SWEDISH MATCH®

March 4, 2020

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

ATTN: Matthew R. Holman, PhD, Director, Office of Science
Subject: Premarket Tobacco Application – ZYN®

Dear Dr. Holman:

Swedish Match USA, Inc. ("Swedish Match", the "Company", or "we") is submitting this Premarket Tobacco Product Application (PMTA) pursuant to Section 910(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the Family Smoking Prevention and Tobacco Control Act, and is requesting a marketing authorization order under Section 910(c)(1)(A)(i) for ZYN.

Although ZYN has been marketed in the United States since prior to 8 August 2016, the product is a "new tobacco product" under Section 910(a)(1) of the FD&C Act, in that it was not commercially marketed in the United States as of 15 February 2007.

There have been no prior submissions to the FDA for ZYN.

Product Description

ZYN is a tobacco-free, smoke-free, and spit-free nicotine pouch that is intended for adult tobacco and nicotine consumers. This PMTA includes detailed information, including labeling, on 20 stock keeping units (SKUs) for 10 flavors and 2 nicotine strengths (3 and 6 mg) as follows:

ZYN Product Flavor	**Unique ID**	
	US	**SE**
Cool Mint 3 mg Cool Mint 6 mg	900510 900520	8105 8106
Peppermint 3 mg Peppermint 6 mg	901510 901520	8107 8108
Spearmint 3 mg Spearmint 6 mg	902510 902520	8109 8110
Wintergreen 3 mg Wintergreen 6 mg	903510 903520	8111 8112

ZYN Product Flavor	Unique ID	
	US	SE
Citrus 3 mg Citrus 6 mg	907510 907520	8122 8123
Coffee 3 mg Coffee 6 mg	904510 904520	8124 8125
Cinnamon 3 mg Cinnamon 6 mg	906510 906520	8128 8129
Smooth 3 mg Smooth 6 mg	914510 914520	8134 8135
Chill 3 mg Chill 6 mg	920510 920520	8136 8137
Fresh 3 mg Fresh 6 mg	921510 921520	8140 8141

ID=identifier; SE=Kungälv, Sweden, manufacturing site; US=Owensboro, Kentucky, United States, manufacturing site.

Dates of Prior Meetings with FDA

Swedish Match and staff from FDA's Center for Tobacco Products met to discuss Swedish Match's plan to submit this application on the following dates:

- 7 December 2016 (STN TC0001638)
- 13 September 2017 (STN TC0002533)

Premarket Tobacco Product Application Organization

Enclosed, please find a complete PMTA, organized according to the recommendations in FDA's *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems Guidance for Industry* (June 2019) and reflective of the proposed rule for PMTAs, containing all the information requested therein. To facilitate review of this PMTA, Swedish Match has provided a reviewer's guide in Section A.3 Reviewer's Guide. The reviewer's guide contains a brief statement of content for each PMTA section or subsection along with corresponding links to the various sections of the application. Information regarding the prior meetings with FDA is included in the reviewer's guide. A comprehensive table of contents for the submission is provided in Section B Table of Contents.

This PMTA also references the (b) (4) Tobacco Products Master File for details of the nicotine bitartrate dihydrate manufacturer and specifications; see Section A.5 TPMF Letters of Authorization for a copy of the letter.

Trade Secrets or Confidential Commercial Information

This PMTA contains non-public, trade secret, and confidential information that is protected under state and federal law from public disclosure. As required by Section 911(e) of the FD&C Act, Swedish Match is providing a detailed, confidential appendix listing the categories of information throughout all sections of the application that the Company considers to be

confidential. This appendix will be provided in a separate, subsequent submission containing the PMTA files marked to show the proposed redactions. The information listed in this appendix should be redacted from the public version of this application. This information should therefore be handled in accordance with the security procedures adopted by the FDA in connection with enforcement of the FD&C Act.

Certification Statement

I, Gerard J. Roerty, Jr., on behalf of the applicant, Swedish Match, hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that such records remain readily available to FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.

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Please contact me if you have any questions regarding this submission:

Swedish Match appreciates FDA's consideration of this application.

Sincerely yours, (b) (6)

(b) (6)

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