

August 16, 2024

Dr. Matthew Farrelly  
Director, Office of Science  
Center for Tobacco Products  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Submitted via CTP Portal

Cc: Tamirra Glover, RHPM via email

**Subject: Amendment to MRTPAs for ZYN Products**

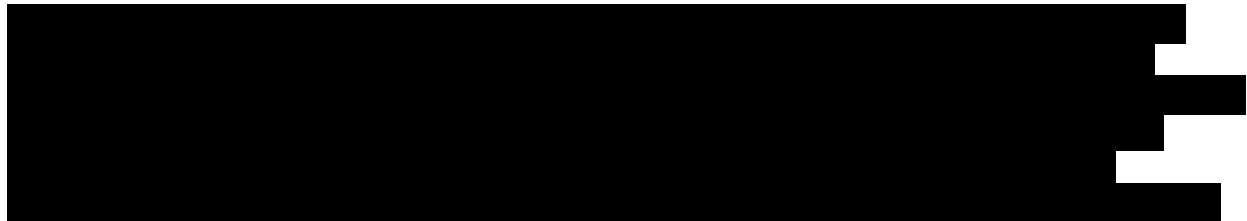
Dear Dr. Farrelly,

We, Swedish Match USA, Inc., the applicant that submitted the MRTPAs for the ZYN Products on April 5, 2024,<sup>1</sup> requested modified risk granted orders for the same reduced risk claim as FDA granted for our authorized MRTPs<sup>2</sup>:

***“Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”***

The proposed MRTPs subject of these applications are in [Table CL.1](#) below.

(b) (4)

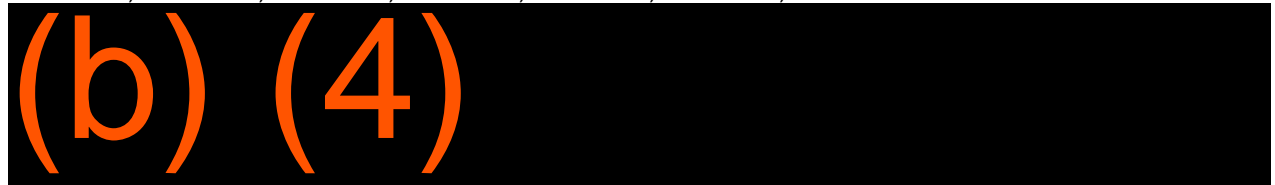
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<sup>1</sup> The bundled applications were submitted under Section 911(g)(1) of the FD&C Act. Submission Tracking Numbers have not yet been assigned, as these MRTPAs are still awaiting Acceptance Review as of this submission.

<sup>2</sup> On October 22, 2019, FDA CTP issued modified risk granted orders for the following General Snus Products: MR0000020, MR0000021, MR0000022, MR0000024, MR0000025, MR0000027, MR0000028, MR0000029.

(b) (4)

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**Table CL.1: *Proposed MRTPs* and Cross-Referenced PMTAs**

<i>Proposed MRTP</i>	Cross-Referenced PMTA
ZYN Cool Mint 3 mg	PM0000593
ZYN Cool Mint 6 mg	PM0000594
ZYN Peppermint 3 mg	PM0000595
ZYN Peppermint 6 mg	PM0000596
ZYN Spearmint 3 mg	PM0000597
ZYN Spearmint 6 mg	PM0000598
ZYN Wintergreen 3 mg	PM0000599
ZYN Wintergreen 6 mg	PM0000600
ZYN Citrus 3 mg	PM0000601
ZYN Citrus 6 mg	PM0000602
ZYN Coffee 3 mg	PM0000603
ZYN Coffee 6 mg	PM0000604
ZYN Cinnamon 3 mg	PM0000605
ZYN Cinnamon 6 mg	PM0000606
ZYN Smooth 3 mg <sup>7</sup>	PM0000607
ZYN Smooth 6 mg <sup>7</sup>	PM0000608
ZYN Chill 3 mg <sup>7</sup>	PM0000609
ZYN Chill 6 mg <sup>7</sup>	PM0000610
ZYN Menthol 3 mg <sup>8</sup>	PM0000611
ZYN Menthol 6 mg <sup>8</sup>	PM0000612

Throughout our applications, unless otherwise noted, *proposed MRTPs* refers to all twenty products listed in Table CL.1 above. (b) (4)

Trade Secrets or Confidential Commercial Information

Our MRTPAs contain non-public, trade secret and confidential information that is protected under state and federal law from public disclosure. As the applications contain such information throughout all sections of the applications, we reserve the right to redact information that we consider to be

<sup>7</sup> (b) (4)

<sup>8</sup> (b) (4)

<sup>9</sup> PM0000593, PM0000594, PM0000595, PM0000596, PM0000597, PM0000598, PM0000599, PM0000600, PM0000601, PM0000602, PM0000603, PM0000604, PM0000605, PM0000606, PM0000607, PM0000608, PM0000609, PM0000610, PM0000611, PM0000612 were submitted to FDA CTP on March 4, 2020.

confidential prior to our MRTPAs being made public. This information should, therefore, be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FD&C Act.

We appreciate your consideration of this (b) (4) and look forward to working with you on these applications. If you have questions, please do not hesitate to contact us directly.

Sincerely,

(b) (6)

Gerard J. Roerty, Jr., Esq.  
Vice President, General Counsel & Secretary  
Swedish Match USA, Inc.

Please note that this submission contains confidential commercial information, and/or trade secret information, and the legal protections provided to such information are hereby claimed under the applicable provisions of United States law, including relevant provisions of the Federal Freedom of Information Act (5 U.S.C. 552(b)(4)), the Trade Secrets Act (18 U.S.C. 1905), the Federal Food, Drug, and Cosmetic Act (21 CFR 301(j) and 906(c)) and FDA's implementing regulations (21 CFR 20.47 and 20.61). We understand that FDA will hold this documentation confidential and will refrain from public disclosure of the information contained in this submission in conformity with such provisions of the law. Accordingly, if FDA tentatively determines that any portion of this submission is disclosable to the public, FDA is required to provide us with notice and an opportunity to object in accordance with 21 CFR 20.47 and 20.61. We reserve all legal rights to protect against public disclosure of its trade secrets and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.