

**Programmatic Environmental Assessment for Modified Risk
Orders for New Nicotine Pouch Products Marketed by
Swedish Match USA, Inc.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

June 29, 2026

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1. Introduction

1.1 Background

Swedish Match USA, Inc. (formerly Swedish Match North America, Inc.) submitted 20 modified risk tobacco product applications (MRTPAs) [MR0000268.PD1-MR0000268.PD20] for nicotine pouch products to FDA seeking authorization under Section 911(g) of the Federal Food Drug, and Cosmetic Act (FD&C Act) on April 5, 2024, to market the products with a proposed modified risk claim. The agency had previously issued a finding of no significant impact (FONSI), dated January 2, 2025, for the Premarket Tobacco Product Applications for these products under section 910(a)(2) of FD&C Act. The FONSI is supported by a programmatic environmental assessment (PEA) issued on the same date.

FDA prepared this PEA to evaluate the potential environmental impacts from marketing the “nicotine pouch with a modified risk claim” (referred to as the “proposed MRTPs”) in the United States and from the no-action alternative of not issuing modified risk granted orders for the products. This PEA is prepared in accordance with the National Environmental Policy Act (NEPA) and FDA’s NEPA regulations (21 CFR Part 25.40).

1.2 Applicant and Manufacturers Information

Applicant Name:	Swedish Match USA Inc.
Applicant Address:	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
Manufacturers Names:	Swedish Match North America LLC, Swedish Match North Europe AB
Product Manufacturing Locations:	1121 Industrial Drive, Owensboro, KY 42301 Swedish Match North Europe Rollsbovagen 45, SE-441 17 Kungälv, Sweden

1.3 Product Information

Proposed MRTPs Names and Submission Tracking Numbers (STNs)

STN Product	Product Name
MR0000268.PD1	ZYN Cool Mint 3 mg
MR0000268.PD2	ZYN Cool Mint 6 mg
MR0000268.PD3	ZYN Peppermint 3 mg
MR0000268.PD4	ZYN Peppermint 6 mg
MR0000268.PD5	ZYN Spearmint 3 mg
MR0000268.PD6	ZYN Spearmint 6 mg
MR0000268.PD7	ZYN Wintergreen 3 mg
MR0000268.PD8	ZYN Wintergreen 6 mg
MR0000268.PD9	ZYN Citrus 3 mg
MR0000268.PD10	ZYN Citrus 6 mg
MR0000268.PD11	ZYN Coffee 3 mg

MR0000268.PD12	ZYN Coffee 6 mg
MR0000268.PD13	ZYN Cinnamon 3 mg
MR0000268.PD14	ZYN Cinnamon 6 mg
MR0000268.PD15	ZYN Smooth 3 mg
MR0000268.PD16	ZYN Smooth 6 mg
MR0000268.PD17	ZYN Chill 3 mg
MR0000268.PD18	ZYN Chill 6 mg
MR0000268.PD19	ZYN Menthol 3 mg
MR0000268.PD20	ZYN Menthol 6 mg

1.4 Product Information

Product Category	Other
Product Subcategory	Other
Product Number per Retail Unit	3 mg, 6 mg nicotine per pouch with 15 pouches per can.
Product Package	Polypropylene can with polyethylene film labels on the front, back, and sides. Cans are packaged in a paperboard carton and corrugated cardboard case.

2. The Purpose and Need for the Proposed Actions

Purpose: Swedish Match USA, Inc. (formerly Swedish Match North America, Inc.) submitted 20 MRTPAs [MR0000268.PD1-MR0000268.PD20] for nicotine pouch products to FDA seeking authorization under Section 911(g) of the FD&C Act on Apr 5, 2024 to market the products with a proposed modified risk claim. To communicate modified risk information to consumers, the applicant proposes to market with the following proposed claim to the advertising of the 20 nicotine pouch products that are the subject of these applications: “Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

Upon receipt of an MRTPA, FDA considers the submission, using criteria detailed in section 911(g) of the FD&C Act, and issues a risk modification order that either allows or denies the proposed risk modification claim for a commercially marketed tobacco product. The purpose of FDA’s MRTPA review is to determine whether an applicant has shown that the tobacco product sold or distributed with the proposed modified risk information will (A) significantly reduce harm and the risk of tobacco related disease to individual tobacco users and (B) benefit the health of the population as a whole considering both users of tobacco products and persons who do not currently use tobacco products.

Need: FDA is responsible for reviewing an MRTPA, making a finding as described in the previous paragraph, and subsequently determining issuance or denial of a modified risk granted orders for the proposed MRTPs.

3. Proposed Actions and Alternatives

The proposed action is for the FDA to issue modified risk granted orders under the provisions of 911(g)(1) authorizing the marketing of the proposed MRTPs with the modified risk claim as identified in Section 2.

The no-action alternative is that FDA does not issue modified risk granted orders for the proposed MRTPs. The products will not be marketed in the United States with the modified risk claim and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there will be no changes to the current nicotine pouch product market and no changes to the current or future use of nicotine pouch products.

4. Potential Environmental Effects of the Proposed Actions and Alternatives – Manufacturing the Proposed MRTPs

The proposed MRTPs subject of this review are the same products evaluated in the ZYN oral nicotine pouch products PMTA. The difference between the proposed MRTPs and the PMTA is the addition of the modified risk claim as identified in Section 2. This claim is not expected to change the environmental impacts associated with manufacturing the proposed modified risk tobacco product. The Agency considered potential effects to resources in the environment that could be affected by manufacturing the proposed MRTPs and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Short-term, construction related localized effects are anticipated due to the expansion of the manufacturing facility for production of the proposed MRTPs.
- The applicant has incorporated additional environmental controls for environmental compliance and to prevent environmental effects.
- The increased net production and sales would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

This analysis will focus on the manufacturing facility in Owensboro, KY. However, the applicant also states that the manufacturing facility located in Sweden complies with all the applicable environmental regulations and does not require any new environmental permits due to manufacturing the proposed MRTPs.

4.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities. The proposed MRTPs are manufactured at Swedish Match North America LLC facility, at 1121 Industrial Drive, Owensboro, KY 42301 (Figure 1). The facility is at the edge of a manufacturing district, with equipment fabricators and a beverage distributor to the north, a mechanical contractor and industrial equipment supplier to the west, a manufacturer and tire shop to the east, and residential housing to the south and southeast.

The proposed MRTPs are also manufactured at Rollsbogavägen 45, SE-441 17 in Kungälv, Sweden (Figure 2). The land surrounding this facility constitutes industrial, residential, and natural areas.

Figure 1. Location of the Domestic Manufacturing Facility (Google, 2025a)

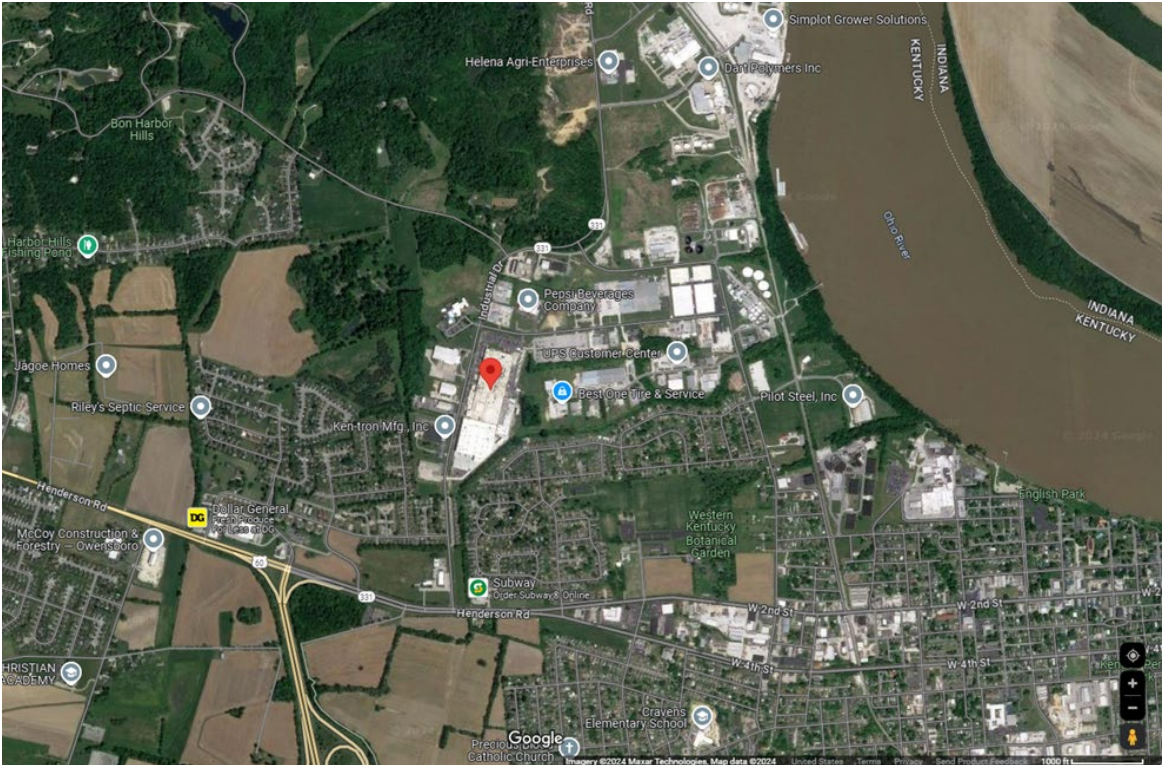


Figure 2. Location of the Foreign Manufacturing Facility (Google, 2025b)



4.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the tobacco products based on information gathered by the Agency and the applicant's submitted information, including projected market volumes for the proposed MRTPs (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	Expansion of the facility for manufacturing the proposed MRTPs required a revised air emissions permit for the manufacturing facility. Additional environmental controls were required and implemented in the Owensboro manufacturing facility in relation to the expansion of the facility for manufacturing the proposed MRTPs. The revised air emissions permit from the Commonwealth of Kentucky allows the applicant to emit up to 90 tons of ethanol per year. In addition, the applicant implemented pollution controls to handle ethanol emissions. Ethanol (190 Proof) is used in the proposed MRTPs manufacturing process as a carrier and is removed through volatilization. During processing, the ethanol volatilizes, leaving no measurable ethanol content in the finished product. The applicant noted that to accommodate this production requirement, two above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Also, two 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. The Regenerative Thermal Oxidizers (RTOs) placed in the facility is used to dispose of the ethanol waste, with an expected performance of the RTOs at 95- 99% destruction efficiency of ethanol. The Agency does not anticipate that manufacturing the proposed MRTPs would lead to new or increased compounds being emitted at the Owensboro facility.
Water resources	Manufacturing the proposed MRTPs resulted in an expansion of existing waste/sanitary water discharge. The applicant states that they obtained an additional water permit from the local Regional Water Resource Agency (Davies County, KY) for building expansion and are in compliance with all applicable regulations. The facility added additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations. The Agency does not anticipate that manufacturing the proposed MRTPs would cause any new chemicals to be discharged into the water and no significant impact on water resources are anticipated.
Soil, Land use and zoning	The Agency does not anticipate that manufacturing the proposed MRTPs will lead to changes in soil, land use, or zoning. The proposed MRTPs are manufactured at the Swedish Match North America LLC in Owensboro, KY, which currently manufactures other tobacco products. The Agency anticipates that the new construction due to manufacturing the proposed MRTPs resulted in localized, short-term construction related activities. Therefore, no zone changes or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

Environmental Resource	Analysis of Potential Impacts
Biological resources	The Agency searched the U.S. Fish and Wildlife Service’s Environmental Conservation Online System (ECOS) which shows that the manufacturing facility is not within or near critical habitat (U.S. Fish & Wildlife Service, 2025a) or endangered animal or plant species (U.S. Fish & Wildlife Service, 2025b). ECOS (U.S. Fish & Wildlife Service, 2024b) identifies five mammals, 12 clams, one bird, and one insect species as endangered, proposed endangered, threatened, candidate, recovery, or under review in Daviess County, KY. Critical habitat has not been designated for these species in Daviess County, KY (U.S. Fish & Wildlife Service, 2025a). The Agency does not anticipate that manufacturing the proposed MRTPs will jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the U.S. Endangered Species Act (ESA). The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County, KY. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. No rare or protected flora or fauna are used as materials or ingredients in the proposed MRTPs.
Solid waste and hazardous materials	The applicant submitted information about solid waste and hazardous materials management and environmental controls, specifically relating to nicotine. Production of the proposed MRTPs differs from the production of other products at the Owensboro facility. Therefore, the applicant states that new environmental controls were implemented at the Owensboro facility to accommodate new waste associated with the facility expansion and the proposed MRTPs, including nicotine. Unused bulk powder containing nicotine is handled as hazardous waste and disposed of by a third-party contractor using controlled methods. The applicant states that the handling of hazardous waste occurs using a laboratory style glove box and the waste does not come into direct contact with personnel. The applicant further describes waste streams associated with production of the proposed MRTPs, including, 1) a granulate waste stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags); 2) a finished waste stream (e.g., destruction of returned unsellable items, which are segregated from other returns and not run through unsaleable shredder); 3) a lab waste stream (e.g., residual materials from samples and the analysis of the proposed MRTPs); and 4) an ethanol waste stream (e.g., resulting from the rinsing of process equipment parts with ethanol). All waste streams are accumulated, then following EPA shipping compliance requirements, shipped to a certified incinerator for destruction. The environmental controls aid in environmental compliance. There may be a net increase in manufacturing owing to manufacturing of the proposed MRTPs. The applicant states that manufacturing the proposed MRTPs would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity. The Agency’s search of EPA’s

Environmental Resource	Analysis of Potential Impacts
	ECHO database did not reveal any Resource Conservation and Recovery Act (RCRA) violations at the manufacturing facility (U.S. Environmental Protection Agency, 2025b). Therefore, the Agency does not anticipate that manufacturing the proposed MRTPs would lead to new or increased solid waste and hazardous wastes.
Floodplains, wetlands, and coastal zones	The Agency does not anticipate that manufacturing the proposed MRTPs would lead to changes in floodplains, wetlands, and coastal zones. The Agency anticipates that construction to accommodate manufacturing the proposed MRTPs is associated with localized, short-term land alterations within an existing industrial footprint.
Regulatory compliance	The applicant states that the manufacturing facility is in compliance with all applicable environmental regulations and provides details on relevant permits at the Owensboro plant for monitoring and controlling emissions as provided by state and local authorities. The Agency's search of the U.S. Environmental Protection Agency's (EPA) Enforcement and Compliance History Online (ECHO) database did not reveal any violations of environmental laws and regulations for the Swedish Match North America LLC manufacturing facility in Owensboro, KY (U.S. Environmental Protection Agency, 2025a). The applicant states that the Kungälv Facility in Sweden is in compliance with all applicable environmental laws. The applicant also states that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

4.3 Effects of the No Action Alternative

The environmental effect of the no-action alternative would not change the existing condition of manufacturing nicotine pouch products, as the current tobacco products would continue to be manufactured at the listed facility.

5. Potential Environmental Effects of the Proposed Action and Alternative – Use of the Proposed MRTPs

The Agency evaluated potential environmental impacts that may be caused by use of the proposed MRTPs with the modified risk claim and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments in the United States because a modified risk granted order would allow the proposed MRTPs to be marketed with the proposed modified risk claim. This could impact sales volumes and consumer use patterns, with associated impacts on the human and natural environments.

5.2 Analysis of Potential Environmental Effects

The proposal action was evaluated for the potential effects to resources in the environment that could be affected by use of the proposed MRTPs with the modified risk claim and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 1) for the first-year and fifth-year of marketing of the proposed MRTPs. Users of the proposed MRTPs, which are intended as spit-free products, are not anticipated to expectorate the proposed MRTPs into the environment. Further, no emissions or introduction of chemicals into the environment are anticipated during the use of the products.

5.3 Impacts from the No-Action Alternative

The environmental effects of the no-action alternative will not change the existing condition of use of nicotine pouch products because the same products without a modified risk claim and other similar tobacco products will continue to be used in the United States.

6. Potential Environmental Effects of the Proposed Action and Alternative – Disposal of the Proposed MRTPs

The Agency evaluated potential environmental effects that may be caused by disposal of the proposed MRTPs and found no significant impacts based on Agency-gathered information and the applicant's submitted information.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because a modified risk granted order would allow the proposed MRTPs to be marketed with the proposed modified risk claim. This could impact sales volumes and consumer use patterns, with associated impacts on the human and natural environments, particularly the disposal of proposed MRTPs and packaging as municipal solid waste (MSW), recycled material, or litter.

6.2 Analysis of Potential Environmental Effects

The proposed actions were evaluated for potential environmental effects from disposal of the tobacco products based on Agency-gathered information and the applicant's submitted information, including market volume information for the tobacco products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate disposal of the proposed MRTPs, or the packaging material would lead to the release of new or increased chemicals into the air. Currently, there are no studies available that describe the air quality effects resulting from the disposal of used nicotine pouches. The applicant provided information on the material composition of the pouches, which includes synthetic polymers and plastic materials. Some of these materials are known to be non-biodegradable or only slowly biodegradable. No changes in air quality from disposal of the packaging materials in the proposed MRTPs would be expected because (1) the paper and cardboard components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste based on the projected market volume of the proposed MRTPs.
Biological resources	The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act. Proper disposal of the used proposed MRTPs and packaging into MSW would not affect biological resources. If improper disposal as litter occurs, the products are not expected to result in new or additional compounds emitted to the environment. Further, unlike combusted tobacco products, smoldering of used products is not a concern with disposal of the proposed MRTPs. Therefore, the risk of fires from smoldering tobacco products and associated effects to natural environments from littering are not a concern. The Agency does not anticipate disposal of the proposed MRTPs, or the packaging material would lead to significant impacts on biological resources.

Environmental Resource	Analysis of Potential Impacts
Water resources	Proper disposal of the used proposed MRTPs and packaging in the municipal solid waste stream will not affect water resources. Improper disposal (littering) of the used proposed MRTPs could result in hazardous substances leaching into water systems. However, littering levels are not expected to change from the current levels due to the existing tobacco products. Introducing the tobacco products into the U.S. market is not expected to increase the nationwide use of nicotine pouch products based on the Agency's assessment and projected market volumes reported by the applicant. The Agency conducted a screening-level assessment of the cumulative acute toxicity risk to aquatic organisms from nicotine in the products. The agency calculated Risk Quotients (RQ) from estimated aquatic expected environmental concentrations (EEC) of nicotine and its lowest acute toxicity endpoint values (Confidential Appendix 3). The RQ values are several orders of magnitude lower than the Level of Concern for acute risks (high, restricted use or endangered species) to aquatic animals (Confidential Appendix 3). Based on the screening-level risk assessment, nicotine in the proposed MRTPs do not pose risks to aquatic animals. Therefore, no significant impacts on water resources and water quality from the disposal of proposed MRTPs are expected.
Solid Waste and Hazardous Materials	The distribution of waste generated due to disposal of the proposed MRTPs and packaging is anticipated to correspond to the pattern of the products' use in the United States. Users of the proposed MRTPs, which are intended as spit-free products, are not anticipated to expectorate the proposed MRTPs into the environment. Based on information provided by the applicant on the market volumes and product packaging materials and the pouch (Confidential Appendices 1 and 2), the agency calculated the municipal solid loads for the proposed MRTPs (Confidential Appendix 4). The agency does not anticipate significant impacts from disposal of the packaging materials and pouch because packaging materials are similar to and will be similarly handled as other similar paper and plastic waste. Waste generated from disposal of the proposed MRTPs is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from tobacco products even without accounting for recycling, although a portion of those would be littered (U. S Environmental Protection Agency, 2018).

6.3 Effects from the No-Action Alternative

The environmental effects of the no-action alternative will not change the existing condition of disposal of nicotine pouch products and their packaging, as the same products without a modified risk claim and many other similar tobacco products will continue to be disposed of in the United States.

7. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology

Experience: Twenty-two years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis, toxicology, ecological risk, and benefit assessments, applied ecology, geo-statistics

Reviewer:

Sharon Edelson-Mammel, DrPH, MS, Center for Tobacco Products

Education: DrPH in Environmental Health

Experience: 25 years regulatory consumer safety of food and/or tobacco products

Expertise: Microbial constituents in tobacco products, environmental science

8. A Listing of Agencies and Persons Consulted

None.

9. References

Google. Map of 1121 Industrial Drive, Owensboro, KY 42301. Google Maps. Accessed June 18, 2025 (2025a) www.google.com/maps

Google. Map of Rollsbogavagen 45, SE-441 17, Kungälv, Sweden. Google Maps. Accessed June 17, 2025 (2024a) www.google.com/maps

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Online. Accessed June 17, 2024 (2025a) <https://echo.epa.gov/detailed-facility-report?fid=110070626060>

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U.S. Fish & Wildlife Service. Listed species believed to or known to occur in Daviess, Kentucky. Accessed June 22, 2025 (2024a) <https://ecos.fws.gov/ecp/report/species-listings-by-current-range-county?fips=21059>

U.S. Fish & Wildlife Service. Critical habitat for threatened & endangered species. Accessed November 8, 2024 (2024b)
<https://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77>

CONFIDENTIAL APPENDIX 1

Weight in metric tons and number of sales units (containers) by marketing year for the individual products

Submission Tracking Number (STN)	Year 1	Year 5	Year 1	Year 5
	Weight in Metric Tons		Number of Sales Units (containers)	
MR0000268.PD1	(b) (4)			
MR0000268.PD2				
MR0000268.PD3				
MR0000268.PD4				
MR0000268.PD5				
MR0000268.PD6				
MR0000268.PD7				
MR0000268.PD8				
MR0000268.PD9				
MR0000268.PD10				
MR0000268.PD11				
MR0000268.PD12				
MR0000268.PD13				
MR0000268.PD14				
MR0000268.PD15				
MR0000268.PD16				
MR0000268.PD17				
MR0000268.PD18				
MR0000268.PD19				
MR0000268.PD20				
Total				

CONFIDENTIAL APPENDIX 2

Weight of pouch components, packaging, and of an individual sales unit (one can with 15 pouches)

Component	Material description	Weight (g)		
		by component	unit multiplier	by unit
Pouch and pouch components (15 pouches/can)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Can base (with ring installed)				
Can Lid				
Top Label				
Side Label				
Bottom Label				
Shrink Wrap (Film)				
Shrink Wrap Label				
Case				
Case Tape				
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

CONFIDENTIAL APPENDIX 3

Screening-level risk assessment of nicotine in ZYN oral pouch products for aquatic animals

The agency calculated risk quotients for nicotine using estimated aquatic expected exposure concentration (EEC) and acute toxicity endpoint data (EC₅₀ or LC₅₀) as shown in the table below. The EEC was calculated using the highest concentration of nicotine added / pouch and the total projected 5th year market volume information provided by the applicant (Confidential Appendix 1).

Product	Aquatic Environmental Introduction Concentration (µg/L) ¹	lowest Acute Toxicity Endpoint Value (EC ₅₀ or LC ₅₀) (µg/L) ²	Species	Risk Quotient ³
ZYN Cool Mint 3 mg	(b)	(4)		
ZYN Cool Mint 6 mg				
ZYN Peppermint 3 mg				
ZYN Peppermint 6 mg				
ZYN Spearmint 3 mg				
ZYN Spearmint 6 mg				
ZYN Wintergreen 3 mg				
ZYN Wintergreen 6 mg				

¹ Expected Introduction Concentration (EIC)-aquatic (ppb or µg/L)=A*B*C*D; where A=kg/yr. shipped quantity, B=1/1.071x10¹¹ L/day entering POTW (Source: U.S. EPA. (2018). "Clean Watersheds Needs Survey (CWNS)." 2012 Data and Reports, Detailed Listing of Waste Water Treatment Plant Flows for the Nation), C=year/365, D=10⁹ µg/kg (Source of EIC estimation equation: Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications, 1998). Available from: <https://www.fda.gov/downloads/Drugs/Guidances/ucm070561.pdf>

² Lowest acute toxicity endpoint value and the corresponding species for each chemical obtained from U. S. Environmental Protection Agency's ECOTOXicology Knowledgebase (ECOTOX) available at <https://cfpub.epa.gov/ecotox/search.cfm> (retrieved December 22, 2021).

³ Risk Quotient (RQ) calculated as Expected Environmental Concentration (EEC)/LC₅₀ or EC₅₀ per U. S. Environmental Protection Agency methodology (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-risk>). For this analysis, the EEC values were assumed to equal the EIC values.

Product	Aquatic Environmental Introduction Concentration (µg/L) ¹	lowest Acute Toxicity Endpoint Value (EC50 or LC50) (µg/L) ²	Species	Risk Quotient ³
ZYN Citrus 3 mg	(b) (4)			
ZYN Citrus 6 mg				
ZYN Coffee 3 mg				
ZYN Coffee 6 mg				
ZYN Cinnamon 3 mg				
ZYN Cinnamon 6 mg				
ZYN Smooth 3 mg				
ZYN Smooth 6 mg				
ZYN Chill 3 mg				
ZYN Chill 6 mg				
ZYN Menthol 3 mg				
ZYN Menthol 6 mg				
Total				

CONFIDENTIAL APPENDIX 4

Estimates of total municipal solid waste generated from the disposal of the proposed MRTPs

Submission Tracking Number (STN)	Year 1	Year 5
	Total municipal solid waste generated (Metric Tons)*	
MR0000268.PD1	(b) (4)	
MR0000268.PD2		
MR0000268.PD3		
MR0000268.PD4		
MR0000268.PD5		
MR0000268.PD6		
MR0000268.PD7		
MR0000268.PD8		
MR0000268.PD9		
MR0000268.PD10		
MR0000268.PD11		
MR0000268.PD12		
MR0000268.PD13		
MR0000268.PD14		
MR0000268.PD15		
MR0000268.PD16		
MR0000268.PD17		
MR0000268.PD18		
MR0000268.PD19		
MR0000268.PD20		
Total		

*Estimates of total municipal solid waste was derived by multiplying the respective number of sales units for each product (Confidential Appendix 1) with (b) (4) grams per unit weight (Confidential Appendix 2).