

January 17, 2024

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA INC.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
Phone: (b) (6)
e-mail: g(b) (6)

FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Rm G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Subject: Solicited Updated Environmental Assessments for: General Snus FDA STNs:
MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9.**

Dear Secretary,

We received your correspondence dated November 30, 2023 (“the Filing Letter”), included as **Attachment A**, relating to the Agency’s preliminary review of certain MRTPAs that Swedish Match USA, Inc. (“Swedish Match”, “we”, “us” or “our”) had previously submitted on July 17, 2023, for the following products in Table 1 (collectively, the “MR reports”):

Table 1

- MR0000256.PD1: General Loose
- MR0000256.PD2: General Dry Mint Portion Original Mini
- MR0000256.PD3: General Portion Original Large
- MR0000256.PD4: General Classic Blend Portion White Large – 12ct
- MR0000256.PD5: General Mint Portion White Large
- MR0000256.PD7: General Nordic Mint Portion White Large – 12ct
- MR0000256.PD8: General Portion White Large
- MR0000256.PD9: General Wintergreen Portion White Large

Furthermore, we received correspondence dated November 30, 2023 (“the Courtesy Copy” mail), included as **Attachment B**, relating to Agency’s recommendation we submit updated Environmental Assessment (“EA”) information for the renewal applications MR0000256, and cross reference of additional post market information.

Swedish Match USA, Inc. (“Swedish Match” or “we”) submits this “Amendment” for the MRTPA’s listed above. The Amendment submission is for a group of tobacco products previously submitted as a grouped MRTPA renewal submission, FDA STNs: MR0000256.

Swedish Match is amending the MRTPA renewal submission to provide updated EA information for the renewal applications. Swedish Match requests to change its MRTPA renewal submission(s) contents. Specifically, the inclusion of our 2023 PMTA MRTP Postmarket Annual Report(s) (collectively, “2023 Annual Report”) to be incorporated by cross-reference. This additional content further supports the MRTPA renewal request. The Amendment is relevant to all amended products in this submission.

FDA Form 4057a – Premarket Tobacco Product Application Amendment and General Correspondence Submission(s) is included.

The Amendment contains non-public, trade secret, proprietary and confidential information that is protected under state and federal law from public disclosure. Swedish Match reserves the right to redact information it considers to be confidential prior to any part of the Amendment being made public. 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.

If further information is required, please contact me.

Sincerely yours,

(b) (6)

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

Document Attachments (List).

Attachment A – 20231222: CTP MRTPAs Filing Letter

Attachment B – 20231222: CTP MRTPAs Courtesy Copy Mail

FDA Form 4057a –General Correspondence Submission(s) is included.

Environmental Assessment (EA) Attachments (List).

Attachment EA – A – 20231222: General Loose

Attachment EA – B – 20231222: General Dry Mint Portion Original Mini

Attachment EA – C – 20231222: General Portion Original Large

Attachment EA – D – 20231222: General Classic Blend Portion White Large – 12ct

Attachment EA – E – 20231222: General Mint Portion White Large

Attachment EA – F – 20231222: General Nordic Mint Portion White Large – 12ct

Attachment EA – G – 20231222: General Portion White Large

Attachment EA – H – 20231222: General Wintergreen Portion White Large

Confidential Appendix (CA) Attachments (List).

Attachment CA – A – 20231222: General Loose Conf Appx

Attachment CA – B – 20231222: General Dry Mint Portion Original Mini Conf Appx

Attachment CA – C – 20231222: General Portion Original Large Conf Appx

Attachment CA – D – 20231222: General Classic Blend Portion White Large – 12ct Conf Appx

Attachment CA – E – 20231222: General Mint Portion White Large Conf Appx

Attachment CA – F – 20231222: General Nordic Mint Portion White Large – 12ct Conf Appx

Attachment CA – G – 20231222: General Portion White Large Conf Appx

Attachment CA – H – 20231222: General Wintergreen Portion White Large Conf Appx



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 30, 2023

FILING

Swedish Match U.S.A. Inc.
Attention: Gerard J. Roerty, Jr., General Counsel
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Gerard J. Roerty, Jr.:

We completed a preliminary review of your MRTPAs¹ and determined that these applications meet the filing requirements for a tobacco product seeking a modified risk order under section 911(d) of the FD&C Act.² As a result, the applications for the tobacco products identified in Appendix A are filed, effective the date of this letter.

The decision to file these MRTPAs does not mean FDA evaluated the adequacy of the data submitted or issued an authorization order. Rather, it represents a decision by the Center for Tobacco Products that the applications are sufficiently complete to enter substantive review phase. Please note, our filing review is only a preliminary evaluation of the applications and not indicative of deficiencies that may be identified during a substantive review. We will contact you if we have a request for any additional information.

Pursuant to section 911(e) of the FD&C Act, FDA will make your MRTPAs available to the public (except matters in the applications that are trade secrets or otherwise confidential, commercial information) and will request comments by interested persons on the information contained in the applications and on the label, labeling, and advertising accompanying the applications. Also, pursuant to Section 911(f) of the FD&C Act, FDA will refer your MRTPAs to the Tobacco Products Scientific Advisory Committee. Please be advised that a member of our Advisors and Consultants Staff will contact you regarding that process.

Your tobacco products specified in Appendix A are subject to the requirements of Chapter IX of the FD&C Act and its regulations. It is your responsibility to ensure that the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. For more information on your compliance responsibilities under the FD&C Act, we encourage you to visit our website.¹ You may also obtain information by contacting us at (877) CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

¹ <https://www.fda.gov/tobacco-products>

Multiple STNs, see Appendix A

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If you have any questions, please contact Tamirra Glover M.S., Regulatory Health Project Manager, at (301) 796-6727 or tamirra.glover@fda.hhs.gov.

Sincerely,

Digitally signed by Jennifer K.
Bernat -S
Date: 2023.11.30 07:11:16 -05'00'

Jennifer K. Bernat, Ph.D.
Supervisory Social Scientist
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – Tobacco Products Subject of This Letter

Appendix A
Tobacco Products Subject of This Letter

| Common Attributes ^{2,3,4,5,6,7} | |
|---|---|
| Submit date | July 17, 2023 |
| Receipt date | July 17, 2023 |
| Applicant | Swedish Match U.S.A. Inc. |
| Product manufacturer | Swedish Match U.S.A. Inc. |
| Product category | Smokeless Tobacco Products |
| Product order under 911(g) | 911(g)(1) Risk Modification Order |
| Proposed Modified Risk Claims | Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis. |
| Attributes | Tobacco Product |
| STN | MR0000256.PD1 |
| Product subcategory | Loose Snus |
| Product Name | General Loose |
| Package Type | Cardboard Can with Plastic Lid |
| Product Quantity | 45.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Tobacco |
| Additional Properties | Tobacco Cut Size: (b) (4) |

² Properties to uniquely identify the new tobacco products were provided by the applicant as of the date of this letter, and not confirmed by FDA. Upon scientific review, the unique identification may be revised.

³ We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

⁴ Product name is brand/sub-brand or other commercial name used in commercial distribution.

⁵ In addition to portion mass, the applicant submitted two of the three dimensions (i.e., portion length, portion width, portion thickness) which allowed for calculation of the third dimension.

⁶ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

⁷ The characterizing flavor previously identified as "None" has been updated to "Tobacco" to accurately reflect that the product provides a tobacco characterizing flavor from the filler. As such, this product does not have any change in characterizing flavor.

Multiple STNs, see Appendix A

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| Attributes | Tobacco Product |
|-------------------------|--|
| STN | MR0000256.PD2 |
| Product subcategory | Portioned Snus |
| Product Name | General Dry Mint Portion Original Mini |
| Package Type | Plastic Can with Lid |
| Product Quantity | 6.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Flavored |
| Flavored, as identified | Mint |
| Portion Count | 20 pouches |
| Portion Mass | 300 mg |
| Portion Length | 28 mm |
| Portion Width | 14 mm |
| Portion Thickness | 5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |
| STN | MR0000256.PD3 |
| Product subcategory | Portioned Snus |
| Product Name | General Portion Original Large |
| Package Type | Plastic Can with Lid |
| Product Quantity | 24.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Tobacco |
| Portion Count | 24 pouches |
| Portion Mass | 1000 mg |
| Portion Length | 33 mm |
| Portion Width | 18 mm |
| Portion Thickness | 6 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |
| STN | MR0000256.PD4 |
| Product subcategory | Portioned Snus |
| Product Name | General Classic Blend Portion White Large - 12ct |
| Package Type | Plastic Can with Lid |
| Product Quantity | 10.8 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Tobacco |
| Portion Count | 12 pouches |
| Portion Mass | 900 mg |
| Portion Length | 34 mm |
| Portion Width | 14 mm |
| Portion Thickness | 5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |

Multiple STNs, see Appendix A

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| Attributes | Tobacco Product |
|-------------------------|--|
| STN | MR0000256.PD5 |
| Product subcategory | Portioned Snus |
| Product Name | General Mint Portion White Large |
| Package Type | Plastic Can with Lid |
| Product Quantity | 24.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Flavored |
| Flavored, as identified | Mint |
| Portion Count | 24 pouches |
| Portion Mass | 1000 mg |
| Portion Length | 34 mm |
| Portion Width | 18 mm |
| Portion Thickness | 5.5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |
| STN | MR0000256.PD7 |
| Product subcategory | Portioned Snus |
| Product Name | General Nordic Mint Portion White Large - 12ct |
| Package Type | Plastic Can with Lid |
| Product Quantity | 10.8 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Flavored |
| Flavored, as identified | Mint |
| Portion Count | 12 pouches |
| Portion Mass | 900 mg |
| Portion Length | 34 mm |
| Portion Width | 14 mm |
| Portion Thickness | 5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |
| STN | MR0000256.PD8 |
| Product subcategory | Portioned Snus |
| Product Name | General Portion White Large |
| Package Type | Plastic Can with Lid |
| Product Quantity | 24.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Tobacco |
| Portion Count | 24 pouches |
| Portion Mass | 1000 mg |
| Portion Length | 34 mm |
| Portion Width | 18 mm |
| Portion Thickness | 5.5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |

Multiple STNs, see Appendix A

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| Attributes | Tobacco Product |
|-------------------------|---|
| STN | MR0000256.PD9 |
| Product subcategory | Portioned Snus |
| Product Name | General Wintergreen Portion White Large |
| Package Type | Plastic Can with Lid |
| Product Quantity | 24.0 g |
| Nicotine Source | Tobacco |
| Characterizing Flavor | Flavored |
| Flavored, as identified | Wintergreen |
| Portion Count | 24 pouches |
| Portion Mass | 1000 mg |
| Portion Length | 34 mm |
| Portion Width | 18 mm |
| Portion Thickness | 5.5 mm |
| Additional Properties | Tobacco Cut Size: (b) (4) |

From: Osemhen, Diana <Diana.Osemhen@fda.hhs.gov>
Sent: Thursday, November 30, 2023 9:06 AM
To: Gerry Roerty <gerry.roerty@swedishmatch.com>
Subject: Courtesy Copy of FDA Filing Letter for Swedish Match U.S.A. Inc. Issued on November 30, 2023

You don't often get email from diana.osemhen@fda.hhs.gov. [Learn why this is important](#)

Good morning Gerard Roerty Jr.,
FDA has issued a filing letter for Swedish Match U.S.A. Inc. for your MRTPA submission that was received on July 17, 2023. The filing letter was issued on November 30, 2023 and mailed to the address on file via UPS. A courtesy copy of your letter has been attached along with this email for your records. Please reply to this email to confirm the receipt of your letter issued.
During our filing review, we noticed additional postmarket information was submitted to FDA. If you want this and any future submissions to be included in review of your renewal, you will need to explicitly cross-reference them to the renewal STNs. Additionally, we recommend you consider submitting updated EA information for the renewal applications. Both of these should be provided in the form of an amendment.
With issuance of your filing letter, we are posting redacted copies of your renewal submission and cross-referenced submissions for public comment as required under 911(e). Additionally, FDA will be planning for a TPSAC meeting for the renewals. There are no additional details at this time, but FDA will be reaching out in the future to provide further information.

Regards,

Diana Osemhen

Regulatory Health Project Manager
Center for Tobacco Products|Office of Science
Email: diana.osemhen@fda.hhs.gov
Accelerate the transition to a healthier America



Premarket Tobacco Product Application Amendment and General Correspondence Submission

The Applicant Identification section is comprised of three parts: Current Applicant Information; Request to Change Ownership; and the Addition, Update, Replacement, or Removal of information. Please provide the Applicant information most recently provided to the FDA under the heading: Subsection A: Current Applicant Information. Please provide the proposed new Applicant information under the heading: Subsection B: Request for Change in Ownership. The addition of other new information should be provided under the heading: Subsection C: Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact.

SECTION I – APPLICANT IDENTIFICATION

Subsection A.

Current Applicant Information (The person or organization (manufacturer/importer) seeking a marketing granted order for a new tobacco product)

Date of Submission

January 17, 2024

Name of Applicant (Provide only either a person's name or an organization's name)

| | | | |
|--------------------------------------|---------------------------------------|------|----------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |

Organization Name

Swedish Match USA Inc.

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

(b) (4)

Company Headquarters' D&B DUNS® Number

(b) (4)

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

1021 E., Cary Street

| | | |
|--------------------------------------|---------|--------------------|
| Address 2 (Apt., Suite, Bldg., etc.) | | City |
| Suite 1600 | | Richmond |
| State, Province, or Territory | Country | ZIP or Postal Code |
| VA | USA | 23219 |

Current Contact Name (Optional, for use only if Applicant is an organization)

| | | | |
|--|---------------------------------------|------|-------------------------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Mr. | Gerard | J. | Roerty |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |
| Jr. | Esg. | | VP, Gen Counsel & Sec |
| Telephone (Include Country Code if applicable) | | FAX | Email Address |
| 804-787-5100 | | | gerry.roerty@swedishmatch.com |

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box)

☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Subsection B.**Request for Change in Ownership****Proposed New Applicant Information** *(Complete this section to change the current Applicant Information, the owner of the PMTA)*

Effective Date of Ownership Change

Name of Applicant *(Provide only either a person's name or an organization's name)*

Prefix (e.g., Mr., Mrs., Dr.)

First Name

M.I.

Last Name

Generational Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Organization Name

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B Duns® Number

Applicant Address and Contact Information

Primary Address (Street Address, P.O. Box)

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Telephone *(Include Country Code if applicable)*

FAX

Email Address

New Contact Name *(Optional, for use only if Applicant is an organization)*

Prefix (e.g., Mr., Mrs., Dr.)

First Name

M.I.

Last Name

Generational Suffix (e.g., Jr., III)

Professional Suffix (e.g., MD, Ph.D.)

Position Title

Telephone *(Include Country Code if applicable)*

FAX

Email Address

Organization Name and Address Information *(Optional, for use only if Applicant is an individual)*

Organization Name

Primary Address (Street Address, P.O. Box)

☐ Select for same address as New Applicant

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

☐ A notice is included stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new applicant.☐ A notice is included stating the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the PMTA.**Transfer Requests**☐ Request to transfer all related submissions for the named product(s) to the new owner

Tobacco Product Name (Brand/Sub-brand)

Related Submissions: List the FDA Submission Tracking Numbers (STNs) for all your previous submissions for the tobacco product.

| Related Submission Type | Related Submission STN | Submission Date |
|-------------------------|------------------------|-----------------|
| | | |

Subsection C.**Addition, Update, Replacement, or Removal of Applicant Identification Information or Point of Contact (Optional)****Addition, Update, Replacement, or Removal of Applicant Identification Information***If "Add" or "Replace" (not allowed for Current Applicant Information; use Subsection B.) is selected, provide all demographic information for the new party.**If "Update" is selected, provide only Person's Name and/or Organization's Name and the information which will replace previously submitted information.**If "Remove" is selected, provide only the Person's Name and/or Organization's Name of the party to be removed.*

Select type of Applicant Identification Information (Select only one)

- ☐ Applicant (Address and Contact information only) ☐ Authorized Representative ☐ U.S. Agent
☐ Manufacturer

Effective Date of Change

Select one *(If "Update" is selected, FDA will update the Applicant Identification address or contact information that was previously submitted):*

- ☐ Add ☐ Update ☐ Replace ☐ Remove

Person's Name *(Provide a person's name for Authorized Representative or U.S. Agent; optional for the Manufacturer)*

| | | | |
|--------------------------------------|---------------------------------------|------|----------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |

Organization Name (Provide an organization name for the Manufacturer)

Address and Contact Information

Primary Address (Street Address, P.O. Box; Provide the postal address for the Authorized Representative; optional for the Manufacturer or the U.S. Agent)

Street Address (Provide the physical location for the Manufacturer or the U.S. Agent; optional for the Authorized Representative)

| | | |
|--|---------|--------------------|
| Address 2 (Apt., Suite, Bldg., etc.) | | City |
| State, Province, or Territory | Country | ZIP or Postal Code |
| Telephone (Include Country Code if applicable) | FAX | Email Address |

New Contact Name *(Optional, for use only if Applicant is an organization; do not use in conjunction with Subsection B)*

| | | | |
|--|---------------------------------------|---------------|----------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |
| Telephone (Include Country Code if applicable) | FAX | Email Address | |

Organization Name and Address Information *(Optional, use for the Applicant only if a person (do not use in conjunction with Subsection B); also may be used for Authorized Representative, or U.S. Agent)*

Organization Name

Primary Address (Street Address, P.O. Box) ☐ Select for same address as New Applicant

| | | |
|--------------------------------------|---------|--------------------|
| Address 2 (Apt., Suite, Bldg., etc.) | | City |
| State, Province, or Territory | Country | ZIP or Postal Code |

Addition, Update, or Removal of Point of Contact

If "Add" is selected, provide all demographic information for the new party.

If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.

If "Remove" is selected, provide only the Company/Institution Name of the party to be removed.

Select type of Point of Contact Information (Select only one)

- | | | |
|-------------------------------------|--|--|
| <input type="checkbox"/> Applicant | <input type="checkbox"/> Manufacturer (Other than Applicant) | <input type="checkbox"/> Authorized Representative |
| <input type="checkbox"/> U.S. Agent | <input type="checkbox"/> Other, Regulatory | <input type="checkbox"/> Other, Technical |

Select one (If "Update" is selected, FDA will update the Point of Contact address or contact information that was previously submitted):

- ☐ Add ☐ Update ☐ Remove

Alternate Point of Contact Name

Company Name

| | | | |
|--------------------------------------|---------------------------------------|------|----------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |

Alternate Point of Contact Address and Contact Information

Primary Address (Street Address, P.O. Box)

| | | |
|--|---------|--------------------|
| Address 2 (Apt., Suite, Bldg., etc.) | | City |
| State, Province, or Territory | Country | ZIP or Postal Code |
| Telephone (Include Country Code if applicable) | FAX | Email Address |

SECTION II – TOBACCO PRODUCT INFORMATION

(Note: Use this section to correct previously submitted information. This section is not intended to be used in place of submissions required for modifications for new tobacco products)

Unique Identification of Previously Submitted New Tobacco Product

(This Subsection is optional and to be used only to change previously submitted information)

For individual tobacco products, fill in the Individual Tobacco Product sub-section below.

For a co-packaged tobacco product, complete Section II for each new tobacco product included within the co-package.

For grouped submissions complete a separate Section II for each tobacco product.)

Individual Tobacco Product

(Only the Previously Submitted New Tobacco Product Name is required. Provide other information only for updates to previously submitted information. Refer to Form 4057, Section VIII, Appendix B to select the appropriate Product Category and Subcategory or Tobacco Product Properties.)

Select to Update or Withdraw New Tobacco Product ☐ Update ☐ Withdraw

Previously Submitted New Tobacco Product Name (Brand/Sub-Brand)

Updated New Tobacco Product Name (Brand/Sub-Brand) *(if applicable)*

Update New Tobacco Product Category or Subcategory or Update New Tobacco Product Subcategory
(Complete only if Category or Subcategory is different than previously submitted)

Previously Submitted New Tobacco Product:

Category:

Subcategory:


Updated New Tobacco Product:

Category:

Subcategory:

Tobacco Product Properties Needed to Uniquely Identify the Product

(Update previously submitted Tobacco Product Properties Needed to Uniquely Identify Product by selecting Add, Update, or Remove and providing the Property Name. When updating properties provide both the previously submitted target value and the updated target value for the previously submitted new tobacco product.)

| | | New Tobacco Product Name (as provided above) | |
|---|---------------|--|----------------------|
| Action (Add, Update, Remove) | Property Name | Previously Submitted Target Value | Updated Target Value |
|  | | | |

To submit information on additional tobacco product(s), use one or more copies of Section II as appropriate.

SECTION III – SUBMISSION INFORMATION**Type of Submission (Select only one)**

- ☐ Amendment (If selected, provide Date of FDA Letter, if applicable; select Amendment Response Type; and indicate the Scientific Content in Section IV - Amendment Contents)
- ☒ General Correspondence *(if selected, provide Subject of Correspondence)*

FDA Submission Tracking Number (STN) to be amended:

Date of FDA Letter *(if applicable mm/dd/yy)*:

Amendment Response Type (Select one)

- ☐ Deficiency Letter
- ☐ Unsolicited (Describe in Submission Summary)
- ☐ Other (Describe in Submission Summary)

Subject of Correspondence (Select all that apply)

- ☐ Request for Change in Ownership (Section I)
- ☐ Change in Authorized Representative, U.S. Agent, or Manufacturer Address or Contact Information (Section I)
- ☐ Addition or Removal of a Point of Contact (Section I)
- ☐ Update to Unique Identification Information (Section II)
- ☒ Change in Cross-referenced Content or Related Submissions (Section III)
- ☐ Change in Submission Contents (Section IV)
- ☐ Change in Manufacturing/Packaging/Sterilization Site Information (Section V)
- ☐ Adverse Experience Report (Describe in Submission Summary)
- ☒ Periodic Report (e.g., Annual Report) (Describe in Submission Summary)
- ☐ Request to Withdraw the PMTA

☐ Select to indicate if the withdrawal is due to a health or safety concern related to the tobacco product

☒ Other (Describe in Submission Summary)

Submission Summary (Required if instructed to "Describe" by a previous selection)

Solicited MRTA Amendment(s) of Content and Updated Environmental Assessments for: General Snus FDA STNs: MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9. Content; the inclusion of our 2023 PMTA MRTTP Postmarket Annual Report(s) (collectively, 2023 Annual Report) to be incorporated by cross-reference.

Purpose of Application (Check only one)

- ☐ This PMTA Amendment is for a single new tobacco product
- ☐ This PMTA Amendment is for a group of PMTA Amendments containing multiple new tobacco products with similar modifications in comparison to one predicate tobacco product

Cross-referenced Content
(Optional, use this subsection to add new cross-referenced content, or update or remove previously submitted information)

Select to Add, Update, or Remove Cross-referenced Content

- ☒ Add
- ☐ Update
- ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

- ☒ Select if this update to Cross-referenced Content is relevant to all amended products in this submission

Identify Cross-referenced Submission Types as one of the following: PMTA, Tobacco Product Master File, or Modified Risk Tobacco Product (MRTPA)

| Cross-referenced Submission Type | Cross-referenced Submission STN |
|----------------------------------|---------------------------------|
| MRTPA | MR0000256 |
| | |
| | |

Related Submissions

(List the FDA Submission Tracking Numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable)

Select to Add, Update, or Remove Related Submissions

☐ Add ☒ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☒ Select if this update to Related Submission(s) is relevant to all amended products in this submission

| Related Submission Type | Related Submission STN |
|-------------------------|------------------------|
| MRTPA | MR0000256 |
| | |
| | |

Formal Meetings Held with FDA pertaining to this tobacco product

(For each meeting, as needed, enter the submission STN and meeting held date.)

Select to Add, Update, or Remove Formal Meetings Held with FDA

☐ Add ☐ Update ☐ Remove

New Tobacco Product Name (either previously submitted or updated name)

☐ Select if this update to Meeting(s) is relevant to all amended products in this submission

| Submission STN | Meeting Held Date |
|----------------|-------------------|
| | |
| | |
| | |

To submit information on additional tobacco product(s), use one or more copies of Section III as appropriate.

SECTION IV – AMENDMENT AND GENERAL CORRESPONDENCE CONTENTS

List all documents included in the PMTA Amendment, according to their respective subject area.

(Refer to Form 4057, Section IV - Application Contents for a representative list of content categories by subject area.)

Administrative

(List the categories of Administrative content provided by this Amendment)

Labeling and Marketing Plans

(List the categories of Labeling and Marketing Plans content provided by this Amendment)

Inspections

(List the categories of Inspections content provided by this Amendment)

Scientific Content*(Select the categories of Scientific Content provided by this Amendment)*

Description of Scientific Content:

Check all that apply

- | | |
|--|---|
| <input type="checkbox"/> General Information | <input type="checkbox"/> Literature Search |
| <input type="checkbox"/> Descriptive Information | <input type="checkbox"/> Organized References |
| <input type="checkbox"/> Product Samples | <input type="checkbox"/> Health Risk Investigations |
| <input type="checkbox"/> Statement of Compliance with 21 CFR part 25 | <input type="checkbox"/> Study Report(s) |
| <input type="checkbox"/> Summary | <input type="checkbox"/> Case Report Form(s) |
| <input type="checkbox"/> Product Formulation | <input type="checkbox"/> Analyzable Data Set(s) |
| <input type="checkbox"/> Manufacturing | |
| <input type="checkbox"/> Other (Specify below) | |

Other Content *(Describe the other content provided by this Amendment)*

Environmental Assessments and cross reference of post-market information, 2023 PMTA MRTP PostMarket Annual Report(s)

SECTION V – MANUFACTURING/PACKAGING/STERILIZATION SITE RELATING TO A SUBMISSION*(This section is optional.**If "Add" is selected, provide all demographic information for the new site.**If "Update" is selected, provide only Company/Institution Name and the information which will replace previously submitted information.**If "Remove" is selected, provide only the Company/Institution Name of the site to be removed.)*

Select to Add, Update, or Remove Manufacturing/Packaging/Sterilization Site

- ☐
- Add
- ☐
- Update
- ☐
- Remove

Company/Institution Name

Specify type of Manufacturing/Packaging/Sterilization site

- ☐
- Manufacturer
- ☐
- Contract Manufacturer
- ☐
- Contract Sterilizer
- ☐
- Re-packer/Relabeler

Company Headquarters' FDA-Assigned Facility Establishment ID (FEI) Number

Company Headquarters' D&B DUNS® Number

Division Name (if applicable)

Street Address (Physical location)

Address 2 (Apt., Suite, Bldg., etc.)

City

State, Province, or Territory

Country

ZIP or Postal Code

Telephone *(Include Country Code if applicable)*

FAX

Email Address

| Contact Name | | | |
|---|---------------------------------------|------|----------------|
| Prefix (e.g., Mr., Mrs., Dr.) | First Name | M.I. | Last Name |
| Generational Suffix (e.g., Jr., III) | Professional Suffix (e.g., MD, Ph.D.) | | Position Title |
| The Manufacturing/Packaging/Sterilization Site is ready for inspection <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |

SECTION VI – CERTIFICATION STATEMENT

Select one of the following, then enter Name of Applicant (or person signing on behalf of the Applicant if Applicant is an organization), Authorized Representative, or U.S. Agent, and the name of the Applicant in the body of the statement.

I am signing as a/an: ☐ Applicant ☒ Authorized Representative ☐ U.S. Agent

| | | | | |
|----|----------------------|------------|---------------------|---|
| I, | First Name Gerard | M.I. J. | Last Name Roerty | Generational Suffix (e.g., Jr., III) Jr. |
|----|----------------------|------------|---------------------|---|

on behalf of the applicant, Swedish Match USA Inc.

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 records remain readily available to the 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.

| | | | |
|-----------|---------|------|------------------|
| Signature | (b) (6) | Date | January 17, 2024 |
|-----------|---------|------|------------------|

**APPENDIX
INSTRUCTIONS FOR USE**

This form and the instructions for use are solely intended to provide the applicant an organized format to supply information required for a Premarket Tobacco Product Application (PMTA) Amendment and General Correspondence Submission.

Section I – Applicant Identification

Subsection A – Current Applicant Information

- Complete the Date of Submission
- Complete Name of Applicant name and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Complete Applicant address information as previously submitted, and optionally provide contact name, telephone, and email address. (Changes to the current Applicant information should be made only in Subsection C.)
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.

Subsection B – Request for Change in Ownership 21 CFR 1114.13

- Provide the effective date of the change in ownership.
- Complete the Name of the New Applicant and optionally other identifying information. Provide only either a person's name, if the Applicant is an individual, or an Organization Name.
- Provide the Applicant address information, and optionally provide contact name, telephone, and email address.
- If the Applicant is an individual, the Organization Name and Address associated with the individual may be provided.
- Indicate if any notices are included in the submission regarding the transfer of ownership. (List the notice(s) in Section IV under Administrative contents.)
- Indicate if you are transferring all related submissions related to a brand or brands. If so, provide the tobacco product names and corresponding STNs subject to the change in ownership

**Subsection C – Addition, Update, or Removal of Applicant Identification Information or Point of Contact
21 CFR 1114.9**

- Optionally select the type of Applicant information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, replace, or remove Applicant Information.
- To add a new party, complete all information. An Authorized Representative or U.S. Agent must be a person. Provide the person's name, address, and contact information.
- To update or remove party information, the Person's Name or Organization Name must match previously submitted information. For updates, the Address and Contact information provided will be used to update previously provided information.
- To replace a party, the Person's Name or Organization Name must match previously submitted information. It is not necessary to provide address information.
- To provide additional Applicant Identification Information, select "Update Additional Applicant Identification Information" on the form.
- Optionally select the type of Point of Contact information (e.g., Applicant, Authorized Representative, etc.) being provided.
- Optionally select to add, update, or remove Point of Contact information.
- Provide the Company Name associated with the Point of Contact
- To add a new Point of Contact, complete all information. Provide the contact's name, address, and contact information.
- To update or remove information for a Point of Contact, the Person's Name must match previously submitted information.
- To provide information for an addition Point of Contact, the Person's Name must match previously submitted information

Section II – Tobacco Product Identification 21 CFR 1114.7(c)

- For an individual tobacco product, provide the previously submitted new tobacco product's names.
 - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a co-packaged tobacco product, provide the new tobacco products' names for all products in the co-packaged tobacco product.
 - Product category, sub-category, and product properties should be provided only if they are changing. When updating product category, sub-category, or properties always give the both previously submitted and the updated information.
- For a grouped submission, add an individual or co-packaged tobacco product by selecting "Add Section II" on the form.

Section III – Submission Information

- Indicate whether the submission is an Amendment or General Correspondence.
 - For Amendments, provide the Date of FDA Letter, if applicable, and select the Amendment Response Type. If the type of response, is "Unsolicited" or "Other", describe the purpose of the submission in the Submission Summary. Also indicate the subject of the amendment provided in Section IV – Amendment and General Correspondence Contents.
 - For General Correspondence, select Subject(s) of Correspondence and provide the appropriate information in the Section indicated. If "Other", describe the subject of the correspondence in the Submission Summary. Also describe the subject of the correspondence in Section IV - Amendment and General Correspondence Contents
 - Provide the FDA STN being amended. The Premarket Tobacco Application Amendment and General Correspondence Submission should be used to update only one STN.
 - If instructed to do so, based on the selection of either Amendment Response Type or Subject of Correspondence, or otherwise optionally, complete the Submission Summary.
 - Indicate whether the Amendment submission is for a single individual tobacco product or for a group of tobacco products previously submitted as a grouped PMTA submission.
 - Optionally add, update, or remove cross-referenced content, including Tobacco Product Master Files
 - Provide the New Tobacco Product Name for which the cross-referenced content is relevant. Optionally, indicate if the content is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.
 - Provide metadata for each document to identify the cross-referenced content.
 - Select "Update Cross-Referenced Content Information" to add metadata for an additional document.
 - Optionally add, update, or remove related submissions, (e.g., ITP, SE Report, MRTPA).
 - Provide the New Tobacco Name for which the related submission is relevant. Optionally, indicate if the submission is relevant to all tobacco products which are the subject of this amendment submission. By selecting this checkbox, multiple products can be updated with one Section III. However, a Section II must be completed for each product updated by this amendment submission.
-

Section IV – Amendment and General Correspondence Contents

- Select the categories of document submitted from among Administrative, Labeling and Marketing Plans, Inspections, Scientific Content, or Other. For each category (except Scientific Content), list the sub-categories that describe the submission contents. For Scientific Content, select the all the content categories that apply to content provided in this amendment submission. For Scientific Content that does not fit into one of the listed categories, select “Other” and describe the content in the space provided.
- Submission Table of Contents: Optionally, select to add, replace, or suspend (i.e., remove from the active documents for review) submission documents. Provide metadata for each submission document: Action (Add, Replace, or Suspend), Date Document was Submitted if replacing or suspending, Document Filename, Document or Study Title, Table of Contents Category, and all applicable Document Keywords.
- To provide metadata for additional documents select “Update Submission Document”. (A Sample of Table of Contents can be found in CTP’s “Electronic Submission File Formats and Specifications”, Appendix A. The technical specification is posted on CTP’s public website page at the very bottom of the “Manufacturing” page under “Resources for Electronic Submissions”: <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing>)

Section V – Manufacturing/Packaging Sites Relating to a Submission

- Optionally select to add, update, or remove Manufacturing/Packaging Site information. To update or remove information for a Manufacturing/Packaging Site, the “Company/Institution Name” must match previously submitted information.
- If "Add" is selected, provide all demographic information for the new site. If "Update" is selected, provide only “Company/ Institution Name” and the information which will replace previously submitted information. If "Remove" is selected, provide only the "Company/ Institution Name" of the site to be removed.

Section VI – Certification Statement 21 CFR 1114.7(m)

- Select if the signer is acting as an Authorized Representative or U.S. Agent.
- Insert the name of the signer, and sign and date the form where indicated.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 10 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug
Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person
is not required to respond to, a collection of
information unless it displays a currently valid OMB
number."*



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration (“FDA” or “Agency”)’s regulations implementing the National Environmental Policy Act of 1969 (“NEPA”), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act (“FD&C Act”). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA’s potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), “There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.”

¹ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Trollhättégatan 1, 411 04 Göteborg (Gothenburg) Sweden |

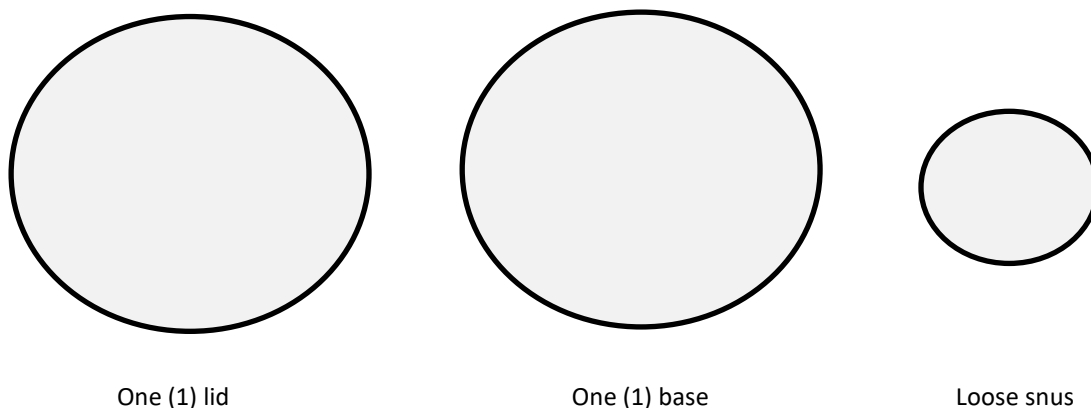
1.1.2. Product Information

| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|---------------------------------------|---|------------------------|
| General Loose | SKU #4852 | PM0000010 MR0000020 |

The proposed modified risk product ("PMRP") is a loose tobacco product within the statutory "smokeless" tobacco product sub-category. The net can weight is 45.0 g (1.59 oz).

The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section 910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable polypropylene resins:

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.



The snus is packaged in a polypropylene and cardboard primary container. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant cardboard can (container). The lid of the PMRP is composed of polypropylene resin. The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market volume projections for the PMRP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.
- b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product's label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB's facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product's label, labeling, or marketing material will not change any aspect of the location of the product's use relative to the currently marketed General Snus product.
- d. Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. *Environmental Issues*

1.1.5.1. *Introduction of Products into the Environment*

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a loose smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Gothenburg facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Gothenburg manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Gothenburg facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of cardboard cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will

not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Trollhättégatan 1, 411 04 Göteborg (Gothenburg) Sweden |

1.1.2. Product Information

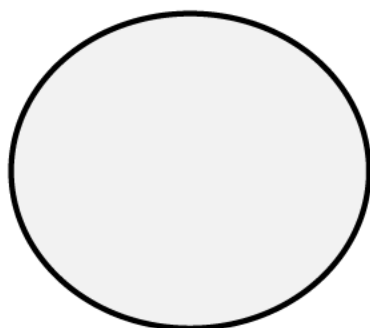
| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|--|---|------------------------|
| General Dry Mint Portion Original Mini | SKU #4800 | PM0000011 MR0000021 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 0.3 g, each can contains 20 pouches and the net can weight is 6 g (0.2 oz).

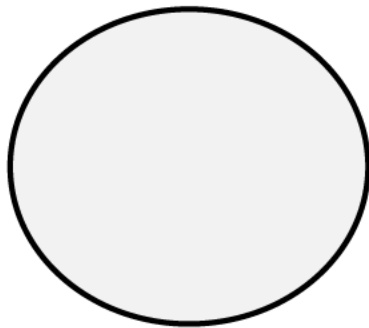
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section 910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

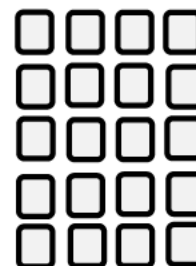
polypropylene resin. The product is packed into portioned pouches. Each container holds twenty (20) individual 0.3 g pouches:



One (1) lid



One (1) base



Twenty (20) pouches

The pouches are packaged in a polypropylene primary container, each containing 20 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 20 pouches. The container and the lid of the PMRP is composed of polypropylene resin. The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market volume projections for the PMRP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.
- b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. **Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.
- d. **Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. *Environmental Issues*

1.1.5.1. *Introduction of Products into the Environment*

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Gothenburg facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Gothenburg manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Gothenburg facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco

products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

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|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Trollhättégatan 1, 411 04 Göteborg (Gothenburg) Sweden |

1.1.2. Product Information

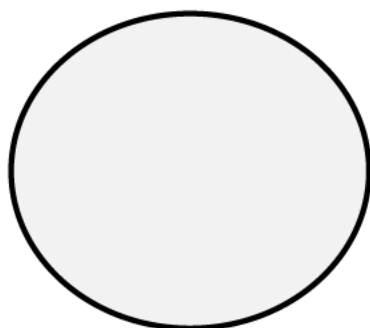
| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|---------------------------------------|---|------------------------|
| General Portion Original Large | SKU #4880 | PM0000012 MR0000022 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 1 g, each can contains 24 pouches and the net can weight is 24 g (0.9 oz).

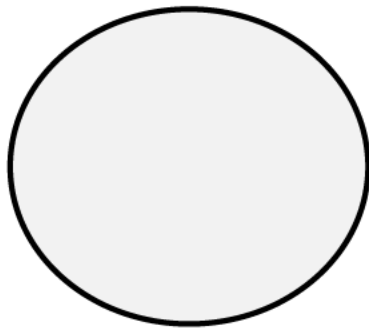
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section 910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

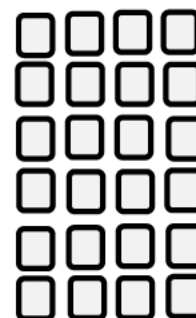
polypropylene resin. The product is packed into portioned pouches. Each container holds twenty-four (24) individual 1 g pouches:



One (1) lid



One (1) base



Twenty-four (24) pouches

The pouches are packaged in a polypropylene primary container, each containing 24 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 24 pouches. The container and the lid of the PMRP is composed of recyclable polypropylene resin with the resin identification code “5” contained within the Universal Recycling Symbol stamped into each respective component:



(Image not to scale)

The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market volume projections for the PMRP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.

b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

c. **Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.

d. **Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

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⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1.1.5. Environmental Issues

1.1.5.1. Introduction of Products into the Environment

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Gothenburg facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species")

and ESA (“Endangered Species Act”) due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Gothenburg manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company’s target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match’s expectation that, even with production of the PMRP, the Gothenburg facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and “spit,” if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP’s characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Trollhättégatan 1, 411 04 Göteborg (Gothenburg) Sweden |

1.1.2. Product Information

| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|--|---|------------------------|
| General Classic Blend Portion White Large | SKU #4878 | PM0000013 MR0000024 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 0.9 g, each can contains 12 pouches and the net can weight is 10.8 g (0.38 oz).

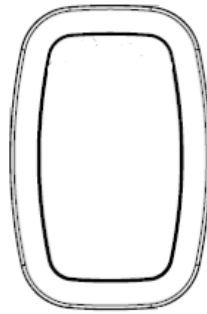
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section 910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

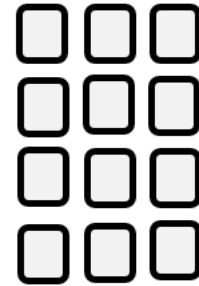
polypropylene resin. The product is packed into portioned pouches. Each ovular container holds twelve (12) individual 0.9 g pouches:



One (1) lid



One (1) base



Twelve (12) pouches

The pouches are packaged in a polypropylene primary container, each containing 12 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 12 pouches. The container and the lid of the PMRP is composed of polypropylene resin. The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market volume projections for the PMRP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.
- b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to

better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. **Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.
- d. **Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. *Environmental Issues*

1.1.5.1. *Introduction of Products into the Environment*

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Gothenburg facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Gothenburg manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Gothenburg facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco

products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date

(b) (6)

(Signa

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Rollsbovägen 45 Kungälv, SE - 442 40 Sweden |

1.1.2. Product Information

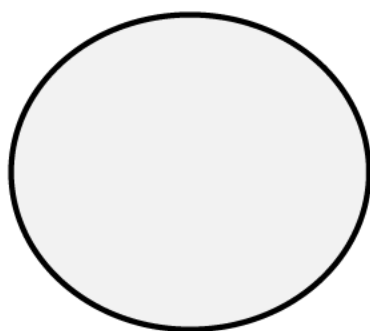
| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|----------------------------------|---|------------------------|
| General Mint Portion White Large | SKU #4352 | PM0000014 MR0000025 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 1 g, each can contains 24 pouches and the net can weight is 24 g (0.9 oz).

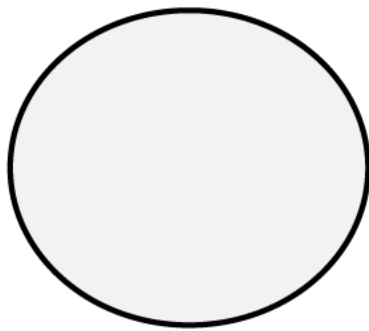
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

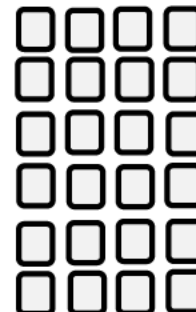
910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable polypropylene resin. The product is packed into portioned pouches. Each container holds twenty-four (24) individual 1 g pouches:



One (1) lid



One (1) base



Twenty-four (24) pouches

The pouches are packaged in a polypropylene primary container, each containing 24 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 24 pouches. The container and the lid of the PMRP is composed of recyclable polypropylene resin with the resin identification code “5” contained within the Universal Recycling Symbol stamped into each respective component:



(Image not to scale)

The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market

volume projections for the PMRP (see Table 1 in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.

- b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. **Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.
- d. **Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental

Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

(e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. Environmental Issues

1.1.5.1. Introduction of Products into the Environment

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Kungälv manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Kungälv facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently

marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. List of Preparers

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Trollhättégatan 1, 411 04 Göteborg (Gothenburg) Sweden |

1.1.2. Product Information

| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|---|---|------------------------|
| General Nordic Mint Portion White Large | SKU #4875 | PM0000015 MR0000027 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 0.9 g, each can contains 12 pouches and the net can weight is 10.8 g (0.38 oz).

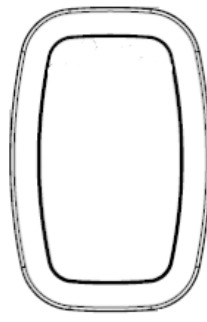
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section 910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

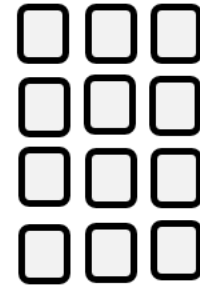
polypropylene resin. The product is packed into portioned pouches. Each ovular container holds twelve (12) individual 0.9 g pouches:



One (1) lid



One (1) base



Twelve (12) pouches

The pouches are packaged in a polypropylene primary container, each containing 12 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 12 pouches. The container and the lid of the PMRP is composed of polypropylene resin. The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market volume projections for the PMRP (see [Table 1](#) in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. **Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.
- b. **Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to

better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. **Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.
- d. **Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. *Environmental Issues*

1.1.5.1. *Introduction of Products into the Environment*

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Gothenburg facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Gothenburg manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Gothenburg facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Gothenburg facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco

products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Rollsbovägen 45 Kungälv, SE - 442 40 Sweden |

1.1.2. Product Information

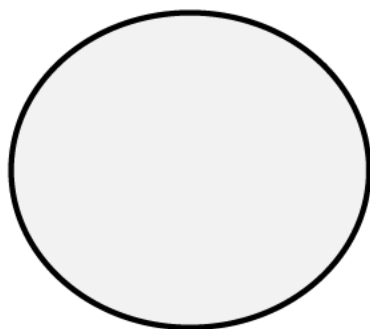
| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|---------------------------------------|---|------------------------|
| General Portion White Large | SKU #4881 | PM0000016 MR0000028 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 1 g, each can contains 24 pouches and the net can weight is 24 g (0.9 oz).

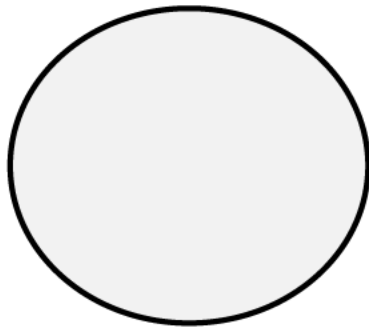
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

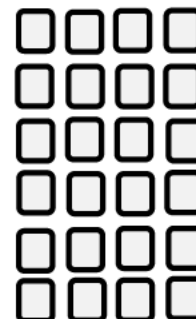
910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable polypropylene resin. The product is packed into portioned pouches. Each container holds twenty-four (24) individual 1 g pouches:



One (1) lid



One (1) base



Twenty-four (24) pouches

The pouches are packaged in a polypropylene primary container, each containing 24 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 24 pouches. The container and the lid of the PMRP is composed of recyclable polypropylene resin with the resin identification code “5” contained within the Universal Recycling Symbol stamped into each respective component:



(Image not to scale)

The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market

volume projections for the PMRP (see Table 1 in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

- a. Requested Action:** Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.

- b. Need for Action:** Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

- c. Location of Use:** The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.
- d. Location of Disposal:** Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental

Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

(e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. Environmental Issues

1.1.5.1. Introduction of Products into the Environment

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Kungälv manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Kungälv facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Kungälv facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently

marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)



Environmental Assessment for the General Snus Proposed Modified Risk Product

Environmental Assessment for a Marketing Authorization for a Non-Combusted, Smoke-free, Spit-free,
Tobacco Product produced by Swedish Match

Prepared by Swedish Match USA, Inc.

January 17, 2024

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration is the issuance of a modified risk tobacco product order for the General Snus product manufactured by Swedish Match. We wish to commercially distribute the proposed modified risk tobacco product in interstate commerce in the U.S. As detailed below, there is no significant¹ environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the proposed modified risk product into the U.S. market may exist in that manufacturing the product may result in a decrease of highly wasteful combustible products, e.g., cigarettes. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

¹ Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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1.1. Environmental Assessment

1.1.1. Applicant and Manufacturer Information

| | |
|---|---|
| Applicant/Submitter Name:² | Gerard J. Roerty, Jr., Esq. Vice President, General Counsel & Secretary Swedish Match USA, Inc. |
| Applicant/Submitter Address: | Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219 USA |
| Product Manufacturing Location Name and Address: | Swedish Match North Europe AB Rollsbovägen 45 Kungälv, SE - 442 40 Sweden |

1.1.2. Product Information

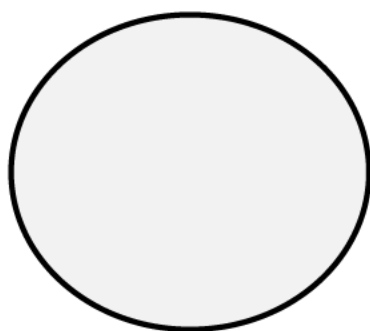
| New Tobacco Product Trade Name | SM Unique ID no. Stock-Keeping Unit ("SKU"): ID# | FDA-STN Numbers |
|---|---|------------------------|
| General Wintergreen Portion White Large | SKU #4882 | PM0000017 MR0000029 |

The proposed modified risk product ("PMRP") is a portioned pouched tobacco product within the statutory "smokeless" tobacco product sub-category. The portion weight for each pouch is 1 g, each can contains 24 pouches and the net can weight is 24 g (0.9 oz).

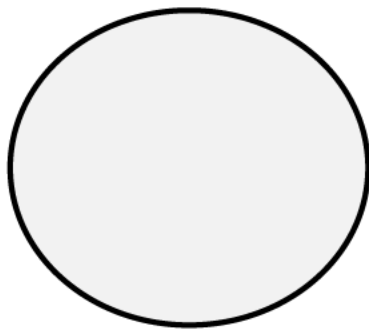
The PMRP's application has been submitted in compliance with section 905(j) of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (i.e., section

² Swedish Match is both the manufacturer and importer of the proposed modified risk tobacco product. As Swedish Match USA, Inc. is the importer of snus products manufactured by Swedish Match North Europe AB, the marketing authorization, labeling requirements, and user fee requirements, would be satisfied per section 910 of the Federal Food, Drug, and Cosmetic Act. The manufacturing location and manufacturing controls remain unchanged from our previous applications.

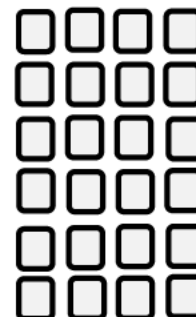
910(a)(1)(A) of the Act). The product is packaged in a container manufactured out of recyclable polypropylene resin. The product is packed into portioned pouches. Each container holds twenty-four (24) individual 1 g pouches:



One (1) lid



One (1) base



Twenty-four (24) pouches

The pouches are packaged in a polypropylene primary container, each containing 24 pouches. The primary container is wrapped into five can rolls (i.e., secondary container). The rolls are packed into a corrugated cardboard case (i.e., tertiary container) containing 18 rolls per case, for a total of 90 cans per case.

The primary packaging of the PMRP consists of a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant polypropylene can (container) and lid, which is designed to contain 24 pouches. The container and the lid of the PMRP is composed of recyclable polypropylene resin with the resin identification code “5” contained within the Universal Recycling Symbol stamped into each respective component:



(Image not to scale)

The packaging material description, ingredients, dimensions, and regulatory authority are found in the Confidential Appendix to the Environmental Assessment (see [Table 2](#) in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the PMRP, Swedish Match is providing forecasted Year One (2024) and Year Five (2028) data of market

volume projections for the PMRP (see Table 1 in the Confidential Appendix to the Environmental Assessment).

1.1.3. Description of Proposed Action

a. Requested Action: Renewal of a modified risk tobacco product order under Section 911(g) of the FDCA.

b. Need for Action: Swedish Match proposes to amend the marketing of its General Snus product, which is currently marketed in the United States. In particular, Swedish Match seeks to continue certain product specific modifications to the label, labeling, and marketing material in order to better communicate to consumers the risks of General Snus relative to other commercially marketed tobacco products:

“Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

No other changes will be made to the product’s label, labeling, and marketing material. Swedish Match wishes to continue commercially distributing the General Snus tobacco product in interstate commerce in the United States (“U.S.”). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the PMRP is found appropriate for the protection of public health.

c. Location of Use: The product will continue to be manufactured at Swedish Match North Europe AB’s facilities in Sweden and imported by Swedish Match USA Inc. The product will likewise continue to be sold to consumers at a variety of retail establishments, and consumed primarily in homes and automobiles. The PMRP will be widely distributed, and use of the PMRP will correspond with national population density, as do other smokeless tobacco and snus products. The modification of the product’s label, labeling, or marketing material will not change any aspect of the location of the product’s use relative to the currently marketed General Snus product.

d. Location of Disposal: Used tobacco products and empty packaging, including those associated with the PMRP, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in Swedish Match smokeless tobacco products. According to the U.S. Environmental

Protection Agency,³ regarding municipal solid waste in the United States, about 52.3% of municipal solid waste was land disposed, 12.7% was combusted, and 35.0% was recovered (recycled and composted). The types of environments present at, and adjacent to, these disposal locations will not differ for the PMRP relative to the currently marketed General Snus product.

Each individual General Snus SKU currently sold on the U.S. market represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the U.S., per the 2016 FTC Smokeless Tobacco Report. The PMRP would be expected to continue this trend: each PMRP SKU would also represent less than 1% of smokeless tobacco sold in the U.S. Accordingly, the PMRP would not significantly⁴ alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

1.1.4. *Alternative to the Proposed Action*

An alternative to the proposed action would be if FDA does not issue a marketing authorization for the proposed modified risk tobacco product. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows in Novotny et al. (2015):⁵

Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered

³ See https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

⁴ Swedish Match uses the term “significantly” as defined at 40 CFR 1508.27.

⁵ Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

(e.g., see Action Research, 2009).⁶ Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

1.1.5. Environmental Issues

1.1.5.1. Introduction of Products into the Environment

The PMRP is not expected to raise any new or additional environmental concerns relative to other tobacco product categories currently sold on the U.S. market. The PMRP, a portioned smokeless tobacco product, reasonably would not be introducing materials or ingredients that are new and novel, relative to materials and ingredients currently sold in the U.S. market. The PMRP is intended to offer alternatives to prevalent and wasteful tobacco product categories (e.g., combustible cigarettes). Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco product categories. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

Amending the marketing associated with the General Snus product is not expected to result in any new or additional adverse environmental impacts. The product with the amended marketing is expected to replace the currently-marketed snus product. Therefore, its manufacture, transport, use and disposal are not expected to contribute to any significant new or additional environmental impacts. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S. Thus any potential increase in the production, transport, use or disposal of the snus product with the revised product marketing is expected to result in a reduction in the sales, production, use and disposal of other tobacco products. As a result, there are not likely to be any added environmental impacts as a result of the marketing change.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects, and there are a great deal of national laws and regulations with which companies comply. Swedish Match's manufacturing location is in compliance with all environmental laws today, and there is no risk in terms of critical habitats, animal species or plants.

⁶ Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the PMRP, or from the production of the PMRP. The plant based materials or ingredients used in the PMRP are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the PMRP. There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the PMRP; (ii) the manufacturing process itself; (iii) the disposal of the PMRP. No expansion of the Kungälv manufacturing facility regarding the PMRP for the U.S. market has occurred or is planned.

1.1.5.2. As a Result of Manufacture and Transport

As discussed in the foregoing application, there are no extraordinary or unusual circumstances associated with the manufacture of this tobacco product compared to other commercially available tobacco products.

We do not expect a significant increase in manufacturing due to the PMRP. No 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 would be needed.

In the time period covered by this EA, waste (in metric tons) generated from the production of all existing tobacco products manufactured at the Kungälv facility is not projected to significantly increase from 2024 - 2028. We anticipate the waste generated from the facility for the manufacturing of these products to be in line with historic trends.

Energy use for the time frame covered by this environmental assessment would not be expected to significantly increase due to production of the PMRP. We anticipate the energy use from the facility for the manufacturing of these products to be in line with historic trends.

It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with production of the PMRP, the Kungälv facility would maintain target goals of continual GHG emission reductions.

1.1.5.3. As a Result of Use

The PMRP will be used similarly to other portioned smokeless tobacco products. No environmental effects of disposal of used product and "spit," if any, generated during product use are anticipated. Contents of the pouch are gradually extracted during use, which should not result in spitting. The pouch will then be disposed of in trash receptacles. The use of the PMRP would result in the direct introduction of little or no change in the complexity of the ingredients nor any of the other ingredients into the environment because these ingredients are consumed during use.

The PMRP's characteristics are similar to other portioned smokeless tobacco products in the market. Further, there is a high likelihood that certain tobacco product users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

1.1.5.4. As a Result of Disposal

The proposed modified risk product and any associated waste will be disposed of in the same manner as the currently marketed General Snus product. Product containers (composed of plastic cans with plastic lids) are not intended for repeat use. Disposal by the ultimate user of the tobacco product, and any other waste material, will be by conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. The proposed modification to the product marketing may result in an increase in product sales. However, this increase is expected to be offset by the potential reduction in the use of other tobacco products. Moreover, the PMRP is expected to comprise less than 1% of the total tobacco sales in the United States, and waste from the product will make up a very small portion of total municipal solid waste. It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

a. Fate of products released into the environment

The PMRP is expected to enter into the environment in extremely small quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any of the materials from this product will be different from snus products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

b. Environmental effects of released products

Only extremely small quantities of the ingredients of the PMRP, if any, are expected to be released into the environment through leeching and combustion, and this quantity is not expected to be any different than the currently marketed product. Consequently, no adverse effects on organisms in the environment are expected.

c. Use of Resources and Energy

As is the case with other smokeless tobacco and snus products and their ingredients, the production, use, and disposal of the PMRP and its ingredients require the use of natural resources such as petroleum products and coal. However, the PMRP will not differ from the currently

marketed product in this respect, especially given that production occurs in Sweden and is, in all respects, the same as for the currently marketed product.

1.1.6. Mitigation Measures

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

1.1.7. Alternatives to the Proposed Action

An alternative to the proposed action would be if a marketing order is not issued. The environmental impact of this action would not change the existing condition.

1.1.8. List of Preparers

Gerard J. Roerty, Jr., Swedish Match USA, Inc.

Title: General Counsel, Swedish Match

Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame

Experience: 26+ years with the company, charged with regulatory compliance

Expertise: Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.

Title: Director Compliance & Risk Management

Education: B.S., Chemistry, Brescia University

Experience: 39 years in various product development and regulatory activities

Expertise: Scientific and Regulatory Affairs

Joshua Schendel, Ph.D., Swedish Match USA, Inc.

Title: Regulatory Social Research Scientist

Education: Ph.D. and M.A. in Anthropology, The University of Tennessee; B.A., The College of William and Mary

Experience: 9+ years in relevant scientific and regulatory activities

Expertise: Scientific and Regulatory Affairs

1.1.9. Agencies and Persons Consulted

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

January 17, 2024

(Date)

(b) (6)

(Signature of responsible official)

Gerard Roerty, Jr. VP, General Counsel & Sec.

(Name and title of responsible official, printed)

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|----------------|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Loose | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

The packaging components for the General Loose (SKU #4852) product are sold to retail in 90 can cardboard cases, consisting of eighteen (18) 5-can rolls. The packaging unit of sale is a 21 Code of Federal Regulations (CFR) 177.1520(c)-compliant copolymer polypropylene resin lid, and a cardboard can, with a silver polyethylene side label. For shipping and retail sale, the secondary packaging consists of rolls containing five cans per roll using low-density polyethylene (LDPE) shrink film. The rolls are packed in corrugated cardboard cases, sealed with clear carton sealing tape composed of polypropylene. Table 2, below, summarizes the packaging component information.

Table 2: Packing Component Information

| | | Ingredients | Material Description | Dimensions | Regulatory Authority |
|---------|-----------|---|----------------------|------------|----------------------|
| Item # | Item Name | Proposed Modified Risk Product (SKU 4852) | | | |
| (b) (4) | | | | | |

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|---|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Dry Mint Portion Original Mini | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packing Component Information

| | | Ingredients | Material Description | Dimensions | Regulatory Authority |
|--------|-----------|---|----------------------|------------|----------------------|
| Item # | Item Name | Proposed Modified Risk Product (SKU 4800) | | | |
| 1 | (b) (4) | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |

(b) (4)

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|--------------------------------|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Portion Original Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packing Component Information

| | | Ingredients | Material Description | Dimensions | Regulatory Authority |
|---------|-----------|---|----------------------|------------|----------------------|
| Item# | Item Name | Proposed Modified Risk Product (SKU 4352) | | | |
| (b) (4) | | | | | |

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|--|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Classic Blend Portion White Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packing Component Information

| | | Ingredients | Material Description | Dimensions | Regulatory Authority |
|---------|-----------|---|----------------------|------------|----------------------|
| Item # | Item Name | Proposed Modified Risk Product (SKU 4878) | | | |
| (b) (4) | | | | | |

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|-------------------------------------|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Mint Portion White Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packing Component Information

| Item # | Item Name | Ingredients | Material Description | Dimensions | Regulatory Authority |
|--------|-----------|---|----------------------|------------|----------------------|
| | | Proposed Modified Risk Product (SKU 4352) | | | |

(b) (4)

(b) (4)

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

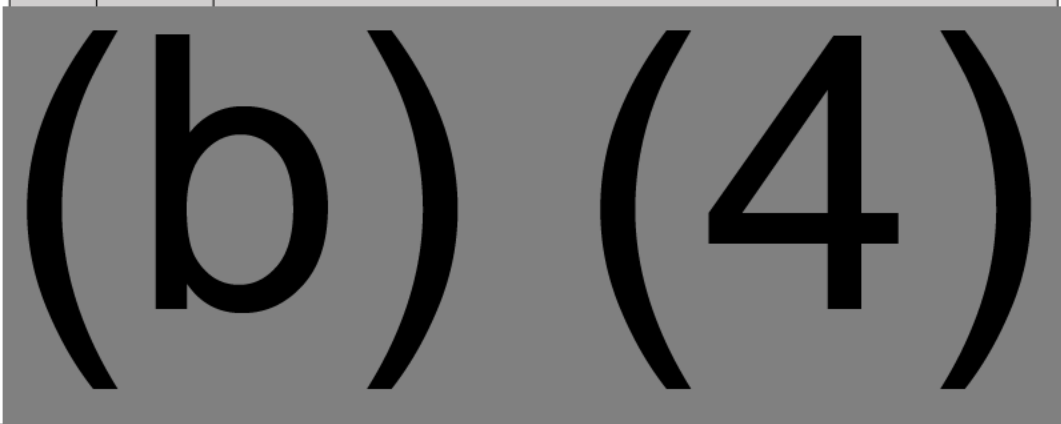
In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|--|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Nordic Mint Portion White Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:**Table 2: Packing Component Information**

| | | Ingredients | Material Description | Dimensions | Regulatory Authority |
|--------|-----------|---|----------------------|------------|----------------------|
| Item # | Item Name | Proposed Modified Risk Product (SKU 4875) | | | |



(b) (4)

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|-----------------------------|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Portion White Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packaging Component Information

| Item# | Item Name | Ingredients | Material Description | Dimensions | Regulatory Authority |
|-------|-----------|---|----------------------|------------|----------------------|
| | | Proposed Modified Risk Product (SKU 4831) | | | |

(b) (4)

(b) (4)

CONFIDENTIAL APPENDIX TO THE ENVIRONMENTAL ASSESSMENT**Projections of Market Volume:**

In Table 1 below, Swedish Match provides projected volumes for the 1st and 5th years of sales of the proposed modified risk tobacco product.

Table 1: Projected Volume:

| Brand/SubBrand | Measure | Projected Volume | |
|--|--------------------|------------------|------------------|
| | | Year 1 (2024) | Year 5 (2028) |
| General Wintergreen Portion White Large | Units (containers) | (b) (4) | |
| | Metric Tons | | |

Packaging Component Information:

(b) (4)

Table 2: Packaging Component Information

| Item# | Item Name | Ingredients | Material Description | Dimensions | Regulatory Authority |
|-------|-----------|---|----------------------|------------|----------------------|
| | | Proposed Modified Risk Product (SKU 4882) | | | |
| | | (b) (4) | | | |
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(b) (4)