

Module 1.3: General Information

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1. CONTACT INFORMATION

Applicant

Contact Name	Gerard J. Roerty, Jr.
Position Title	Vice President, General Counsel & Secretary
Email Address	(b) (6)
Company Name	SWEDISH MATCH USA INC.
Address	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
Telephone Number	(b) (6)

2. PROPOSED MRTPs IDENTIFICATION

Manufacturer	Swedish Match North America LLC, Swedish Match North Europe AB
Product name(s), including the brand and subbrand if applicable ¹	<i>ZYN Cool Mint 3 mg</i> <i>ZYN Cool Mint 6 mg</i> <i>ZYN Peppermint 3 mg</i> <i>ZYN Peppermint 6 mg</i> <i>ZYN Spearmint 3 mg</i> <i>ZYN Spearmint 6 mg</i> <i>ZYN Wintergreen 3 mg</i> <i>ZYN Wintergreen 6 mg</i> <i>ZYN Citrus 3 mg</i> <i>ZYN Citrus 6 mg</i> <i>ZYN Coffee 3 mg</i> <i>ZYN Coffee 6 mg</i> <i>ZYN Cinnamon 3 mg</i> <i>ZYN Cinnamon 6 mg</i> <i>ZYN Smooth 3 mg²</i> <i>ZYN Smooth 6 mg²</i> <i>ZYN Chill 3 mg²</i> <i>ZYN Chill 6 mg²</i> <i>ZYN Menthol 3 mg³</i> <i>ZYN Menthol 6 mg³</i>
Product category	Other Tobacco Derived Nicotine (OTDN)
Product subcategory	Pouches
Product properties	
Package Type:	Polypropylene Can and Polypropylene Lid

¹ The commercial name includes the nicotine concentration (mg/pouch) and the characterizing flavor.

² On March 27, 2023, we provided the FDA with notification of a product name/label change for ZYN.

³ On December 1, 2020, we provided the FDA with notification of a product name/label change for ZYN.

Package Quantity:	15 pouches
Nicotine Source	Tobacco
Portion Mass:	0.40 g
Portion Length:	28 mm
Portion Width:	13 mm
Portion Thickness:	4.5 mm

3. APPLICATION

Swedish Match USA Inc. is submitting these applications under section 911(g)(1) of the FD&C Act to request modified risk granted orders for the *proposed MRTPs*.

Type of Application	MRTPA, initial submission
STNs / FDA identifying numbers	N/A
Prior communication and meetings with FDA	N/A
Request to refer the MRTPAs to TPSAC	N/A
Dates during which the tobacco product was marketed	N/A
Address of manufacturer and Facility Establishment Identifier (FEI) of the establishment(s) involved in the manufacture of the new tobacco product	<p>Swedish Match North America LLC Contact Person: Shane Dukes Director, Smokefree Operations, Manufacturing Operations Address: 1121 Industrial Drive Owensboro, KY 42301 Phone: (b) (6) Email: (b) (6) DUNS: (b) (4) FEI: (b) (4)</p> <p>Swedish Match North Europe AB Address: Rollsbövägen 45 SE-442 40 Kungälv, Sweden Contact Person (Manufacturing and packaging): Cecilia Wiksfors, Director Supply Chain Kungälv Phone: (b) (6) Email: (b) (6) Contact Person (Storage and distribution): Mikael Brunsten, Manager Warehouse Phone: (b) (6) Email: (b) (6) DUNS: (b) (4) FEI: (b) (4)</p>

4. APPLICATION BACKGROUND AND PROTECTION OF PUBLIC HEALTH

These MRTPAs are filed to extend the FDA-authorized modified risk claims for the *authorized MRTPs*⁴ to the *proposed MRTPs*. In the context of these MRTPAs, we cross-reference the corresponding submitted PMTAs where possible to aid in FDA's review⁵. Scientific evidence and information are provided in the corresponding PMTAs, as well as in our TPMF (b) (4). Any cross-referenced data or information in the TPMF analyzed in the context of the PMTA review for the *proposed MRTPs* remain valid and do not require reanalysis to assess the reduced risk claim for the *proposed MRTPs*. Therefore, since the *proposed MRTPs* have a similar risk profile as and potentially greater benefit than the *authorized MRTPs*, the *proposed MRTPs*, which will be sold or distributed with the proposed modified risk claims, meet the standard under section 911(g)(1) of the FD&C Act and are expected to benefit the health of the population as a whole taking into account both users and non-users of the tobacco products.

5. COMPLIANCE WITH REQUIREMENTS OF SECTION 911(G)(1) OF THE FD&C ACT

Scientific evidence and data referenced in these applications meet the criteria under section 911(g)(1) of the FD&C Act, specifically the *proposed MRTPs*:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users
- 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.

6. STRUCTURE OF THE APPLICATION

The structure of these MRTPAs is based on seven modules with information from the corresponding PMTAs. We, therefore, cross-reference to the corresponding PMTAs for the *proposed MRTPs* and to the MRTPAs and subsequent amendments for the *authorized MRTPs*⁴.

Data and information from the original PMTAs, as well as data from subsequent amendments to the PMTAs, were added to a tobacco product master file (TPMF) owned by Swedish Match USA Inc. (b) (4), which is cross-referenced throughout these MRTPAs (see [Attachment 1-3-1](#) in Module 1 for the list of cross-referenced documents).

Additional information is cross-referenced from the PMSS reports for the *authorized MRTPs*, which are in Attachment C of the January 30, 2024 amendment to the MRTPA renewal for the *authorized MRTPs* (MR0000256).

7. REQUIREMENTS FULFILMENT OF SECTION [911(D)(5)]

The fulfilment of the requirements of section 911(d)(5) of the FD&C Act is described in [MRTPA section 1-11](#).

8. ENCLOSURES, LABELS AND LABELING

Details on Product Labels and Labeling are provided in [MRTPA section 1-6](#).

⁴ MR0000020, MR0000021, MR0000022, MR0000024, MR0000025, MR0000027, MR0000028, MR0000029. These products will be referred to as *authorized MRTPs* throughout these applications.

⁵ PM0000010, PM0000011, PM0000012, PM0000013, PM0000014, PM0000015, PM0000016, PM0000017