

**Programmatic Environmental Assessment for
Market Authorizations of “Timber Wolf Pouches
Wintergreen and Timber Wolf Pouches Natural”**

Prepared by Center for Tobacco Products U.S.

Food and Drug Administration

December 30, 2015

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This programmatic environmental assessment (PEA) is for the market authorizations of two smokeless tobacco products, portioned moist snuff, manufactured by “Swedish Match North America, Inc.” Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance with 21 CFR 25.40 in support of the market authorization orders under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

Swedish Match North America, Inc.

2. Address

Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

3. Manufacturer

Swedish Match North America, Inc.

4. Description of the Proposed Action

The proposed action is for FDA to issue market authorizations under section 910(a)(2) of the FD&C Act for the introduction of two smokeless tobacco products into interstate commerce. The Agency has found the new smokeless tobacco products to be substantially equivalent to the predicate products, Timber Wolf Packs Wintergreen and Timber Wolf Packs Natural, that were on the market as of February 15, 2007.

4.1. Requested Action

Orders finding the listed tobacco products are substantially equivalent to the corresponding predicate products.

4.2. Need for Action

Swedish Match North America Inc. wishes to introduce the new tobacco products (as described) into interstate commerce for commercial distribution in the United States (U.S.). The applicant claims that the new products and the corresponding predicate products have the same characteristics (sec. 910(a)(3)(A)(i)) as described in FDA guidance to industry issued on March 4, 2015 .¹ After considering the SE Reports, the Agency shall issue orders pursuant to section 910(a)(2) of the FD&C Act when finding the new products to have the same characteristics as the predicate product.

¹ FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions. Issued March 4, 2015. Available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>. Accessed on December 28, 2015)

4.3. Identification of the New Tobacco Products that are Subjects of the Proposed Action

4.3.1. Type of Tobacco Products

Smokeless tobacco product, portioned moist snuff.

4.3.2. Names of Tobacco Products

Names of the new products are listed below (Also see Appendix 1 for submission tracking numbers (STNs) associated with the new products and their corresponding predicate products).

STNs	New Product	Predicate Product
SE0012445	Timber Wolf Pouches Wintergreen	Timber Wolf Packs Wintergreen
SE0012446	Timber Wolf Pouches Natural	Timber Wolf Packs Natural

4.3.3. Description of the Product Package

The new products are portioned moist snuff smokeless tobacco products. Fifteen pouches of the snuff are contained in a can and five cans are combined into a roll by wrapping them with a shrink film. Eighteen rolls are combined into a ninety-can corrugated cardboard shipping case.

4.3.4. Location of Manufacturing

1121 Industrial Drive,
Owensboro,
KY 42301

4.3.5. Location of Use

Swedish Match North America Inc. intends to distribute and sell the new tobacco products to consumers in the U.S.

4.3.6. Location of Disposal

The used and unused portioned moist snuff will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as any other marketed portioned moist snuff. Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of the product use.

4.4. Modification(s) Identified as Compared to the Predicate Products

The applicant claims that a change in product name is the only difference between the new products and their corresponding predicate products.

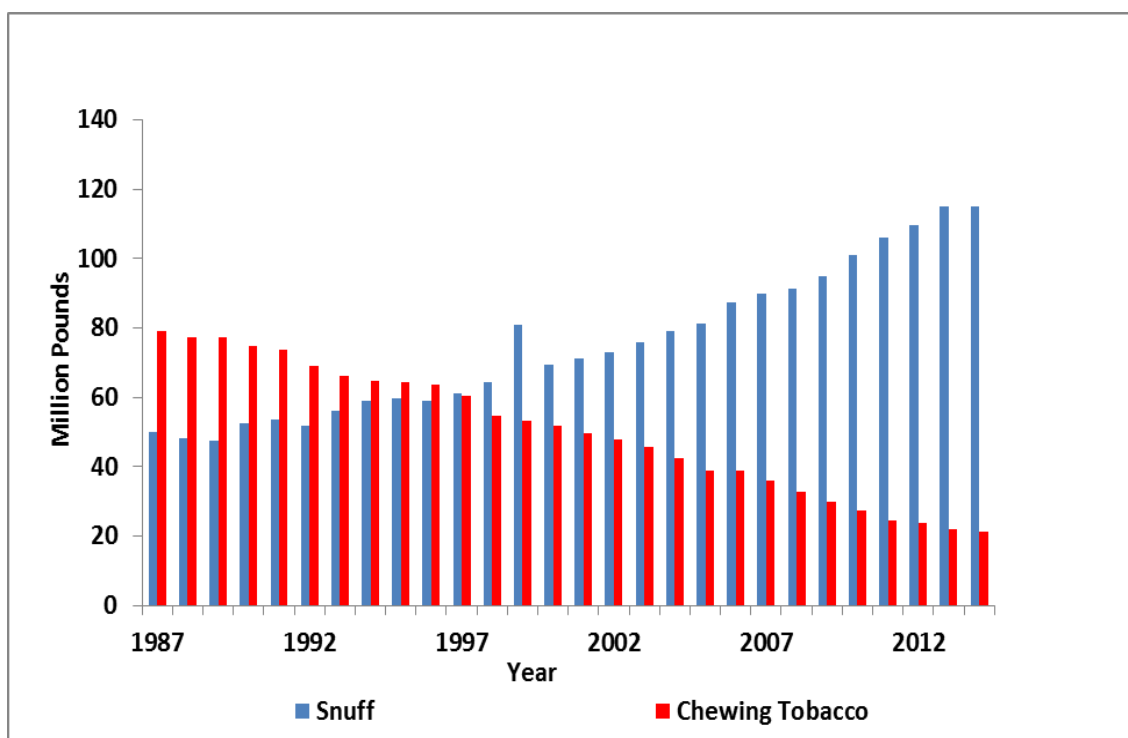
5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Products

5.1.1 *Smokeless Tobacco Product Manufacture in the U.S.*

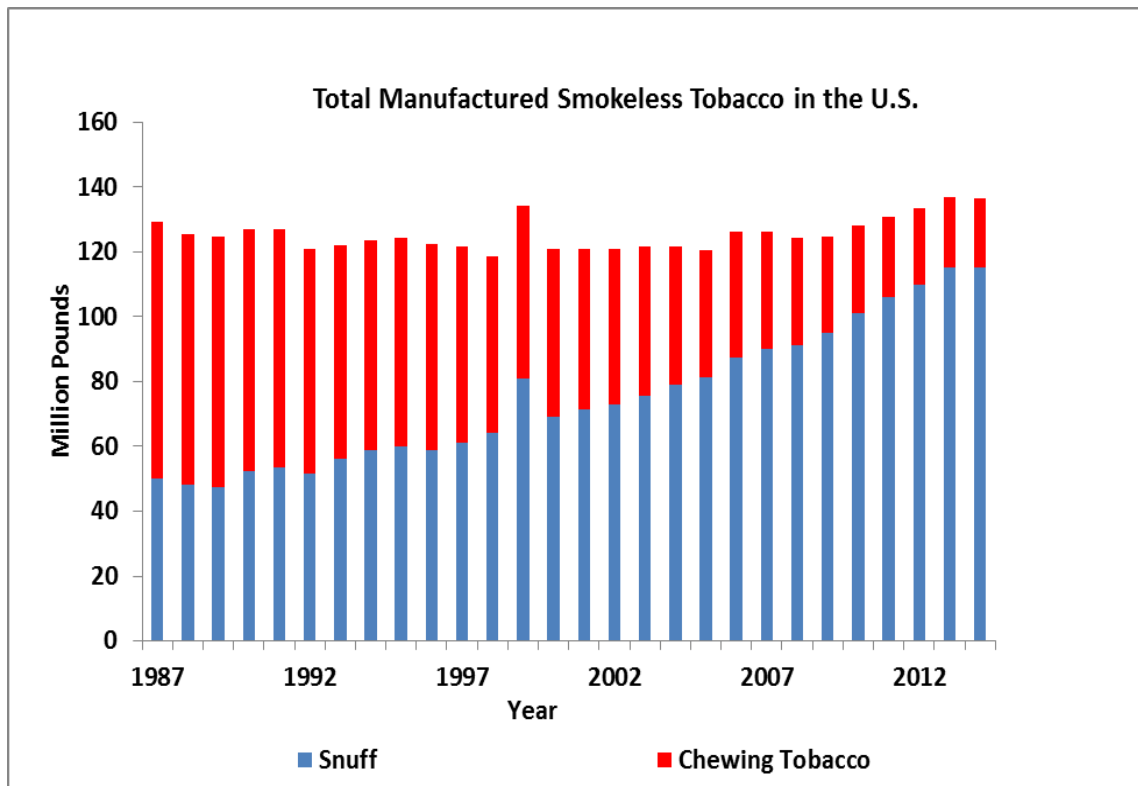
Smokeless tobacco products are moist snuff, chew, snus, dry snuff, and dissolvable products. According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) production of chewing tobacco decreased to 21 million pounds in 2014 from 79 million pounds in 1987; snus production increased tenfold from 1986 to 2014, from 12 million pounds to 115 million pounds (Figure 1).² However, combined production remained almost constant and did not change over the years (Figure 2).

Figure 1 Manufactured Snus and Chewing Tobacco in the U.S. 1986-2014



² U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 13, 2015.

Figure 2. Total Manufactured Smokeless Tobacco in the U.S in 1986 – 2014¹



No environmental emission information on portioned moist snuff is available to the Agency; however, the emission information associated with all tobacco products as reported in the EPA’s Toxic Release Inventory (TRI) program is publicly available.³ U.S. tobacco manufacturers released 438,000 pounds of ammonia and 255,000 pounds of nicotine and salts to the air;⁴ no ammonia to the land;⁵ 167 pounds of ammonia and 276 pounds of nicotine and salts to the water;⁶ and 28,653 pounds of ammonia and 84,843

³ The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the U.S., including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical (<http://www.epa.gov/tri/trichemicals/listchanges/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

⁴ http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=air_total_release

⁵ http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=land_total_release

⁶ http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=water_total_release

pounds of nicotine and salts transferred to publicly owned treatment works (POTWs) or an off-site location.⁷ A search in the TRI database found no record on toxic chemicals registered for Swedish Match North America Inc.

5.1.2 Environmental Introduction from Manufacturing the New Products

Introduction from manufacturing new products in the proposed actions. The Agency anticipates the waste generated as a result of manufacturing the new products will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as any other products manufactured in the same facility and in a similar manner to other portioned moist snuff manufactured in the U.S. In addition, the new products are anticipated to compete with other portioned moist snuff and therefore, the Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all smokeless tobacco.

Based on information in the SE Reports, the only difference between the new products and the predicate products are in name. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

To evaluate the environmental impact of the proposed action due to manufacturing of the new products, historic data regarding manufacturing of smokeless tobacco from 2005 to 2014 was used to forecast the use of smokeless tobacco products. This was achieved by using one best-fit linear trend line with the R² value of 0.99 and 0.97 for snuff and chewing tobacco, respectively. Accordingly, the forecasted amounts of snuff and chewing tobacco in the U.S. are estimated to be 128 and 18 million pounds in 2015 and 150 and 13 million pounds in 2020, respectively (Appendix 2).

The applicant provided the first- and fifth-year market volumes for the new products (See Confidential Appendix 1). Comparing the projected market volumes of the new products with the forecasted market volumes of snuff manufactured in the U.S. in 2015 and 2020, the individual and cumulative projected market volumes of the new products are small fractions of the total forecasted market volumes in 2015 and 2020. (See Appendix 2 and Confidential Appendix 1). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

Furthermore, the applicant provided information on the manufacturer's operating permit issued by the Kentucky Department for Environmental Protection. The permit is applicable for air emission, storm water discharges, wastewater discharges, and solid and liquid waste. The permit expires in January 2020. The applicant stated that the facility complies with all requirements mentioned in the permit.

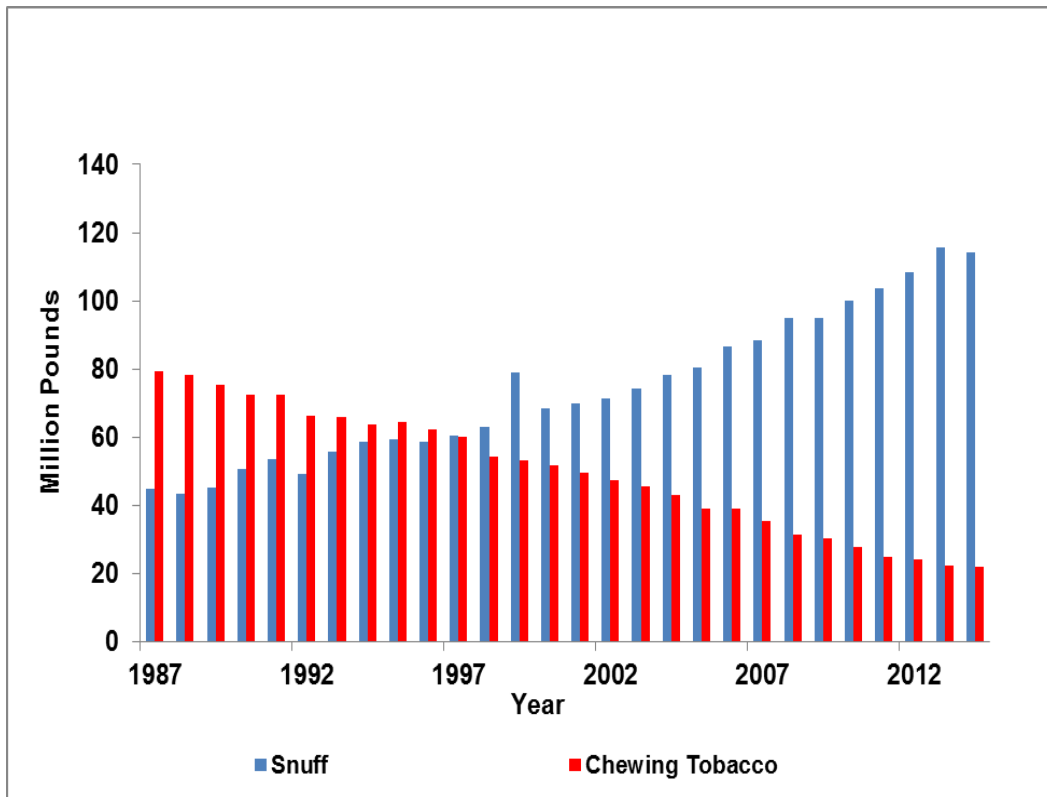
⁷ http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=off_site_total_transfers

5.2. Environmental Introduction as a Result of Use of the New Products

5.2.1 Use of Smokeless Tobacco Products in the U.S.

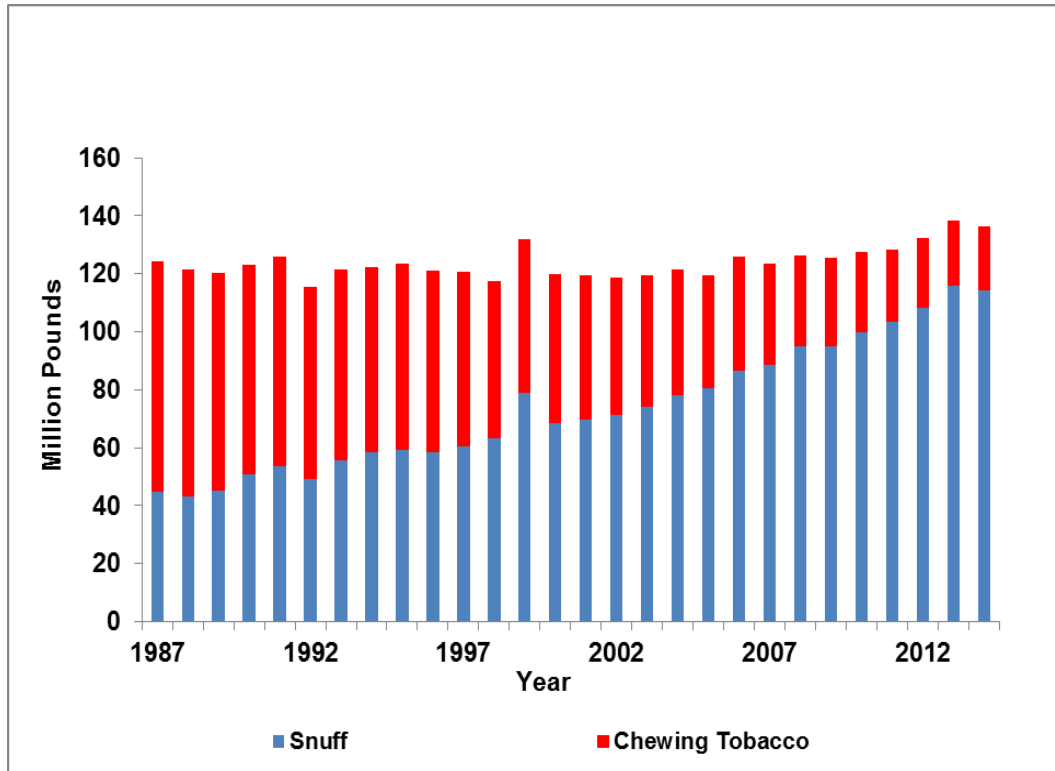
According to the TTB statistical reports, the use of chewing tobacco in the U.S. decreased from 79 million pounds in 1987 to 22 million pounds in 2014; the use of snuff increased from 45 million pounds in 1987 to 114 million pounds in 2014 (Figure 3).⁸ However, total use of all smokeless products remained relatively unchanged (Figure 4).

Figure 3 Use of Smokeless Tobacco Products in the U.S. in 1986 – 2014



⁸ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 13, 2015.

Figure 4 Total Use of Smokeless Tobacco Products in the U.S in 1986 – 2014



5.2.2 Environmental Introduction from Use of the New products

As noted, the only difference between the predicate products and corresponding new tobacco products is in name. The new products are usually used in similar manner to the predicate products and other portioned moist snuff. To the Agency's best knowledge, there is no environmental introduction from the use of portioned moist snuff..

5.3. Environmental Introduction as a Result of Disposal Following Use in the U.S.

The environmental consequences resulting from disposal following use of smokeless tobacco products are 1) disposal of packaging, 2) discarding of the used portioned smokeless products, and 3) excretion of other ingredients in smokeless products.

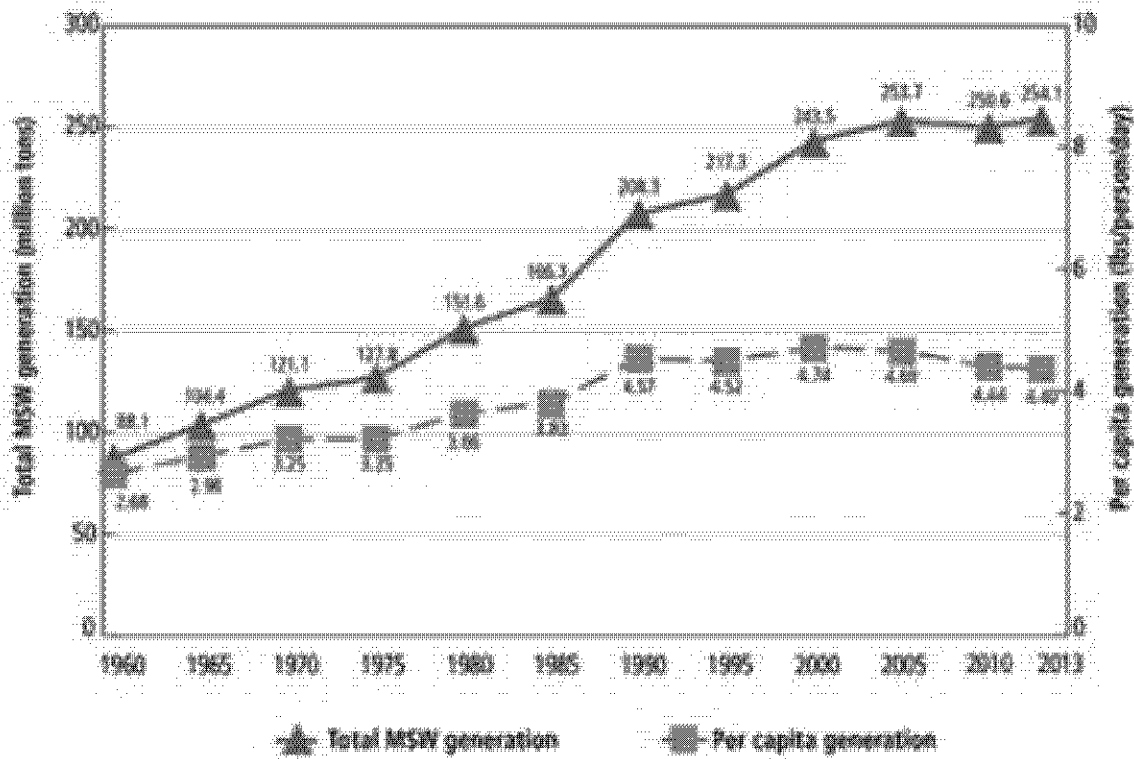
5.3.1 Disposal Following Use of Smokeless Tobacco

a) Disposal of packaging material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of, either in MSW landfills or as litter. In 2013, the amount of waste generated in the U.S. was approximately 254 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.3% recycling rate (Figure 5 and Figure 6). The recovery of newspaper/mechanical papers was about 67% (5.7 million tons). On average, 4.40 pounds per person per day of

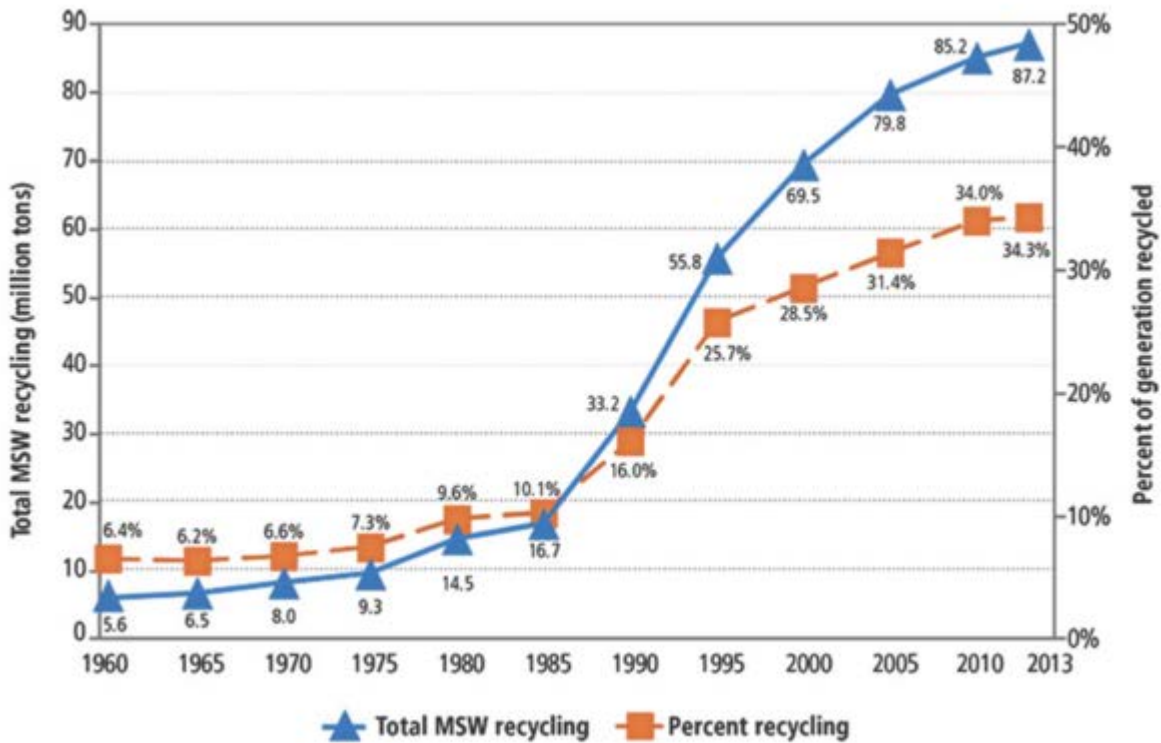
waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2013.⁹

Figure 5. Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 – 2013



⁹ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed December 28, 2015.

Figure 6. MSW Recycling Rates in the U.S.



b) Discarding of the used portioned smokeless products in smokeless products

Used portioned smokeless tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent product is likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the tobacco would enter landfills. The Agency utilized the historic data for use of smokeless tobacco products in the U.S. to forecast the future use of smokeless products and calculate the projected tobacco waste accordingly (Appendix 3). Assuming that all used smokeless or snuff products will be disposed of as MSW, the estimated waste of used smokeless or snuff products is a fraction of a percent of the total 254 million tons of projected MSW to be generated in the U.S (Table 2).¹⁰

¹⁰ Based on trend of MSW reported in the referenced EPA report.

Table 1 Forecast of Waste of Used Smokeless Tobacco as Compared to Total MSW Forecast in the U.S.¹²

Year	Projected Use (Equivalent to Projected Waste) of Smokeless in the U.S. (Tons) ^a	Percent of Projected Waste of Smokeless to Total MSW Forecasted in the U.S. (%)	Projected Use (Equivalent to Projected Waste) of Snuff in the U.S. (Tons)	Percent of Projected Waste of Snuff to Total MSW Forecasted in the U.S. (%)
1 st Year	65,736	0.026	57,512	0.023
5 th Year	73,522	0.029	67,357	0.027

^aSee Table 2 in Appendix 3

c) Excretion of other ingredients in smokeless tobacco products

In addition to the disposal of the product in MSWs or as litter, there will also be excretion of other ingredients in the smokeless products by the user. Those ingredients might enter the sewer system as components in human waste. The excreted waste is anticipated to be digested by microbial systems in the home's septic system or treated in POTW.

5.3.2 Environmental introduction from disposal following use of the new products

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other portioned moist snuff products and any other smokeless tobacco products that are currently being marketed. The waste generated as a result of use of the new products, i.e. the spent tobacco and the other ingredients (see above), will be released to the environment and transferred to POTWs in the same manner as the waste generated from any other smokeless tobacco products used in the U.S.

To determine the amount of waste due to disposal of paper and cardboard packaging material, in the worst case scenario, the Agency used the projected market volumes in the first and fifth years after issuance of the authorization orders for the new products (Confidential Appendix 2). The calculated waste of the cardboard packaging material of the new products was determined to be miniscule compared to the forecasted MSW to be generated in the U.S. In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

The polypropylene packaging waste generated from the can base of the pouched products, can lids and film wrap is also negligible compared to the amount of forecasted MSW to be generated in the U.S. (Confidential Appendix 3).

As previously discussed, the new products will compete with other similar smokeless tobacco products on the market. Due to that, plus the above information regarding

waste, construction of new POTWs or landfills are not anticipated due to the proposed action.

6. Fate of Materials Released into the Environment Due to the Proposed Action

The Agency does not anticipate that the proposed action will lead to the release of new substances into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other smokeless tobacco products, including portioned moist snuff. Therefore, the fate of the materials emitted is anticipated to be the same as any materials from other smokeless tobacco products, including portioned moist snuff, manufactured in the facility.

7. Environmental Effects of Due to the Proposed Action

The applicant stated that the manufacturing operation is in compliance with all local, state and federal environmental laws. Therefore, the cumulative introduction is not expected to exceed that which is allowed under relevant environmental laws.

Furthermore, as discussed above, the amount of materials anticipated to enter the environment due to manufacturing and use of the new products are small fractions when compared to that of the projected snuff manufactured and used in the U.S. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The new products will compete with other currently marketed smokeless products. When comparing the market volume projections with the forecasted total snuff market volumes in the U.S., the Agency found that the total snuff market volume would likely remain unchanged as a result of marketing the new products. In addition, the applicant stated that all ingredients used to manufacture the new products are from sustainable sources. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify any adverse environmental effects for the new products and their proposed use as portioned moist snuff. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the new tobacco products in the U.S. The environmental impact of this action would not change

the existing condition of the manufacturing, use, and disposal following use of tobacco products as many other similar smokeless tobacco products will continue to be marketed.

Alternative B (Proposed action): There is no substantial environmental effect due to the proposed action of authorizing the new products and the associated manufacture, use, and disposal from use of the new tobacco products.

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

11. List of Preparers:

In accordance with 40 CFR § 1502.17, this section includes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Mehran Niazi, PhD, Center for Tobacco Products

Education: PhD, in Environmental Science

Experience: 12 years in Environmental Fate and Transport and Environmental Modeling

Expertise: Environmental Risk Assessment, Water Quality Modeling, Environmental Fate & Transport

12. Appendix List

Appendix 1: List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA).

Appendix 2: Forecast of Manufactured Smokeless Tobacco in the U.S.

Appendix 3: Forecast of Use of Smokeless Tobacco Products in the U.S.

13. Confidential Appendix List

Confidential Appendix 1: The First- and Fifth-Year Market Volume Projections of the New Products and the Respective Predicate Products.

Confidential Appendix 2: The First- and Fifth-Year Projections of Waste of Packaging Materials Associated with Marketing the Products.

Confidential Appendix 3: The First- and Fifth-Year Projections of Plastic Waste of Packaging Materials Associated with Marketing the Products

APPENDIX 1

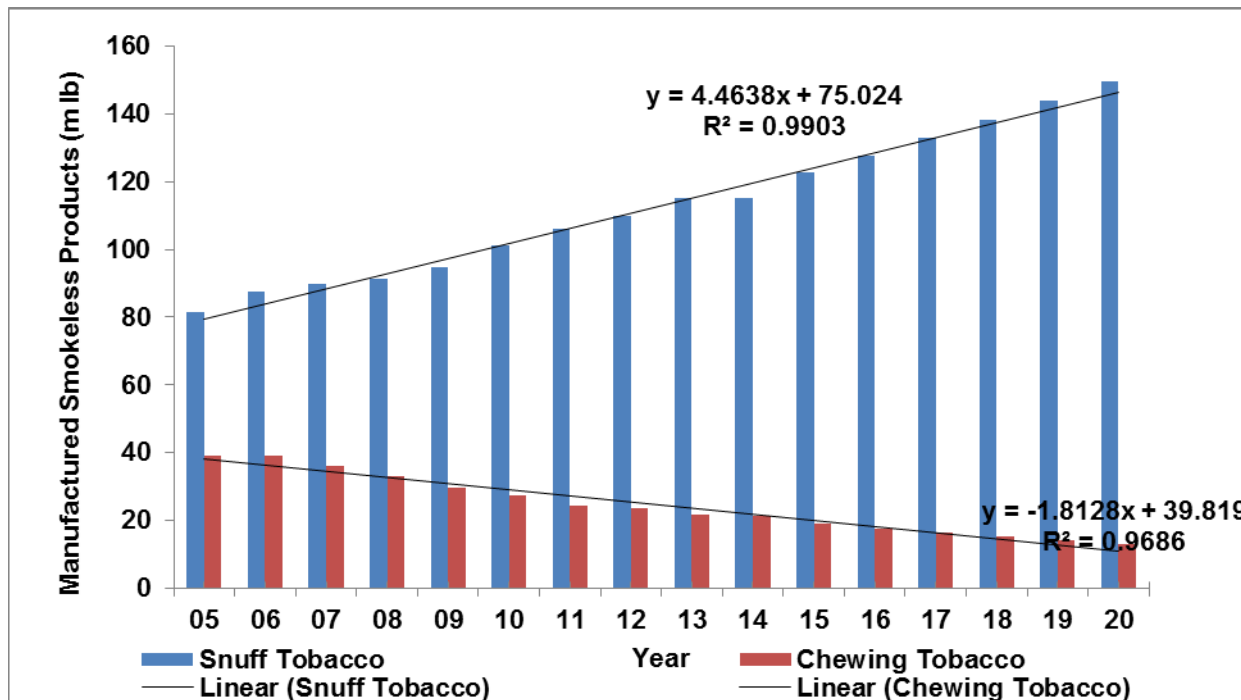
List of Submission Tracking Numbers for the SE Reports with Names and Package Size of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Package Size	Predicate Product	Package size	Amendments
SE0012445	Timber Wolf Pouches Wintergreen	15 per can	Timber Wolf Packs Wintergreen	15 per can	SE0012587, SE0012727
SE0012446	Timber Wolf Pouches Natural	15 per can	Timber Wolf Packs Natural	15 per can	SE0012588, SE0012726

Appendix 2

Forecast of Manufactured Smokeless Tobacco in the U.S.

To evaluate the environmental impact of the proposed action due to manufacturing of the new products, historic data regarding use of smokeless tobacco from 2005 to 2014 was used to forecast the use of smokeless tobacco products. This was achieved by using one best-fit linear trend line with the R^2 value of 0.99 and 0.97 for snuff and chewing tobacco, respectively. Accordingly, the forecasted amounts of snuff and chewing tobacco in the U.S. are estimated to be 128 and 18 million pounds in 2015 and 150 and 13 million pounds in 2020, respectively.



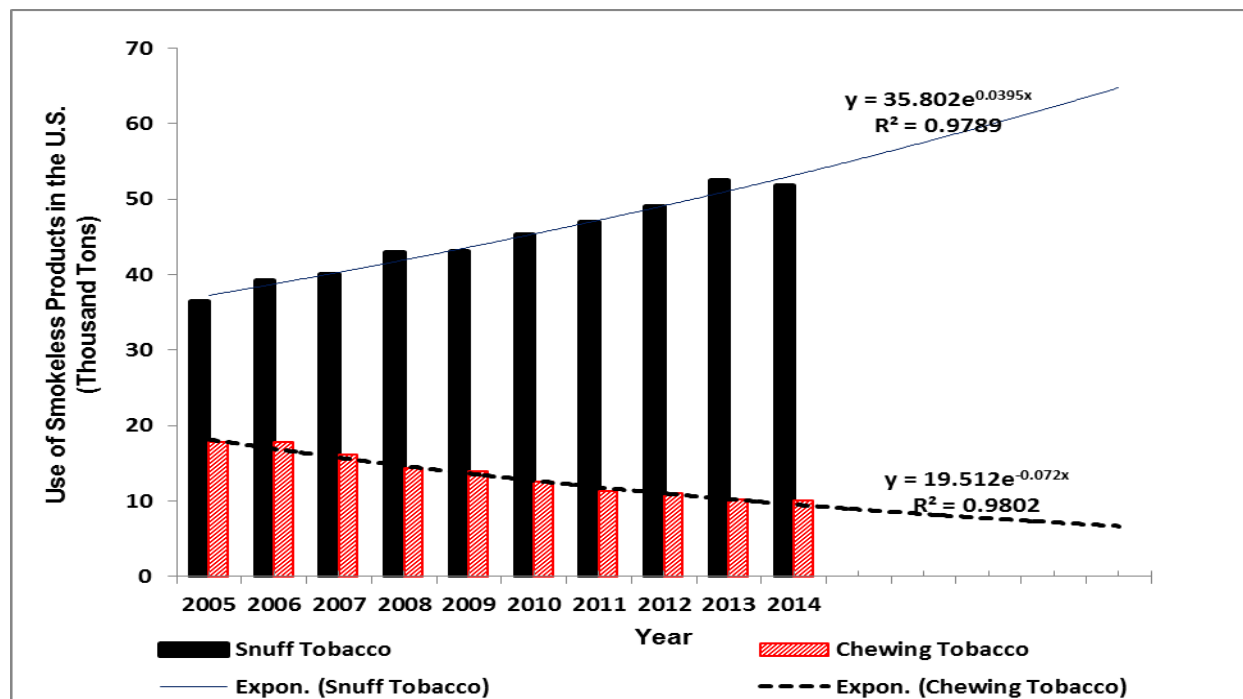
Appendix 3

Forecast of Use of Smokeless Tobacco Products in the U.S.

To evaluate the environmental impact of the proposed action due to use of the new products, the Agency utilized the historic data of use in 2005 – 2014 to forecast the use of smokeless tobacco products, chewing tobacco and snuff, in the U.S. This was achieved by using one best-fit exponential trendline with the R^2 value of 0.9789 for snuff and another best-fit exponential trendline with the R^2 value of 0.9802 for chewing tobacco (Figure 7).

Utilizing trendlines, the forecast of use of smokeless tobacco products in the U.S. was estimated mathematically (Table 2).

Figure 7 Forecast of Use of Smokeless Tobacco Products in the U.S.¹¹



¹¹ Based on TTB data

Table 2 Forecast of Use of Smokeless Products in the U.S.

Year	Snuff Use (Tons)	Chewing Tobacco Use (Tons)	Total Smokeless Use (Tons)
1 st Year	57,512	8,224	65,736
5 th Year	67,357	6,166	73,523

CONFIDENTIAL APPENDIX 1

The First- and Fifth-Year Market Volume Projections of the New Products and the Corresponding Predicate Products

STN	Product Name	First-Year Projected Market Volume (# of Cans)	First- Year Projected Market Volume (Tons)	Fifth-Year Projected Market Volume (# of Cans)	Fifth-Year Projected Market Volume (Tons)
SE0012445	Timber Wolf Pouches Wintergreen	(b) (4)			
SE0012446	Timber Wolf Pouches Natural				
Total Projected Market Volume of New Products					

Compared to the forecasted use of snuff in the U.S. for 2015 and 2020, (b) (4) tons and (b) (4) tons (See Table 2), the first- and fifth-year market volume projections occupied (b) (4) and (b) (4) of the forecasted market volume of the total snuff used in the U.S., respectively.

CONFIDENTIAL APPENDIX 2

The First- and Fifth-Year Projections of Paper Box Waste of Packaging Materials Associated with Marketing the Products

The Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in tons) that is generated from disposal after use of the new products as follows:

A= B x C x D, where

A= Projected packaging material waste (tons) for the label and the cardboard shipping case separately

B= Projected market volume (number of cans)

C= Weight of the packaging material (grams/box)

D= 10⁻⁶ (tons/gram)

STN	Projected Market Volume (# of Cans)	Projected Total Label Weight (Metric Tons)	Projected Total Cardboard Shipping Case Weight (Metric Tons)	Projected Total Paper Waste (Metric Tons)
SE0012445				
First Year	(b) (4)			
Fifth Year				
SE0012446				
First Year	(b) (4)			
Fifth Year				
Totals				
First Year	(b) (4)			
Fifth Year				

Paper Waste. Estimation for generated total paper waste is [REDACTED] metric tons in the first year and [REDACTED] metric tons in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 70% in the U.S. according to the U.S. EPA¹². Therefore, if 30% of the box is disposed of as waste based on the 2012 waste generation data in the U.S., the estimated cumulative cardboard waste will be [REDACTED] metric tons in the first year of marketing the products. The estimated cumulative cardboard waste will be [REDACTED] metric tons in the fifth year of marketing the products.

If the entire packaging cardboard is disposed of as waste, in the worst case scenario, the projected cumulative cardboard waste in the first year of marketing the products is [REDACTED] metric tons. In the fifth year of marketing the products the worst case scenario is [REDACTED] metric tons of total cardboard waste. This is a small fraction of the 254 million tons of total waste reported in the U.S. in 2013.

¹² EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed January 20, 2015

CONFIDENTIAL APPENDIX 3

The First- and Fifth-Year Projections of Plastic Waste of Packaging Materials Associated with Marketing the Products

The Agency estimated the first- and fifth-year weights of the projected plastic packaging materials waste (in tons) that is generated from disposal after use of the new products as follows:

A= B x C x D, where

- A= Projected packaging material waste (tons)
- B= Projected market volume (number of cans)
- C= Weight of the packaging material (grams/box)
- D= 10⁻⁶ (tons/gram)

STN	Projected Market Volume (# of Cans)	Projected Total Plastic Can Weight (Metric Tons)	Projected Total Plastic Shrink Wrap Weight (Metric Tons)	Projected Total Plastic Waste (Metric Tons)
SE0012445				
First Year	(b) (4)			
Fifth Year				
SE0012446				
First Year	(b) (4)			
Fifth Year				
Totals				
First Year	(b) (4)			
Fifth Year				

Paper Waste. Estimation for generated total plastic waste (can and shrink film) is [REDACTED] metric tons in the first year and [REDACTED] metric tons in the fifth year.

If the entire packaging can and shrink wrap film is disposed of as waste, in the worst case scenario, the projected cumulative plastic waste in the first year will be [REDACTED] of the 33 million tons of total plastic waste reported in the U.S. in 2013; the projected cumulative plastic waste in the fifth year will be [REDACTED] of the 33 million tons.