

April 05, 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: ZYN Product MRTPAs

Dear Dr. Farrelly,

We, Swedish Match USA, Inc., are submitting these bundled MRTPAs under Section 911(g)(1) of the FD&C Act and are requesting authorization to market our *proposed MRTPs*, the *ZYN Products*, under Section 911(g)(1) of the FD&C Act with the same reduced risk claim and the same modified risk information that FDA granted for our *authorized MRTPs*¹:

“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 shown in Table CL.1 below. Also shown in this table are the corresponding PMTAs submitted to FDA for the same products as the subject of these MRTPAs. These MRTPAs largely cross-reference data and information in the corresponding PMTAs, with a limited amount of data and information that has not been previously submitted as part of the PMTAs. Relatedly, these MRTPAs rely on FDA’s conclusions when it granted MRGOs for our *authorized MRTPs*. As demonstrated in these MRTPAs, FDA’s conclusions for the *authorized MRTPs* should be extrapolated to our *proposed MRTPs* for all of the following reasons:

- The *authorized MRTPs* and *proposed MRTPs* are oral tobacco products intended for use in the same manner (i.e., held between the lip and gum for a period of use and then discarded) by the same population (i.e., current 21 years and older tobacco product consumers).
- Patterns of Use Studies (POUs) that show similar populations use the *authorized MRTPs* and *proposed MRTPs* to decrease use of combusted cigarettes.
- The *proposed MRTPs* deliver similar quantities of nicotine but greater reduction in HPHCs than the *authorized MRTPs*.
- The *authorized MRTPs* and *proposed MRTPs* show comparable outcomes of non-clinical and clinical end points, which are significantly improved compared to combusted cigarette smoking.

¹ 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.

- Studies on the *authorized MRTPs* and *proposed MRTPs* show users and non-users understand the proposed reduced risk claim.
- The *authorized MRTPs* and *proposed MRTPs*, according to many sources including the most recent NYTS, are not used by many youth.
- Population Health Impact Modeling shows that U.S. marketing of the *proposed MRTPs* will likely reduce tobacco product-related deaths by 600,000 by the year 2050.

Given the robust evidence presented for the *proposed MRTPs* and *authorized MRTPs* (i.e., relative to combusted cigarettes), the same claim language should be authorized for the *proposed MRTPs*. This authorization will allow adult smokers to receive the same modified risk information as consumers of the *authorized MRTPs*. It is, therefore, reasonably expected that the marketing of the *proposed MRTPs* with the modified risk information, combined with the proven ability of the *proposed MRTPs* to drive complete switching away from combusted tobacco products, would significantly reduce harm and the risk of tobacco-related diseases to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Table CL.1: *Proposed MRTPs* and Cross-References 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 ²	PM0000607
ZYN Smooth 6 mg ³	PM0000608
ZYN Chill 3 mg ³	PM0000609
ZYN Chill 6 mg ³	PM0000610

² On March 27, 2023, we provided the FDA with notification (b) (4)

. See (b) (4) for complete details. (b) (4)

<i>Proposed MRTTP</i>	<i>Cross-Referenced PMTA</i>
ZYN Menthol 3 mg ³	PM0000611
ZYN Menthol 6 mg ⁴	PM0000612

Throughout our applications, unless otherwise noted, *proposed MRTTPs* refers to all twenty products listed in the Table CL.1 above. Corresponding PMTAs have been submitted for the *proposed MRTTPs* and are currently under scientific review.⁴ *Authorized MRTTPs*, unless otherwise specified, refers to the eight General Snus products that previously received Modified Risk Granted Orders from FDA¹.

Nicotine Source

All *proposed MRTTPs* contain nicotine derived from tobacco.

Prior Submissions

A complete list of all previous communications with the FDA related to the *proposed MRTTPs* is located in the (b) (4). (b) (4).

(b) (4) (b) (4)⁵.

(b) (4)

(b) (4)

(b) (4). The LoA provided with the corresponding PMTAs remains valid and should be used in the context of these MRTTPAs.⁹

³ (b) (4)

(b) (4)

⁴ 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.

⁵ (b) (4)

⁶ (b) (4)

⁷ (b) (4)

⁸ (b) (4)

⁹ (b) (4)

MRTPA Organization

To facilitate FDA's review, our MRTPAs rely on cross-reference to the corresponding PMTAs, as well as additional pertinent information, (b) (4). A comprehensive table of contents for the MRTPAs can be found in [MRTPA Module 1, section 1-2](#). The MRTPAs also reference the file location paths in which relevant information is cross-referenced. [Module 1, Section 1-9](#) provides more information (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 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.

Authorized Contact

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Our MRTPAs have been prepared using FDA's eSubmitter and associated data capturing tools. If you have questions, please do not hesitate to contact us directly.

Sincerely,

Gerard J.
Roerty, Jr.

Digitally signed by Gerard
J. Roerty, Jr.
Date: 2024.04.04
14:39:44 -04'00'

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.