

1 March 15, 2022

2  
3 Gerard J. Roerty, Jr.  
4 Vice President, General Counsel & Secretary  
5 SWEDISH MATCH USA, INC.  
6 Two James Center  
7 1021 East Cary Street, Suite 1600  
8 Richmond, VA 23219  
9 Phone: (b) (6)  
10 e-mail: (b) (6)

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13 **SUBMISSION TRACKING NUMBER (STN): PS0000124, PS0000125, PS0000146 AND PS0000151**

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15 CENTER FOR TOBACCO PRODUCTS  
16 FOOD AND DRUG ADMINISTRATION  
17 Attn: Document Control Center  
18 10903 New Hampshire Avenue  
19 Building 71, Room G335  
20 Silver Spring, MD 20993-0002

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23 **SUBJECT: SWEDISH MATCH RESPONSE TO LETTER FROM CENTER FOR TOBACCO PRODUCTS**  
24 **DATED March 2, 2022 – (STN) PS0000124, PS0000125, PS0000146 and PS0000151**  
25 **("Response Letter")**  
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28 Dear Ms. Simoneau:

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30 Swedish Match USA, Inc. ("Swedish Match", "we" or "our") writes in response to FDA's Center  
31 for Tobacco Products letter ("CTP"), dated March 2, 2022 (the "Information Request Letter"), included  
32 as **Attachment A**, regarding certain advertising materials from our recent Annual Report dated  
33 November 10, 2021 and our recent Periodic Report dated December 9, 2021, for General Snus Products  
34 (STN) MR0000022, MR0000025 and MR0000028 – MR0000029.

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36 We set forth our response to the request for information, identified in the numbered items  
37 found beginning on page 3 of the Information Request Letter, which are reproduced below in bold type.  
38 Swedish Match follows with our submission response (in italics).

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40 We appreciate your consideration of this Response Letter. If further information is required,  
41 please contact us.

42  
43 Respectfully,

44 (b) (6)

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46 Gerard J. Roerty, Jr.  
47 Vice President, General Counsel & Secretary

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50 Document Attachments:

**SWEDISH MATCH'S RESPONSES TO NUMBERED INFORMATION REQUESTS**

1. Confirm whether marketing materials, as described above or materials with similar claims or representations, are still being disseminated to the public.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

2. Provide date of initial dissemination of these and similar materials, channels of circulation, and location, audience, and describe use of past and present General Snus advertising and promotion (b)(4)

The materials listed below have been removed and are no longer being disseminated to the public:

(b)(4)

(b)(4)

(b)(4)

## CENTER FOR TOBACCO PRODUCTS

VIA UPS

March 2, 2022

Mr. Gerard J. Roerty, Jr.  
Vice President, General Counsel & Secretary  
Two James Center  
1021 East Cary Street, Suite 1600  
Richmond, VA 23219

(b) (6)

Submission Tracking Numbers: PS0000124, PS0000125, PS0000146, and PS0000151

Dear Mr. Roerty:

FDA has reviewed your correspondences dated August 6, 2021, and August 11, 2021, in response to our August 5, 2021, letter in which we outlined our concern that your advertising for General Snus products, (b)(4) and accompanying statements, (b)(4)

(b)(4)

In the August 6, 2021, email, Swedish Match USA (SMUSA) states it would “appreciate the opportunity for a discussion with the agency about how we can appropriately balance communicating the agencies findings from our submission with our responsibilities under the order.”

In the August 11, 2021, letter, SMUSA states the following:

a)

(b)(4)

- b) SMUSA “will agree to no longer disseminate this advertisement at this time” and that “(t)hese materials are no longer being disseminated to the public.”
- c) SMUSA “requests the opportunity to discuss this matter further with CTP, to determine if we can set up a process whereby Swedish Match can submit materials in advance to the CTP for discussion, to avoid disagreements taking place after advertisements have been disseminated.”

With respect to SMUSA's request to discuss establishing a process whereby Swedish Match can submit materials in advance for review, FDA does not believe such a discussion is needed. The MRGOs authorize the marketing of the General Snus products with the following modified risk information: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis." Under the MRGOs, SMUSA is responsible for ensuring the modified risk tobacco products specified in the MRGOs comply with all applicable statutory and regulatory requirements. (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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<sup>1</sup> STN PS0000146

<sup>2</sup> STN PS0000151

<sup>3</sup> PS0000146 at p. 512 and p. 565

<sup>4</sup> PS0000151 at p. 158

<sup>5</sup> PS0000146 at p. 513 and p. 566

<sup>6</sup> PS0000151 at p. 159



1. Confirm whether marketing materials, as described above or materials with similar claims or representations, are still being disseminated to the public.
2. Provide date of initial dissemination of these and similar materials, channels of circulation, and location, audience, and describe use of past and present General Snus advertising and (b)(4)

We remind you of your responsibility to comply with applicable requirements under the FD&C Act, implementing regulations, and MRGOs. You should review all marketing materials, labeling, advertising, and other promotional materials and ensure that they are in compliance.

We request that a written response be submitted within 15 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Submission Tracking Numbers listed above. We encourage you to send your response electronically via the CTP Portal using eSubmitter. However, you may also send your response by mail to our Document Control Center:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
10903 New Hampshire Avenue  
Building 71, Room G335  
Silver Spring, MD 20993-0002

If you have any questions concerning this matter, please contact the Center for Tobacco Product's Office of Compliance and Enforcement via email at [CTP-OCE-Postmarket@fda.hhs.gov](mailto:CTP-OCE-Postmarket@fda.hhs.gov).

Sincerely yours,



Ann Simoneau, J.D.  
Director  
Office of Compliance and Enforcement  
Center for Tobacco Products