Madam:
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26 We received your correspondence dated July 24, 2020, relating to your review of certain PMTAs
27 that Swedish Match USA, Inc. ("Swedish Match", "we", "us" or "our") had previously submitted on
28 March 4, 2020. You requested that we respond within 14 days from the date of your correspondence to
29 inform Center for Tobacco Products how much time Swedish Match would need to address and submit
30 deficiency information.
31

32 Swedish Match will be submitting our response on or before September 25, 2020. But for the
33 information requested in Question #8, we would be in a position to respond by September 9, 2020.
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35 In Question #8, the Agency identified as a deficiency the lack of evidence in the PMTAs
36 addressing the impact of flavors on nicotine uptake and abuse liability. (b) (4)

37 (b) (4) In order to address the deficiency, therefore, (b) (4)
38 (b) (4), a
39 process that cannot be completed by September 9.
40

41 If you should have any questions, please let me know. I thank you in advance for your
42 consideration.
43

44 Sincerely yours, (b) (6)

45 (b) (6)
46 (b) (6)
47 (b) (6)
48 (b) (6)

49 Gerard J. Roerty, Jr.
50 Vice President, General Counsel & Secretary
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