

**Environmental Assessment for Marketing Order for U.S.
Smokeless Tobacco Company, LLC “Red Seal Fine Cut Natural”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 20, 2018

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This environmental assessment (EA) is for the marketing order for a smokeless tobacco moist snuff manufactured by U.S. Smokeless Tobacco Company, LLC. Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

U.S. Smokeless Tobacco Company, LLC

2. Address

2325 Bells Road
Richmond, VA 23235

3. Manufacturer

U.S. Smokeless Tobacco Company, LLC

4. Description of Proposed Action

This proposed action is for FDA to issue a marketing order under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of the smokeless tobacco, Red Seal Fine Cut Natural, into interstate commercial distribution in the United States. The authorization is based on the finding that this new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007. The predicate product is not currently marketed, and the applicant does not intend to market the new and predicate products simultaneously after receiving a marketing order for the new product.

4.1 Requested Action

An order finding the listed tobacco product is substantially equivalent to the predicate product.

4.2 Need for Action

U.S. Smokeless Tobacco Company, LLC wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claimed that the new product differs from the predicate product in product ingredients and tobacco and nicotine content (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) report (SE0004824), the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

4.3 Identification of the New Tobacco Product that is the Subject of the Proposed Action

4.3.1 Type of Tobacco Product

Smokeless tobacco product, loose moist snuff

4.3.2 Product Name and Its Original STN

The name of the new product is listed below, along with the original submission tracking number (STN) and the name of the predicate product. See Appendix 1 for additional STNs associated with the new product and the predicate product.

STN	New Product	Predicate Product
SE0004824	Red Seal Fine Cut Natural	Red Seal Fine Cut Natural (2007)

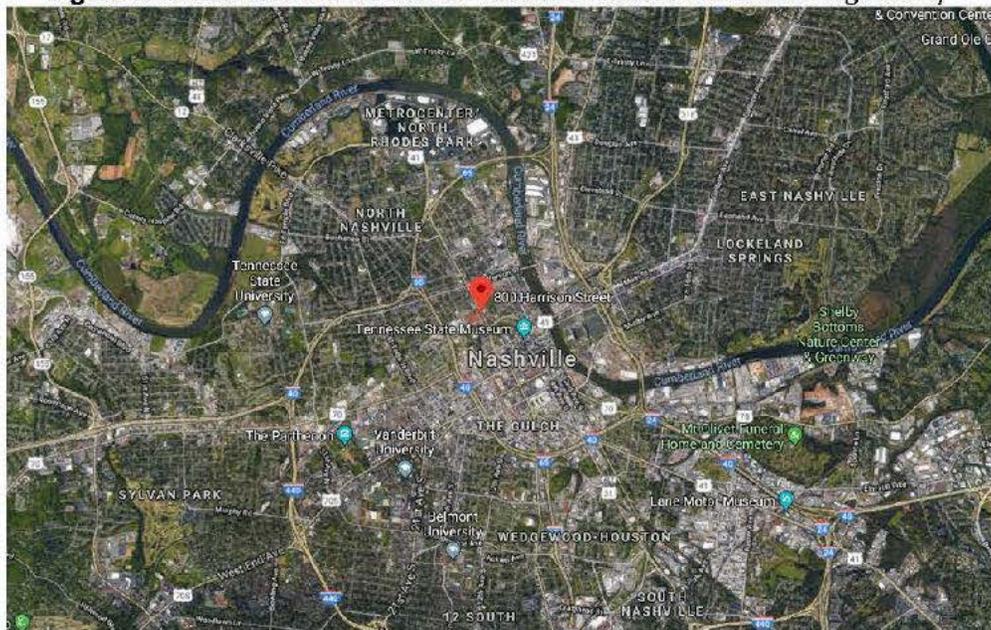
4.3.3 Description of the Product Package

The new product is packaged in individual cans that are shrink-wrapped into log rolls of five cans per roll and placed 18 log rolls to a shipping case. The new product may be purchased at retail locations in individual cans or in five-can log rolls. Detail of the package components and weights of each packaging component for the new product are described in Confidential Appendix.

4.3.4 Location of Manufacturing

The manufacturer of the smokeless tobacco moist snuff is located at 800 Harrison Street, Nashville, TN 37203 (Figure 1).

Figure 1. Location of the Smokeless Tobacco Product Manufacturing Facility¹



¹ Manufacturer address via Google Map. Accessed January 9, 2018.

4.3.5 Location of Use

U.S. Smokeless Tobacco Company, LLC intends to distribute and sell the new tobacco product to consumers in the United States.

4.3.6 Location of Disposal

Once used, the new tobacco product will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product and any other smokeless tobacco products. Disposal of the packaging materials will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that the distribution of waste from disposal will correspond to the pattern of the product use.

4.4 Modification(s) Identified as Compared to the Predicate Product

The applicant claims that the new product differs from the predicate product in product ingredients, tobacco and nicotine content, and a packaging component. Details of product and packaging changes are described in Confidential Appendix 1.

5. Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Product

Smokeless tobacco products include moist snuff, chew, snus, dry snuff, and some dissolvable products. As of January 2018, a total of 2,524 tobacco establishments are registered under 915(c) of the FD&C Act.² According to Tobacco Statistical Release Reports of the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), the production of chewing tobacco decreased from 61 million pounds in 1997 to 19 million pounds in 2016, whereas snuff production increased from 61 million pounds in 1997 to 120 million pounds in 2016 (Figure 2).³ The combined manufacture of total smokeless products has remained relatively constant with a slight increase from 122 million pounds in 1997 to 139 million pounds in 2016 (Figure 3).

² Based on FDA's Establishment Registration & Tobacco Product Listing Database. Available at <https://www.accessdata.fda.gov/scripts/ctpocerl/index.cfm?action=main.home>. Accessed January 8, 2018.

³ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed January 9, 2018.

Figure 2. Manufactured Snuff and Chewing Tobacco in the United States in 1997-2016

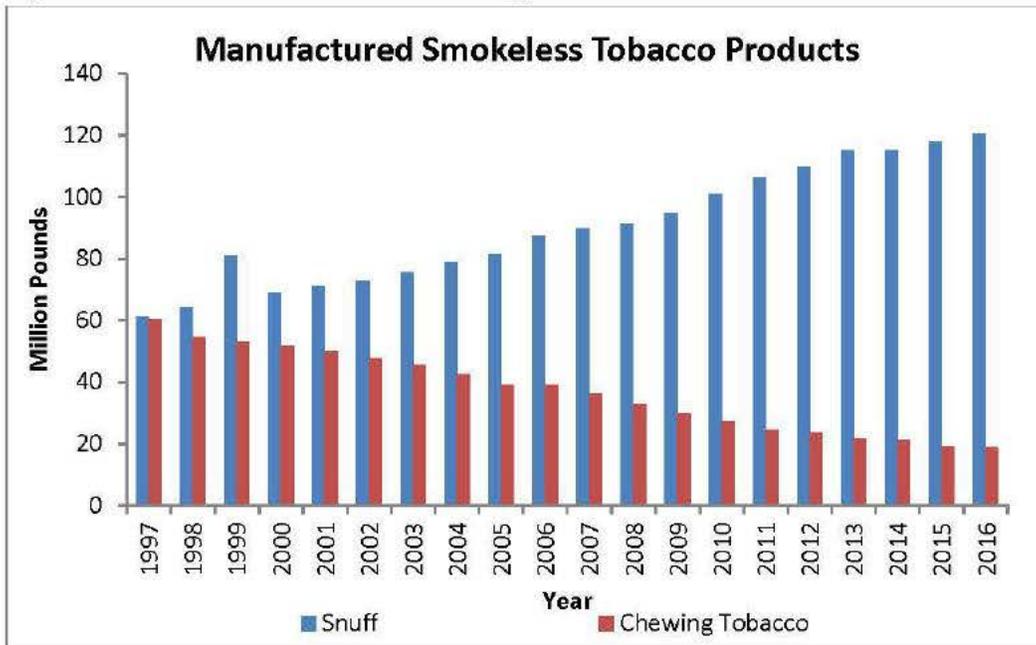
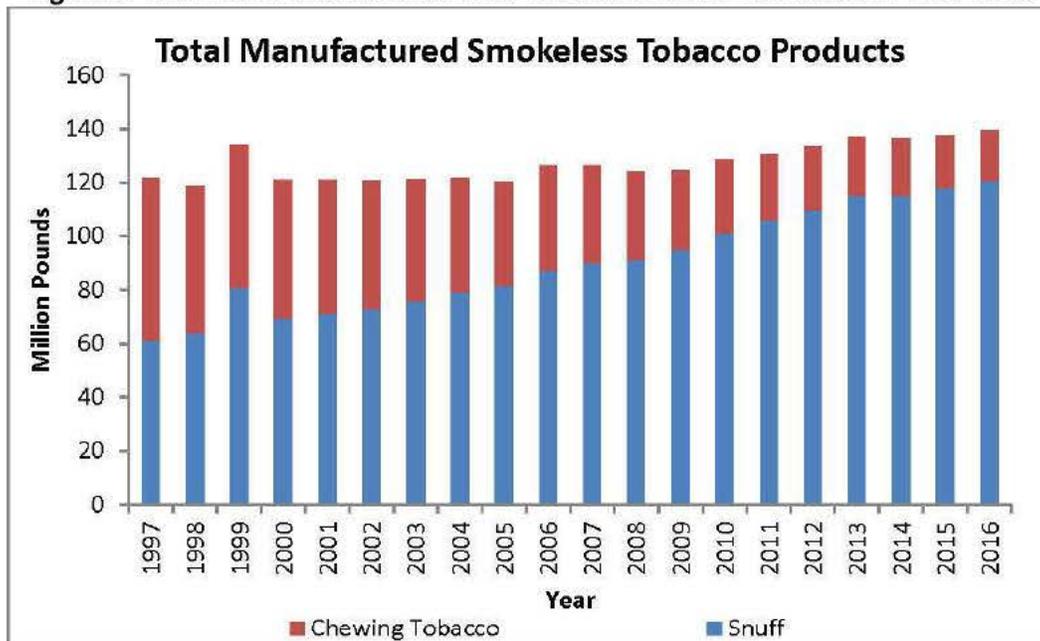


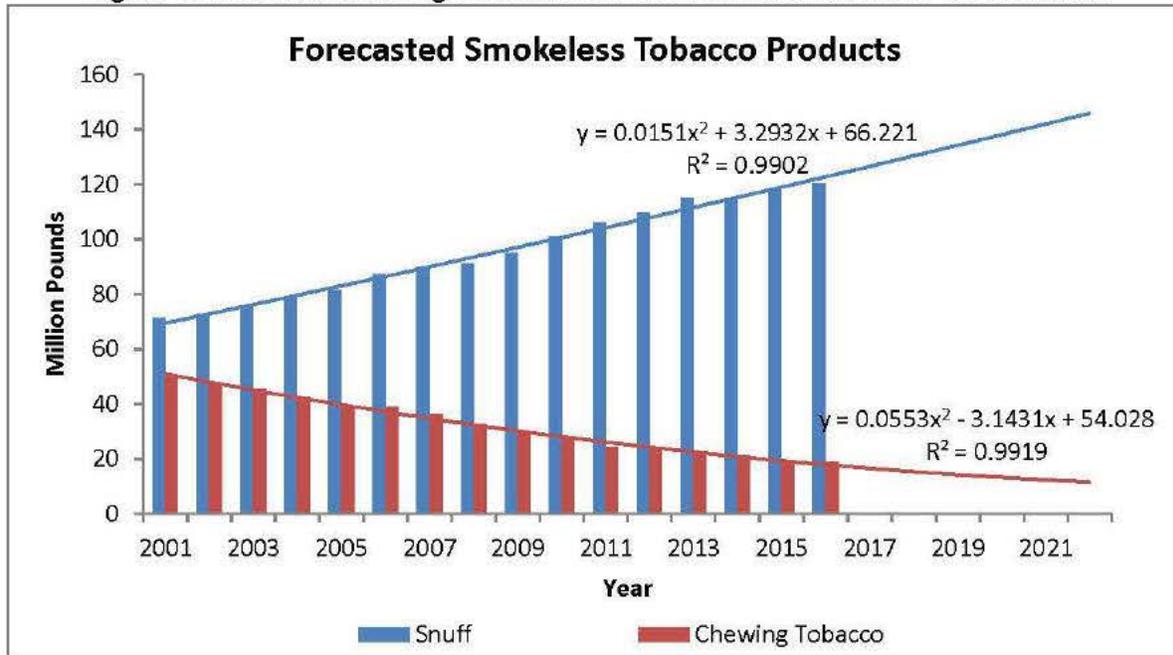
Figure 3. Total Manufactured Smokeless Tobacco in the United States in 1997-2016



The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 2). To evaluate the environmental impact of the proposed action due to manufacturing the new product, historical data regarding the manufacture of smokeless tobacco products in the United States from 2001 to 2016 was used to forecast the manufacture of chewing tobacco and snuff. This was achieved by using best-fit polynomial (order of two) trend lines with the R^2 values of 0.9919 and 0.9902,

respectively, for snuff and chewing tobacco.⁴ Accordingly, the forecasted amount of chewing tobacco to be manufactured in the United States is estimated to be 15 million pounds in 2018 and 12 million pounds in 2022, while the forecasted amount of snuff to be manufactured in the United States is estimated to be 130 million pounds in 2018 and 142 million pounds in 2022 (Figure 4).

Figure 4. Forecast of Chewing Tobacco and Snuff Manufactured in the United States



Comparing the projected market volume of the new product with the forecasted market volume of smokeless tobacco products in 2018 and 2022, the projected market volume of the new product is a small fraction of the total forecasted market volume in 2018 and 2022 (Figure 4 and Confidential Appendix 2). Additionally, the applicant stated that manufacturing of the new product would not result in an increase in overall permitted manufacturing capacity at the facility. Therefore, no expansion of the manufacturing facility is anticipated due to the authorization of the new product. The applicant stated that the manufacturing facility does not dispose of waste on-site, and all waste generated from the manufacture of the new product will be accommodated by existing waste management and storage practices. The applicant also stated that the nature of the waste generated from manufacturing the new product is not expected to change and therefore no new or additional disposal resources (e.g., landfills or recycling centers) are anticipated.

The emission information associated with all tobacco products as reported in the EPA’s Toxic Release Inventory (TRI) database is publicly available. The Agency uses TRI data to assess the environmental impacts from the emissions released by tobacco manufacturing facilities. In 2016, the U.S. Smokeless Tobacco Company Nashville facility released 154 pounds of nicotine and salts to the air and 68,479 pounds of nicotine and salts were transferred off-site for landfill disposal and waste management, compared to 253,436 pounds of nicotine and salts released to the air and 463,441 pounds of nicotine and salts transferred off-site by reporting tobacco facilities in the United States.

⁴ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on January 9, 2018. Note: 2017 annual TTB values have not been released. Since the SE Report was received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

The applicant stated that manufacturing the new product will not result in emissions of new compounds or increases in the current emissions due to the predicate or other smokeless tobacco products. Additionally, the applicant stated that no material changes in solid waste generation are expected from manufacturing the new product. Furthermore, the applicant stated that manufacturing the new product would not result in changes in wastewater discharges from the manufacturing facility or require additional environmental controls. The applicant also stated compliance to current federal and state air and wastewater permits, and that manufacturing the new product would not result in revised or new permits.

The applicant provided the annual energy usage at the manufacturing facility (Confidential Appendix 2). The applicant stated that the potential increase in energy use associated with manufacturing the new product is a minute fraction and therefore would not result in a significant net increase of energy use at the manufacturing facility. Additionally, because the new product will compete with other currently marketed smokeless tobacco products, no different or increase in greenhouse gas (GHG) emissions is anticipated from the proposed action.

5.2 Potential Environmental Impacts Due to Use of the New Tobacco Product

According to the TTB Statistical Release reports, the use of chewing tobacco in the United States decreased from 60 million pounds in 1997 to 20 million pounds in 2016, while the use of snuff in the United States increased from 61 million pounds in 1997 to 119 million pounds in 2016 (Figure 5).⁵ (U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau, 2018).

To evaluate the environmental impact of the proposed action due to the use of the new product, the Agency analyzed historical use data for 2001-2016 to forecast the future use of chewing tobacco and snuff in the United States. This was achieved by using best-fit polynomial (order of two) trend lines with the R² values of 0.9895 and 0.9912, respectively, for snuff and chewing tobacco.⁶ Accordingly, the forecasted amount of chewing tobacco to be consumed in the United States is estimated to be 17 million pounds in 2018 and 13 million pounds in 2022, while the forecasted amount of snuff to be consumed in the United States is estimated to be 128 million pounds in 2018 and 142 million pounds in 2022 (Figure 6).

⁵ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed January 9, 2018.

⁶ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on January 9, 2018. Note: 2017 annual TTB values have not been released. Since the SE Report was received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

Figure 5. Use of Snuff and Chewing Tobacco in the United States in 1997-2016

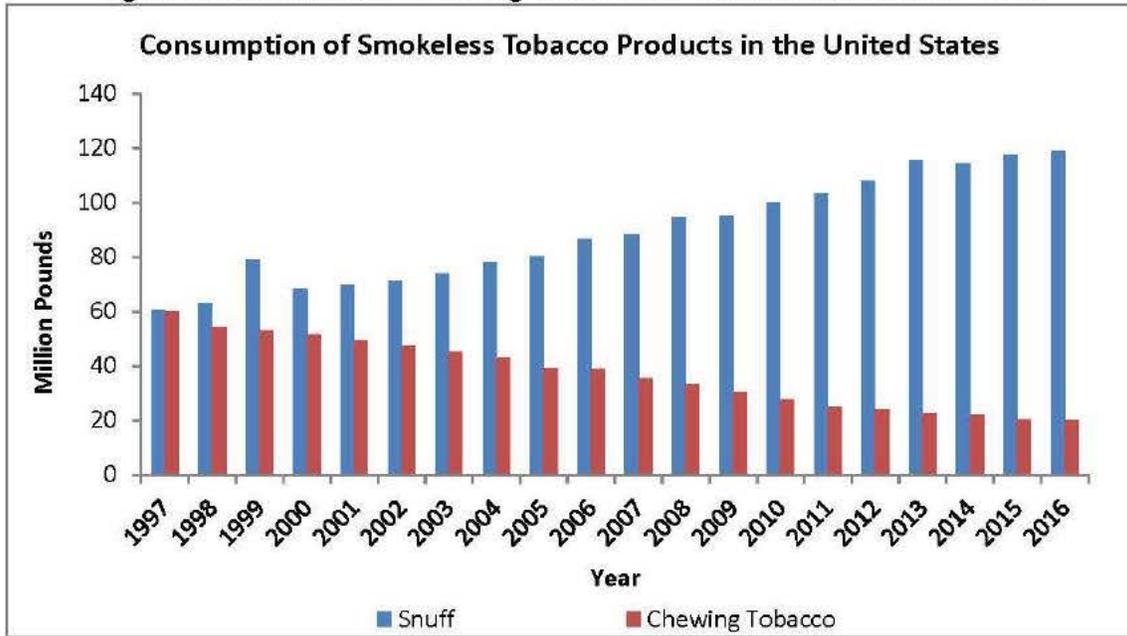
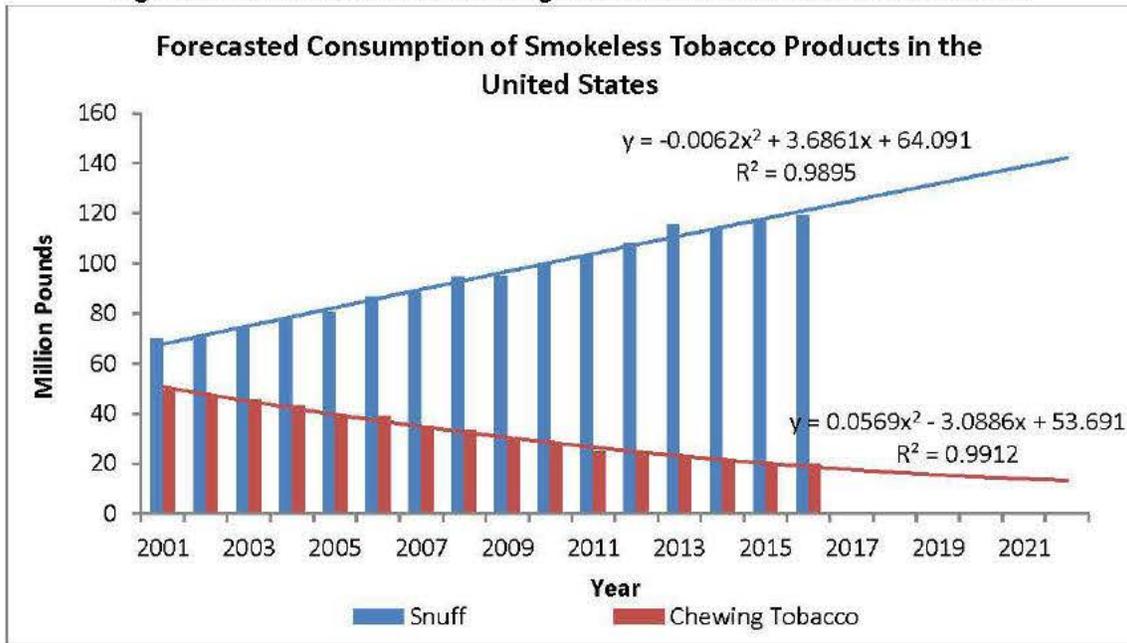


Figure 6. Forecasted Use of Chewing Tobacco and Snuff in the United States



Because the new product is expected to compete with other smokeless tobacco products on the market, the Agency anticipates minimal or no net increase in the use of all smokeless tobacco products. Additionally, the new product is used in a similar manner to the predicate product and other moist snuff products. Subsequently, the Agency does not anticipate new substances to be released into the environment from the use of the new smokeless tobacco product, relative to the substances released by other similar products already on the market.

5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Product

The environmental consequences resulting from disposal of smokeless tobacco products are related to a) disposal of packaging material, b) discarding of the used smokeless tobacco product, and c) users' excretion of ingredients other than tobacco in smokeless products.

5.3.1 Disposal of Packaging Material

Disposal of the packaging materials would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in smokeless tobacco products, can be informative about the disposal of packaging materials associated with smokeless tobacco products. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 7 and 8). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. Of the total metal MSW generated, specifically steel at 17.69 million tons, 5.84 million tons (33.0%) was recycled, 9.83 million tons (55.6%) was disposed of in landfills, and 2.02 million tons (11.4%) was combusted with energy recovery. Of the total plastic MSW generated at 33.25 million tons, 3.17 million tons (9.5%) was recycled, 25.10 million tons (75.5%) was disposed of in landfills, and 4.98 million tons (15.0%) was combusted with energy recovery. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the United States in 2014 (U.S. Environmental Protection Agency, 2016).

Figure 7. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

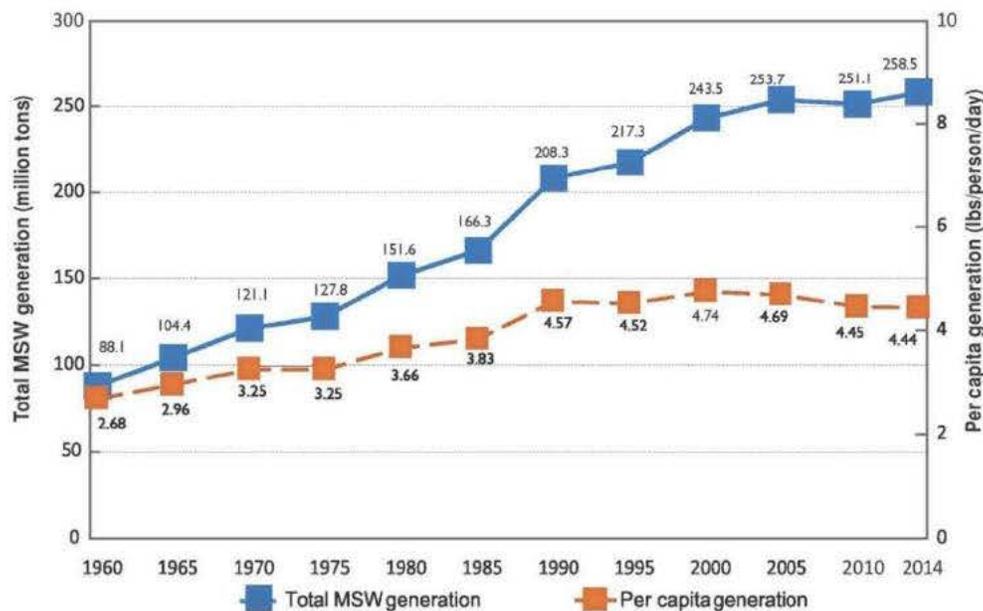


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 8. MSW Recycling Rates in the United States, 1960-2014

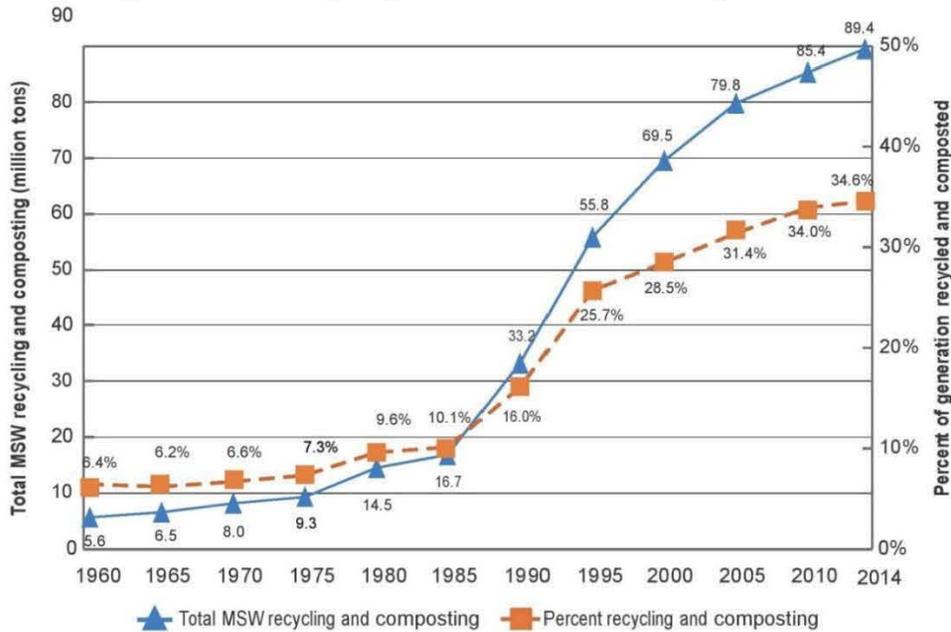


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the packaging materials associated with the new product will be the same as the disposal conditions of other smokeless tobacco products that are currently being marketed. After using the new product, users may recycle or dispose of the packaging material as MSW or litter.

To determine the amount of waste due to disposal of the packaging material, the Agency used the projected market volumes in the first and fifth years after issuance of a marketing order for the new product. The calculated waste of the packaging materials of the new product were determined to be miniscule compared to the forecasted MSW to be generated in the United States (Confidential Appendix 4).

As previously discussed, because the new smokeless tobacco product will compete with other similar smokeless tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills as a result of disposal of the new product packaging material are not anticipated due to the proposed action.

5.3.2 Discarding of the Used Smokeless Tobacco Product

Used 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. When discarded as MSW, the tobacco would enter landfills. The Agency utilized the historical data for use of smokeless tobacco products in the United States to forecast the future use of smokeless products and calculate the projected tobacco waste accordingly (Figures 5 and 6 in Section 5.2). 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 miniscule fraction of a percent of the total 258.46 million tons (234.47 million metric tons; 516,920

million pounds) of projected MSW to be generated in the United States (Table 1) (U.S. Environmental Protection Agency, 2016).

Table 1. Forecast of Waste Generated from Used Smokeless Tobacco Products as Compared to Total MSW Forecast in the United States

Year*	Total U.S. Smokeless Tobacco Products (million pounds)	Total Smokeless Tobacco Products as a Percent of Total MSW in the United States	Total U.S. Snuff (million pounds)	Total Snuff as a Percent of Total MSW in the United States
2016	139	0.00027%	119	0.00023%
First Year (2018)	144	0.00028%	128	0.00025%
Fifth Year (2022)	154	0.00030%	142	0.00027%

* Because the SE Report was received in 2017 and 2017 TTB year-end reports are not yet available, the first- and fifth-years of marketing are assumed to be 2018 and 2022.

Introducing the new product into the U.S. market is not expected to increase the nationwide use of smokeless tobacco; instead, they would compete for market share with existing products. Therefore, a marketing order for the new product is not expected to affect the overall level of snuff waste in the United States due to use of the new product, but it may displace the level of waste from other smokeless products.

5.3.3 Users' Excretion of Ingredients other than Tobacco in Smokeless Products

In addition to the disposal of the product in MSW or as litter, users will excrete ingredients and constituents which are part of the smokeless product, as well as their metabolites, excluding the tobacco itself, into the waste stream. For instance, studies have shown that nicotine metabolites can be detected in excreted waste of smokeless tobacco users (Hecht, 2002; Jacob, 1999; Stepanov I. a., 2005). These metabolites and other constituents may enter the sewage system as components in human excreted waste, which is transferred to and treated at POTWs in the same manner as other wastewater. The excreted waste may also be digested by microbial systems in the home's septic system.

Recent efforts have been taken to detect and measure nicotine metabolites in wastewater, groundwater and surface waters (Castiglioni, 2014; Katz, 2009; Buerge, 2008; Rodriguez-Alvarez, 2014). Although, to date, some studies have demonstrated deleterious effects of nicotine exposure on zebrafish, such as abnormal neural and muscle development, and behavioral changes, these studies have not linked these effects directly to nicotine metabolites (Stewart, 2015; Klee, 2011). The ecotoxicological risks associated with nicotine metabolites are still unknown. Therefore, a marketing order for the new product is not expected to affect the overall excretory waste produced by users in the United States.

6. Use of Resources and Energy

The applicant provided the annual energy usage at the manufacturing facility (Confidential Appendix 2). The applicant stated that the potential increase in energy use associated with manufacturing the new product is a minute fraction and therefore would not result in a significant net increase of energy use at the manufacturing facility, which does not generate its own energy or use renewable energy or fuels or

alternative green energy resources. Furthermore, because the new product will compete with other currently marketed smokeless tobacco products, no different or increase in GHG emissions is anticipated from the proposed action.

The applicant stated and provided evidence that the manufacturing facility is not within or in close proximity to a known critical habitat of a threatened or endangered species as listed by the Endangered Species Act (ESA). The applicant also stated that none of the materials or ingredients used to manufacture the new product originate from threatened or endangered species as defined by the U.S. Fish and Wildlife Service and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

7. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for manufacturing, use, and disposal of the new product. Therefore, no mitigation measures are discussed.

8. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco product in the United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal of smokeless 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 actions of authorizing the new product (Confidential Appendices 2 and 3) and associated manufacturing, use, and disposal of the new tobacco product.

9. List of Preparers

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

Preparer:

Catherine W. McCollum, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and Cell Biology

Experience: 3 years in NEPA practice, 10 years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: 9 years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10. List of Agencies and Persons Consulted

Not applicable.

11. Appendix List

Appendix 1: Submission Tracking Number and Related Amendments for the SE Report and Package Sizes of the New and Predicate Products Covered Under this Environmental Assessment (EA)

12. Confidential Appendix List

Confidential Appendix 1: Modifications between the New Product and Predicate Product

Confidential Appendix 2: The First- and Fifth-Year Market Volume Projections of the New Product and Energy Usage

Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Product with Total Smokeless Tobacco Products Used in the United States

Confidential Appendix 4: The First- and Fifth-Year Projection of Waste of Packaging Materials Associated with Marketing the New Product

13. References

Buerge, I. K.-R. (2008). Nicotine derivatives in wastewater and surface waters: application as chemical markers for domestic wastewater. *Environmental Science & Technology*, 42: 6354-6360.

Castiglioni, S. S. (2014). A novel approach for monitoring tobacco use in local communities by wastewater analysis. *Tobacco Control*, 0: 1-5.

Hecht, S. C. (2002). Quantification of metabolites of 4-(methylnitrosamine)-1-(3-pyridyl)-1-butanone after cessation of smokeless tobacco use. *Cancer Research*, 62: 129-134.

Jacob, P. Y. (1999). Minor tobacco alkaloids as biomarkers for tobacco use: Comparison of users of cigarettes, smokeless tobacco, cigars, and pipes. *American Journal of Public Health*, 89(5): 731-736.

Katz, B. G. (2009). Groundwater quality impacts from land application of treated municipal wastewater in a large karstic spring basin: chemical and microbiological indicators. *Science of Total Environment*, 407: 2872-2886.

Klee, E. E. (2011). Zebrafish for the study of the biological effects of nicotine. *Nicotine & Tobacco Research*, 13(5): 301-312.

- Rodriguez-Alvarez, T. R. (2014). Assessment of local tobacco consumption by liquid chromatography-tandem mass spectrometry sewage analysis of nicotine and its metabolites, cotinine and trans-3'-hydroxycotinine, after enzymatic deconjugation. *Analytical Chemistry*, 86: 10274-10281.
- Stepanov, I. a. (2005). Tobacco-specific nitrosamines and their pyridine-N-glucuronides in the urine of smokers and smokeless tobacco users. *Cancer Epidemiology, Biomarkers & Prevention*, 14(4): 885-891.
- Stepanov, I. J. (2008). New and traditional smokeless tobacco: comparison of toxicant and carcinogen levels. *Nicotine & Tobacco Research*, 10(2): 1773-1782.
- Stewart, A. G. (2015). Anxiogenic-like effects of chronic nicotine exposure in zebrafish. *Pharmacology, Biochemistry and Behavior*, 139: 112-120.
- U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau. (2018, January 9). *Tobacco Statistics*. Retrieved from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>
- U.S. Environmental Protection Agency. (2016). *Advancing Sustainable Material Management: Facts and Figures*. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf
- U.S. Environmental Protection Agency. (2017). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*. Retrieved from https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf

APPENDIX 1

Submission Tracking Number and Related Amendments for the SE Report and Package Sizes of the New and Predicate Products Covered Under this Environmental Assessment (EA)

STN	Product Name	Product	Packaging Size			Amendments
			Grams/Can	Cans per Shrink-Wrapped Log Roll	Log Rolls per Shipping Case	
SE0004824	Red Seal Fine Cut Natural	New	42.53	5	18	SE0004869, SE0007946, SE0008172, SE0008711, SE0008712, SE0008994, SE0010130, SE0010172, SE0010382, SE0010396, SE0010905, SE0013719, SE0014272, SE0014438
	Red Seal Fine Cut Natural (2007) (GF1200202)	Predicate	42.53	N/A	N/A	

CONFIDENTIAL APPENDIX 1
Modifications between the New Product and Predicate Product

Component/Ingredient	Unit of Measure	New	Predicate
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)
(b) (4)	mg/g	(b) (4)	(b) (4)

Component/Ingredient	Unit of Measure	New	Predicate
(b) (4)	mg/g	(b) (4)	(4)
(b) (4)	mg/g	(b) (4)	(4)
(b) (4)	mg/g	(b) (4)	(4)
(b) (4)	-	(b) (4)	(4)

CONFIDENTIAL APPENDIX 2

The First- and Fifth-Year Market Volume Projections of the New Product and Energy Usage

STN	Unit	New Product First-Year Market Volume	New Product Fifth-Year Market Volume
SE0004824	Pounds	(b) (4)	(b) (4)
	Metric Tons		

The applicant stated that the manufacturing facility operated at approximately 94% of its permitted capacity in 2016 and the five-year projection of the manufacturing at this facility, including the manufacturing of the new product, is within existing capacity.

The applicant stated that the manufacturing facility uses approximately (b) (4) (b) (4)) of energy annually. Power at the manufacturing facility is supplied by (b) (4) (b) (4) , which purchases electric power from the Tennessee Valley Authority. The applicant estimated the potential increase in energy use associated with manufacturing the new product to be less than three percent. Using the EPA Greenhouse Gas Equivalencies Calculator,⁷ the increase in energy use would be less than (b) (4) metric tons carbon dioxide-equivalent (CO₂-eq) of GHG emissions. This is a negligible fraction of the 6.59 million metric tons of CO₂-eq reported in the United States in 2015 (U.S. Environmental Protection Agency, 2017).

⁷ U.S. Environmental Protection Agency. Energy and the Environment. Greenhouse Gas Equivalencies Calculator. Available at <https://www.epa.gov/energy/greenhouse-gas-equivalencies-calculator>. Accessed January 17, 2018.

CONFIDENTIAL APPENDIX 3

Comparison of the First- and Fifth-Year Market Volume Projections for the New Product with Total Smokeless Tobacco and Snuff Products Used in the United States

The first- and fifth-year market volumes of the new product to occupy the U.S. market were determined by comparing the projected market volume of the new product to the forecasted use of total smokeless tobacco and snuff in the United States (Figure 6 and Confidential Appendix 2). The percent of the total smokeless tobacco and snuff market occupied in the projected first and fifth year of marketing of the new product was calculated using the equations below.⁸

First Year Market Occupation of New Product (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of Smokeless or Snuff in the U.S. for 2018}} \times 100\%$$

Fifth Year Market Occupation of New Product (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Use of Smokeless or Snuff in the U.S. for 2022}} \times 100\%$$

Year	Forecasted Use of Total Smokeless Tobacco in the U.S. ⁹ (Pounds)	Forecasted Use of Snuff in the U.S. ⁹ (Pounds)	Projected Market Volume of New Product ¹⁰ (Pounds)	Projected Smokeless Market Occupation of New Product (%)	Projected Snuff Market Occupation of New Product (%)
First	144,963,800	128,432,000	(b) (4)		
Fifth	155,465,800	142,184,400	(b) (4)		

⁸ 2017 annual TTb values have not been released. Since the SE Report was received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

⁹ See Figure 6.

¹⁰ See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 4

The First- and Fifth-Year Projection of Waste of Packaging Materials Associated with Marketing the New Product

To analyze the environmental effects from waste due to the proposed action, the Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in metric tons) that are generated from disposal after use of the new product in 2018 and 2022. Projected total waste is the summation of the projected paper, plastic, and metal waste generation of the product. Projected total paper waste is the summation of the projected recyclable (shipping case) and non-recyclable (coated paper side label) paper waste generation of the product. Projected total plastic waste is the summation of the projected recyclable (can bottom) and non-recyclable (shrink wrap) plastic waste generation of the product.

$$\sum_{i=1}^1 A_i = \sum_{i=1}^1 (B_i + C_i + D_i)$$

$$B_i = \sum_{i=1}^1 (G_i + H_i)$$

$$C_i = \sum_{i=1}^1 (E_i + F_i)$$

$$D_i = J_i \times M \times Z$$

$$E_i = J_i \times N \times Z$$

$$F_i = \frac{J_i}{K} \times P \times Z$$

$$G_i = \frac{J_i}{I_i \times H_i} \times Q \times Z$$

$$H_i = J_i \times O \times Z$$

- A_i : Projected total waste generation of the product (metric tons)
- B_i : Projected paper waste generation of the product (metric tons)
- C_i : Projected plastic waste generation of the product (metric tons)
- D_i : Projected metal waste of the product (metric tons)
- E_i : Projected recyclable plastic waste generation of the product (metric tons)
- F_i : Projected non-recyclable plastic waste generation of the product (metric tons)
- G_i : Projected recyclable paper waste generation of the product (metric tons)
- H_i : Projected non-recyclable paper waste generation of the product (metric tons)
- I_i : Projected market volume of the product (pounds)
- J_i : Number of individual units (each unit comprises of one can bottom, one can lid, and one coated side label)
- K : Number of individual units per log roll
- L : Number of log rolls per shipping case
- M : Weight of metal (tin-plated steel) can lid (grams)
- N : Weight of plastic (polypropylene) can bottom (grams)
- O : Weight of coated paper side label (grams)
- P : Weight of plastic shrink wrap (grams)
- Q : Weight of shipping case (grams)
- Z : 1.0×10^{-6} metric tons/gram

STN	Year	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
SE0004824	First	220	2.1	0.39	8.82	7.22	18	5	(b) (4)									
	Fifth	220	2.1	0.39	8.82	7.22	18	5	(b) (4)									

Total Waste. The shipping case is disposed of, recycled, or both, as paper waste; the coated paper side label is disposed of as waste or litter. Estimation of generated total paper waste for the new product is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the shipping case waste is likely to be recycled; there is an overall recycling rate for paper products of 64.7% in the United States, according to U.S. EPA (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the coated paper side label and 35.3% of the shipping cases are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative paper waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.¹¹ The plastic can bottom is disposed of, recycled, or both, as plastic waste; the shrink wrap is disposed of as waste or litter. Estimation of generated total plastic waste for the new product is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the plastic can bottom is likely to be recycled; there is an overall recycling rate for plastic products of 9.5% in the United States (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the shrink wrap and 90.5% of the plastic can bottoms are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative plastic waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.¹² The metal can lid is disposed of, recycled, or both as metal waste. Estimation of generated total metal waste for the new product is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the metal can lid is likely to be recycled; there is an overall recycling rate for metal products of 33.0% in the United States (U.S. Environmental Protection Agency, 2016). Therefore, if 67.0% of the metal can lids are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative metal waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.¹³

If the entire packaging paper, plastic, and metal components are disposed of as waste, which is a more conservative approach, the projected cumulative paper, plastic, and metal waste in the first and fifth years of marketing the new product is (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible fraction of the (b) (4) metric tons of total waste reported in the United States in 2014.

(b) (4)