

Module 7: Environmental Impact Assessment

1. INTRODUCTION

We provide new environmental information for the *proposed MRTPs* in these MRTPAs. These new Environmental Impact Assessments reflect updates in certain permitting, marketing forecasts, and projections pertaining to energy use that have occurred since environmental impact assessments were last submitted for the original PMTAs. [Table 1](#) below contains a tabular listing of the attachments applicable to each of the *proposed MRTPs*.

The submitted environmental assessments have been prepared in accordance with 21 CFR 25.20 and 25.40, the U.S. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969. Under NEPA, "all applications or petitions requesting Agency action require the submission of an environmental assessment or a claim of categorical exclusion" (21 CFR 25.15(a)).

Table 1: ZYN Product Environmental Assessments (“EA”) and Attachment Name¹

Product Name	Attachment Name
ZYN Cool Mint 3 mg EA	7-01-coolmint-3mg-ea
ZYN Cool Mint 3 mg EA Confidential Appendix	7-02-coolmint-3mg-conf-app
ZYN Cool Mint 6 mg EA	7-03-coolmint-6mg-ea
ZYN Cool Mint 6 mg EA Confidential Appendix	7-04-coolmint-6mg-conf-app
ZYN Peppermint 3 mg EA	7-05-peppermint-3mg-ea
ZYN Peppermint 3 mg EA Confidential Appendix	7-06-peppermint-3mg-conf-app
ZYN Peppermint 6 mg EA	7-07-peppermint-6mg-ea
ZYN Peppermint 6 mg EA Confidential Appendix	7-08-peppermint-6mg-conf-app
ZYN Spearmint 3 mg EA	7-09-spearmint-3mg-ea
ZYN Spearmint 3 mg EA Confidential Appendix	7-10-spearmint-3mg-conf-app
ZYN Spearmint 6 mg EA	7-11-spearmint-6mg-ea
ZYN Spearmint 6 mg EA Confidential Appendix	7-12-spearmint-6mg-conf-app
ZYN Wintergreen 3 mg EA	7-13-wintergreen-3mg-ea
ZYN Wintergreen 3 mg EA Confidential Appendix	7-14-wintergreen-3mg-conf-app
ZYN Wintergreen 6 mg EA	7-15-wintergreen-6mg-ea
ZYN Wintergreen 6 mg EA Confidential Appendix	7-16-wintergreen-6mg-conf-app
ZYN Citrus 3 mg EA	7-17-citrus-3mg-ea
ZYN Citrus 3 mg EA Confidential Appendix	7-18-citrus-3mg-conf-app
ZYN Citrus 6 mg EA	7-19-citrus-6mg-ea
ZYN Citrus 6 mg EA Confidential Appendix	7-20-citrus-6mg-conf-app
ZYN Coffee 3 mg EA	7-21-coffee-3mg-ea
ZYN Coffee 3 mg EA Confidential Appendix	7-22-coffee-3mg-conf-app
ZYN Coffee 6 mg EA	7-23-coffee-6mg-ea
ZYN Coffee 6 mg EA Confidential Appendix	7-24-coffee-6mg-conf-app
ZYN Cinnamon 3 mg EA	7-25-cinnamon-3mg-ea
ZYN Cinnamon 3 mg EA Confidential Appendix	7-26-cinnamon-3mg-conf-app
ZYN Cinnamon 6 mg EA	7-27-cinnamon-6mg-ea
ZYN Cinnamon 6 mg EA Confidential Appendix	7-28-cinnamon-6mg-conf-app

¹ On March 27, 2023, Swedish Match provided FDA with notification of a product name/label change for ZYN Smooth 3 mg (PM0000607), ZYN Smooth 6 mg (PM0000608), ZYN Chill 3 mg (PM0000609), and ZYN Chill 6 mg (PM0000610). The newly named tobacco products (ZYN Original 3 mg, ZYN Original 6 mg, ZYN Classic 3 mg and ZYN Classic 6 mg) are identical to currently marketed tobacco products and are simply a name/label change not requiring a separate path to market application. ZYN Original and ZYN Classic are only present in California, US.

ZYN Smooth 3 mg EA	7-29-smooth-3mg-ea
ZYN Smooth 3 mg EA Confidential Appendix	7-30-smooth-3mg-conf-app
ZYN Smooth 6 mg EA	7-31-smooth-6mg-ea
ZYN Smooth 6 mg EA Confidential Appendix	7-32-smooth-6mg-conf-app
ZYN Chill 3 mg EA	7-33-chill-3mg-ea
ZYN Chill 3 mg EA Confidential Appendix	7-34-chill-3mg-conf-app
ZYN Chill 6 mg EA	7-35-chill-6mg-ea
ZYN Chill 6 mg EA Confidential Appendix	7-36-chill-6mg-conf-app
ZYN Menthol 3 mg EA	7-37-menthol-3mg-ea
ZYN Menthol 3 mg EA Confidential Appendix	7-38-menthol-3mg-conf-app
ZYN Menthol 6 mg EA	7-39-menthol-6mg-ea
ZYN Menthol 6 mg EA Confidential Appendix	7-40-menthol-6mg-conf-app
ZYN Original 3 mg EA	7-41-original-3mg-ea
ZYN Original 3 mg EA Confidential Appendix	7-42-original-3mg-conf-app
ZYN Original 6 mg EA	7-43-original-6mg-ea
ZYN Original 6 mg EA Confidential Appendix	7-44-original-6mg-conf-app
ZYN Classic 3 mg EA	7-45-classic-3mg-ea
ZYN Classic 3 mg EA Confidential Appendix	7-46-classic-3mg-conf-app
ZYN Classic 6 mg EA	7-47-classic-6mg-ea
ZYN Classic 6 mg EA Confidential Appendix	7-48-classic-6mg-conf-app